Appendix 11.25a Overdose: Reporting Period Case Listings

Case ID	Country	Report Type	ALL PT'S	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	WW Identifier	Batch/Lot Number
4.1(b)	4.1(b)	Regulatory Authority	Chills, Dizziness, Fatigue, Headache, Injection site erythema, Injection site swelling, Intentional overdose, Malaise, Myalgia, Nausea, Pyrexia	Serious	35.00	420.00	Female	0	0	0	4.1(b)	LOT000137A
	4.1(b)	Spontaneous	Bone pain, Chest pain, Chills, Fatigue, Headache, Inappropriate schedule of product administration, Myalgia, Myocarditis, Overdose, Palpitations, Pericarditis, Pyrexia, Somnolence, Vomiting	Serious	46.00	552.00	Female	Hypokalaemia(C); Drug hypersensitivity; Hyperthyroidism(H)	VITAMIN D [COLECALCIFEROL]	0		0
	PHILIPPINES	Spontaneous	Death, Overdose, Pyrexia	Serious	0.00	0.00	Female	0	0	0		0
	4.1	Spontaneous	Arthralgia, Contusion, Fall, Humerus fracture, Overdose, Presyncope	Serious	81.00	972.00	Female	Dyslipidaemia(C)	PITAVASTATIN CA; MAGNESIUM OXIDE	0		3006343
	JAPAN	Spontaneous	Cardiac failure, Cardio-respiratory arrest, Overdose, Pulmonary oedema	Serious	62.00	744.00	Female	Diabetes mellitus(H); Depression(H)	CLOPIDOGREL; BERAPROST NA	0		000021A
	4.1	Spontaneous	Interstitial lung disease, Overdose, Pyrexia	Serious	70.00	840.00	Male	Atopy(C); Seasonal allergy; Hypertension(H); Asthma(H); PIPERACILLIN SODIUM(H); PIPERACILLIN SODIUM(H)	EPINASTINE; 4.1(	0		0
	4.1	Spontaneous	Myopericarditis, Overdose	Serious	44.00	528.00	Male	Asthma(C); COMIRNATY; COMIRNATY	0	0		0
	4.1	Spontaneous	Altered state of consciousness, Cerebral ventricle dilatation, Delirium, Meningitis, Overdose, Peripheral venous disease, Pyrexia, Renal cyst, Restlessness, Seizure	Serious	62.00	744.00	Male	Venous thrombosis limb(C); COMIRNATY; COMIRNATY; Hypertension(C); Cellulitis(H); Meningitis(H)	LIXIANA; RABEPRAZOLE SODIUM; HALFDIGOXIN	0		000001A
	4.1	Spontaneous	Agitation, Overdose, Tonic convulsion	Serious	84.00	1008.00	Female	Hypertension(C); Epilepsy(C); Seizure(C); COMIRNATY; COMIRNATY	0	0		000013A
	4.1(b)	Spontaneous	Accidental overdose, Dizziness, Feeling abnormal, Headache, Hypotension, Inappropriate schedule of product administration, Interchange of vaccine products, Nausea, Syncope, Vomiting, Wound	Serious	57.00	684.00	Female	Myasthenia gravis(C); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	MESTINON	0		037M21A
	4.1(b)	Spontaneous	Accidental overdose, Deafness, Influenza like illness, Poor quality sleep	Serious	65.00	780.00	Male	Blood pressure measurement(C); Cholesterosis(C)	0	0		054C21A; 016M20A; 025L20A
	4.1(b)	Spontaneous	Accidental overdose, Arrhythmia, Ventricular extrasystoles	Serious	73.00	876.00	Female	4.1(b) (H); Drug hypersensitivity; Glucose tolerance impaired(C); ZOSTER; Ventricular extrasystoles(C)	0	0		01421A; 038A21A; 028L20A
	4.1(	Spontaneous	Arteriosclerosis, Cardiac arrest, Chest pain, Memory impairment, Overdose, Rib fracture	Serious	43.00	516.00	Male	Overweight(H); Hyperglycaemia(H); Non-tobacco user(C); Substance use(H); Alcohol use(H); Cardiac disorderFH	METOPROLOL; ROSUVASTATIN; ASPIRIN [ACETYLSALICYLIC ACID]; CALCIUM; RAMIPRIL; TICAGRELOR	0		3002538
	4.1(b)	Spontaneous	Accidental overdose, Fatigue, Gait inability, Herpes ophthalmic, Muscle spasticity, Pain	Serious	0.00	0.00	Female	Trigeminal neuropathy(C); Surgery; Surgery; Secondary progressive multiple sclerosis(C); Hypoaesthesia(C); Dacryostenosis acquired(C); Anosmia(C); Hypoacusis(C); COVID-19(H)	FENISTIL; DRONABINOL; QLAIRA; DEKRISTOL; HYLO VISION HD PLUS; BEPANTHENE; GABAPENTIN	OCREVUS, OCREVUS, OCREVUS, OCREVUS, OCREVUS, OCREVUS, OCREVUS		0

Appendix 11.25b Overdose: Reporting Period Case Narratives

Case ID	WW Identifier	Narrative (Complete)
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 31-Jan-2022 and was forwarded to Moderna on 31-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of INJECTION SITE ERYTHEMA (Injection site redness), FATIGUE (Note: due to immunodeficiency, the full dose of vaccine was injected not half, but the full dose), HEADACHE (Headache), INTENTIONAL OVERDOSE (Note: due to immunodeficiency, the full dose of vaccine was injected not half, but the full dose), CHILLS (Chills), PYREXIA (above all sinus vein thrombosis, inpatient stay, exclusion in MRT. 40C Fieber, visual impairment, consciousness slightly clouded, so weakened that running no longer possible, sitting hardly possible), MYALGIA (Myalgia), MALAISE (Malaise), NAUSEA (Nausea), INJECTION SITE SWELLING (Injection site swelling) and DIZZINESS (Dizziness) in a 35-year-old female patient who received mRNA-1273 (Spikevax) (batch no. LOT000137A) for COVID-19 vaccination. Information on risk factors or pre existing diseases included mast cell disease, neutropenia. Due to mast cell disease patient had various allergies. On 10-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 10-Jan-2022, the patient experienced INJECTION SITE ERYTHEMA (Injection site redness) (seriousness criterion hospitalization), FATIGUE (Note: due to immunodeficiency, the full dose of vaccine was injected not half, but the full dose) (seriousness criterion hospitalization), INTENTIONAL OVERDOSE (Note: due to immunodeficiency, the full dose of vaccine was injected not half, but the full dose) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), PYREXIA (above all sinus vein thrombosis, inpatient stay, exclusion in MRT. 40C Fieber, visual impairment, consciousness slightly clouded, so weakened that running no longer possible, sitting hardly possible) (seriousness criterion hospitalization), MYALGIA (Myalgia) (seriousness criterion hospitalization), MALAISE (Malaise) (seriousness criterion hospitalization), NAUSEA (Nausea) (seriousness criterion hospitalization), INJECTION SITE SWELLING (Injection site swelling) (seriousness criterion hospitalization) and DIZZINESS (Dizziness) (seriousness criterion hospitalization). On 11-Jan-2022, the patient experienced HEADACHE (Headache) (seriousness criterion hospitalization). On 11-Jan-2022, HEADACHE (Headache) and CHILLS (Chills) had resolved. On 12-Jan-2022, INJECTION SITE ERYTHEMA (Injection site redness), FATIGUE (Note: due to immunodeficiency, the full dose of vaccine was injected not half, but the full dose), INTENTIONAL OVERDOSE (Note: due to immunodeficiency, the full dose of vaccine was injected not half, but the full dose), MALAISE (Malaise), NAUSEA (Nausea) and INJECTION SITE SWELLING (Injection site swelling) had not resolved and PYREXIA (above all sinus vein thrombosis, inpatient stay, exclusion in MRT. 40C Fieber, visual impairment, consciousness slightly clouded, so weakened that running no longer possible, sitting hardly possible), MYALGIA (Myalgia) and DIZZINESS (Dizziness) was resolving. Patient experienced onset of high fever approx. 7 hours after vaccination, severe deterioration of condition at night. 2500mg paracetamol nevertheless fever above 40 C increases nausea and vision problems (as if all lamps were defective and different), no longer be able to drink, next morning to the clinic. There fluid i.v. and paracetamol i.v. since condition persistent poor and consciousness slightly clouded and severe head and neck pain. Patient was went through MRI mainly sinus vein thrombosis. Subsequently continue to drink liquid, paracetamol and vomex i.v. since not possible, inpatient intake. Fever for about 40 hours at just under 40 C despite paracetamol. At 12th AZ and temperature a little better, pain in the tolerable area. Patient not yet possible to eat but drink small amounts so that dismissal.

Case ID	WW Identifier	Narrative (Complete)
		Company comment. This regulatory authority case concerns a 35-year-old female patient, with no reported medical history, who experienced the serious (hospitalization) unexpected events of PYREXIA, HEADACHE, NAUSEA and DIZZINESS (amongst others) that occurred within the first 2 days after receiving a third dose of mRNA-1273. Intentional overdose was also reported, however; there is no information regarding dose received. According to source document narrative, patient has a history of mast cell disease and neutropenia. She developed fever after vaccination and due to worsening condition and no response to paracetamol, she went to the clinic. She received intravenous fluids and paracetamol. Due to consciousness slightly clouded and severe head and neck pain MRI was performed. Result is not clearly provided and its is stated "MRI wg mainly sinus vein thrombosis". Patient was not able to eat or drink liquids due to nausea, so she was admitted to the hospital. Patient was discharged by the time of the report. Patient's history of mast cell disease and neutropenia remains as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report
4.1(b) [redacted]	4. 1(b) 4.1(b) [redacted]	This spontaneous case was reported by a consumer and describes the occurrence of PERICARDITIS (Myocarditis/pericarditis) and MYOCARDITIS (Myocarditis/pericarditis.) in a 46-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Hyperthyroidism. Concurrent medical conditions included Hypokalemia (suffering for 35 years, with pathology is low in potassium) and Penicillin allergy. Concomitant products included COLECALCIFEROL (VITAMIN D [COLECALCIFEROL]) for an unknown indication. On 17-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 2.5 milliliter. On 03-Feb-2022 at 1:00 PM, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 5 milliliter. On 03-Feb-2022, the patient experienced BONE PAIN (Sore in the bones throughout the body/bone sore) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (On December 17, 2021 she made the first dose of Spikevax and on February 3, 2022 received the second dose of Spikevax/There was also also a delay between dose 1 and dose 2 (17Dec2021 to 03Feb2022) - 48 days, which is an off-label use.). On 03-Feb-2022 at 1:00 PM, the patient experienced OVERDOSE (Received the second dose of Spikevax 5ml). On 03-Feb-2022 at 5:00 PM, after starting mRNA-1273 (Spikevax), the patient experienced PALPITATIONS (Had palpitations for 3 days, 4 days), HEADACHE (Severe headache/sore head/ headache), PYREXIA (Fever 38 / 2 days of fever/fever of 38°), MYALGIA (Body aches) and CHILLS (Had chills). On 04-Feb-2022, the patient experienced VOMITING (Vomited 3 times/vomited 3 times in the morning). On 05-Feb-2022, the patient experienced SOMNOLENCE (Drowsiness 2 days in bed) and FATIGUE (Fatigue). In February 2022, the patient experienced CHEST PAIN (Felt pain in the left chest/pain in the heart strong as if it had been punched/when she pressed her fist and felt pain in her upper chest). On an unknown date, the patient experienced PERICARDITIS (Myocarditis/pericarditis) (seriousness criterion medically significant) and MYOCARDITIS (Myocarditis/pericarditis.) (seriousness criterion medically significant). At the time of the report, PERICARDITIS (Myocarditis/pericarditis), MYOCARDITIS (Myocarditis/pericarditis.), CHEST PAIN (Felt pain in the left chest/pain in the heart strong as if it had been punched/when she pressed her fist and felt pain in her upper chest), BONE PAIN (Sore in the bones throughout the body/bone sore), PALPITATIONS (Had palpitations for 3 days, 4 days), SOMNOLENCE (Drowsiness 2 days in bed), HEADACHE (Severe headache/sore head/ headache), PYREXIA (Fever 38 / 2 days of fever/fever of 38°), FATIGUE (Fatigue), VOMITING (Vomited 3 times/vomited 3 times in the morning), MYALGIA (Body aches), CHILLS (Had chills), INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (On December 17, 2021 she made the first dose of Spikevax and on February 3, 2022 received the second dose of Spikevax/There was also also a delay between dose 1 and dose 2 (17Dec2021 to 03Feb2022) - 48 days, which is an off-label use.) and OVERDOSE (Received the second dose of Spikevax 5ml) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Dec-2021, Antibody test: 0.40 0.40. On 01-Feb-2022, Antibody test: 290 (normal) 290.

Case ID	WW Identifier	Narrative (Complete)
		On 01-Feb-2022, Blood potassium: 3 (Low) 3. On 06-Feb-2022, Blood pressure measurement: 100/70 (Low) 100/70. In February 2022, Blood pressure measurement: 125/80 (normal) 125/80. In February 2022, Electrocardiogram: normal (normal) normal. In February 2022, Oxygen saturation: 99 99. On an unknown date, Respiratory rate: 125/80 125/80. Concomitant medication include potassium preparate for low potassium, Jodit 200mg% for thyroid, Decristol 50mg% . Her daughter in 35 years had no cold, and no fever. She was about to do ECG control. Her daughter was scared if she get an heart attack. No treatment medications were reported. Company Comment: This is a spontaneous case concerning a 46-year-old, female patient with no relevant medical history reported, who experienced the expected serious (medically significant) AESI of myocarditis and pericarditis, which were suspected by the reporter as the patient experienced non-serious events palpitations and chest pain, although no medical confirmation nor additional studies were available. The event palpitations occurred approximately 4 hours after the second dose of mRNA-1273 vaccine, while chest pain appeared after approximately 3-4 days. Inappropriate schedule of vaccine administered (49 days) and Overdose were also noted in the case. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 16-Feb-2022: Follow-up received on 16-FEB-2021, Case upgraded to serious as per medical judgement by medical reviewer. Country change from 4.1(b) to 4.1(b) Patient details (DOB, Age) added,Medical history (Penicillin allergy, Hyperthyroid) added, Lab test (Respiratory rate) added, Concomitant (Vitamin D) added, Event Chills, Pain, Palpitation , Myocarditis, Pericarditis) added , and event cold remove as per Medical reviewer suggestion, Narrative updated.
4.1(b)	4.1 (b) 4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Death) and PYREXIA (Fever) in a female patient of an unknown age who received mRNA-1273 (COVID-19 Vaccine Moderna) for an unknown indication. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 100 microgram. On an unknown date, the patient experienced DEATH (Death) (seriousness criteria death and medically significant), PYREXIA (Fever) (seriousness criterion medically significant) and OVERDOSE (100 mcg booster dose). The patient died on an unknown date. It is unknown if an autopsy was performed. At the time of death, PYREXIA (Fever) and OVERDOSE (100 mcg booster dose) outcome was unknown.

Case ID	WW Identifier	Narrative (Complete)
		No concomitant medications were reported. The report was received through social media monitoring. The patient posted via Facebook that knows someone who experienced fever and eventually died three days upon receiving the booster dose of Moderna vaccine. No treatment medications were reported. Company Comment: This spontaneous case concerns a female patient of unspecified age with no reported medical history, who experienced the unexpected, serious (medically significant) event of Pyrexia and who reportedly died 3 days after receiving booster dose of mRNA-1273 vaccine. The event of pyrexia occurred on an unspecified date after receiving booster dose of mRNA-1273 vaccine. The clinical course leading to demise and the cause of death were not reported. It is unknown if autopsy was conducted. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b) on 24-Feb-2022. The most recent information was received on 23-Mar-2022 and was forwarded to Moderna on 31-Mar-2022. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)). On 23-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.0 degrees Celsius. On 22-Feb-2022, at 14:00, the patient received the 3rd vaccination with this vaccine. The patient received 2.5 mL, which was overdose. The patient was followed up for 15 minutes after the vaccination with no significant lesion. The patient experienced vagal reflex while preparing to return home. The patient's eyes began flickering in the waiting room, and she tripped over the sofa and fell. The left shoulder was bruised. BP: 104/70, and HR: 60. The patient was awake and alert. The patient complained of left shoulder pain. BP: 80/50, HR: 63, and SpO2: 90. The patient lay down in bed with the trachea secured. Fracture of greater tubercle of humerus was noted in left shoulder XP. BP: 130/70, HR: 68, and SpO2: 96. The symptoms were resolving. Left shoulder was fixed with a band, and the patient was prescribed analgesics and returned home. On 04-Mar-2022, the patient visited the hospital. Left shoulder pain was mild. On 11-Mar-2022, the patient visited the hospital. Left shoulder pain was mild. Treatment was continued. The outcome of vagal reflex, fall, left shoulder bruise, and fracture of greater tuberosity of humerus was unknown. The outcome of left shoulder pain was reported as resolving. No follow-up investigation will be made. Follow-up received on 23-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 29-Mar-2022. The most recent information was received on 19-Apr-2022 and was forwarded to Moderna on 24-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a pharmacist, was received via the PMDA (Ref, 4.1(b)). On 19-Apr-2022, follow-up information was received from a pharmacist. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 25-Feb-2022, at 15:43, the patient received the 3rd dose of this vaccine. Vaccination at a dose of 0.5 mL was performed, resulting in overdose. On 26-Feb-2022, around 04:40, a family member saw the patient taking a bath. When the family member heard a noise while bathing, went to check on the patient, who had the face in the hot water, and called for an ambulance. The family member started cardiopulmonary resuscitation. At 04:50, cardio-respiratory arrest was noted. At 05:02, at the time of an examination by the ambulance team, the electrocardiographic waveform showed cardiac arrest. At 05:23, at the time of transporting to the reporting hospital, cardiac arrest was confirmed. At 05:27, tracheal intubation was performed. At 05:31, adrenaline 1A was administered. At 05:34, adrenaline 1A was administered. At 05:37, adrenaline 1A was administered. At 05:42, cardiopulmonary resuscitation was discontinued. At 05:47, the patient was confirmed dead. At 06:00, plain CT from the head to the thoracoabdominal region showed no head abnormalities. Ground-glass opacities and wall thickening of the interlobular septum were detected in both lungs. Pulmonary edema and cardiac failure were

Case ID	WW Identifier	Narrative (Complete)
		suspected. On an unknown date, an autopsy was performed at another hospital. The outcome of cardio-respiratory arrest was reported as fatal. The outcome of suspected pulmonary oedema and suspected cardiac failure was unknown. No follow-up investigation will be made. Reporter comments continuation: Since the reported medical history did not match the indications for the reported oral medications, it is assumed that there were other underlying medical conditions that were not reported. The patient had cardiopulmonary arrest on admission, and the details of other contributing factors are unknown. Follow-up received on 19-APR-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b) on 01-Apr-2022. The most recent information was received on 27-Apr-2022 and was forwarded to Moderna on 02-May-2022. This spontaneous case was reported by a physician and describes the occurrence of INTERSTITIAL LUNG DISEASE (Interstitial pneumonia (After the third vaccination)) in a 7-decade-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Hypertension and Asthma. Previously administered products included for Product used for unknown indication: Piperacillin sodium and Piperacillin sodium. Past adverse reactions to the above products included Queasy with Piperacillin sodium; and Vomiting with Piperacillin sodium. Concurrent medical conditions included Atopy and Pollinosis. Concomitant products included EPINASTINE for Atopy and Pollinosis, AZILSARTAN (4.1(b) for Hypertension. On 14-Mar-2022, the patient received third dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) .5 milliliter. On 14-Mar-2022, the patient experienced OVERDOSE (Overdose (the 3rd vaccination with 0.5 mL) (After the third vaccination)). On an unknown date, the patient experienced INTERSTITIAL LUNG DISEASE (Interstitial pneumonia (After the third vaccination)) (seriousness criterion medically significant) and PYREXIA (Pyrexia (After the third vaccination)). At the time of the report, INTERSTITIAL LUNG DISEASE (Interstitial pneumonia (After the third vaccination)) and PYREXIA (Pyrexia (After the third vaccination)) had resolved and OVERDOSE (Overdose (the 3rd vaccination with 0.5 mL) (After the third vaccination)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Mar-2022, SARS-CoV-2 test: test result:negative (Negative) Test Result:Negative. On 28-Mar-2022, C-reactive protein: test result:2.00 Test Result:2.00. On 28-Mar-2022, Chest X-ray: shadows in the upper lung fields. (abnormal) Shadows in the upper lung fields.. On 28-Mar-2022, Computerised tomogram thorax: ground-glass opacities in both lungs. (abnormal) Ground-glass opacities in both lungs.. On 28-Mar-2022, SARS-CoV-2 test: test result:negative (Negative) Test Result:Negative. On 28-Mar-2022, White blood cell count: test result:6400 Test Result:6400. On 31-Mar-2022, Aspergillus test: test result:negative (Negative) Test Result:Negative. On 31-Mar-2022, Blood beta-D-glucan: 7.8 7.8 pg/mL. On 31-Mar-2022, Blood culture: test result:negative (Negative) Test Result:Negative. On 31-Mar-2022, C-reactive protein: test result:1.32 Test Result:1.32. On 31-Mar-2022, Candida test: test result:0.0 Test Result:0.0. On 31-Mar-2022, KL-6: 377 377 iU/L. On 31-Mar-2022, Mycobacterium tuberculosis complex test: test result:negative (Negative) Test Result:Negative.

Case ID	WW Identifier	Narrative (Complete)
		On 31-Mar-2022, Sputum culture: 3+ for resident microbiota and 1+ for candida albi (abnormal) 3+ for resident microbiota and 1+ for candida albicans.. On 31-Mar-2022, Surfactant protein (Unknown-43.8): 76.1 (High) 76.1 ng/mL. On 31-Mar-2022, White blood cell count: test result:6200 Test Result:6200. On 09-Apr-2022, C-reactive protein: test result:0.55 Test Result:0.55. On 09-Apr-2022, White blood cell count: test result:7800 Test Result:7800. On an unknown date, Fungal test: test result:negative (Negative) Test Result:Negative. On an unknown date, Influenza virus test: test result:negative (Negative) Test Result:Negative. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered INTERSTITIAL LUNG DISEASE (Interstitial pneumonia (After the third vaccination)), OVERDOSE (Overdose (the 3rd vaccination with 0.5 mL) (After the third vaccination)) and PYREXIA (Pyrexia (After the third vaccination)) to be possibly related. Most recent FOLLOW-UP information incorporated above includes: On 27-Apr-2022: Added events. Added concomitant medications, medical history and laboratory data. Updated date of mRNA-1273 administered. Added initials and patient gender.
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b) on 01-Apr-2022. The most recent information was received on 19-May-2022 and was forwarded to Moderna on 27-May-2022. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)). On 19-May-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before vaccination: 36.7 degrees Celsius. On 26-Feb-2022, around 16:00, the patient received the 3rd vaccination with this vaccine. The patient received this vaccine at a dose of 0.3 mL, resulting in overdose. On 27-Feb-2022, the patient experienced pyrexia up to 38.5 degrees Celsius. The pyrexia persisted, and thus the patient used acetaminophen. On 01-Mar-2022, acute perimyocarditis developed. The patient experienced pyrexia of 38.8 degrees Celsius. In the morning, the patient was aware of pain from the neck to the precordial region, which was associated with body motion and deep breathing. The patient visited the reporting hospital. There were no findings on physical examination that suggested pericardial effusion. Shoulder pain, upper back pain, and intermittent pyrexia were noted. Chest X-ray showed no findings of cardiac enlargement. Electrocardiogram showed concave ST-segment elevation above the maximum in extensive areas of V2-V4, characteristic of acute pericarditis, and generalized decreased PR findings. Blood samples were also taken, and since the inflammatory response was elevated with troponin I 0.28 ng/mL and CRP 11.11 mg/dL. The patient was diagnosed with perimyocarditis and was hospitalized. The patient started aspirin 1.6 g in four divided doses and 1 tablet of vonoprazan fumarate 20 mg once daily. When the patient had strong pain, the patient used loxoprofen sodium hydrate 60 mg on an as-needed basis. Acetaminophen was discontinued. On an unspecified date in Mar-2022, pain was resolving. Various viral antibodies for influenza and coxsackie were all negative. On 02-Mar-2022, echocardiography revealed no abnormal pericardial effusion, but there was a finding of suspected pericardial inflammation. Body temperature was 37.9 degrees Celsius. On 03-Mar-2022, pyrexia resolved, and pain also improved. Body temperature was 36.4 degrees Celsius. On 08-Mar-2022, echocardiography showed continued absence of pericardial effusion and disappearance of increased endocardial brightness. On 09-Mar-2022, pain almost disappeared, and the symptoms were resolving. On 10-Mar-2022, it was confirmed that there was no exacerbation of the symptom. The patient was discharged from the hospital. The outcome of acute perimyocarditis was reported as resolving. No follow-up investigation will be made. Follow-up received on 19-MAY-2022 Updated: Patient Information, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.

Case ID	WW Identifier	Narrative (Complete)
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b) on 08-Apr-2022. The most recent information was received on 18-May-2022 and was forwarded to Moderna on 27-May-2022. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)). On 18-May-2022, follow-up information was received from a physician. On 29-Jul-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 17-Aug-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.3 degrees Celsius. On 22-Mar-2022, the patient received the 3rd vaccination with this vaccine. The patient received the vaccine at a dose of 0.3 mL, resulting in overdose. On 23-Mar-2022, around 13:00, the patient experienced convulsion and disturbed consciousness at the workplace. The patients family member was contacted, and the patient returned home. Around 14:00, disturbed consciousness was noted at home, and an emergency call was made. The patient was raced to the reporting hospital. While the patient was being transported, BT: 38.4 degrees Celsius, HR: 83/min with sinus rhythm, BP: 163/117 mmHg, SpO2: 94% (RA), respiration rate: 20/min, pupils: 2 mm/2 mm, and light reflex: slow in both eyes. GCS: E4V4M5, and pyrexia and disturbed consciousness were observed. There was no neck rigidity, and other physical and neurological abnormalities were not apparently found. Mild delirium and unrest were noted. While intravenous injection of midazolam 10 mg/2mL 1 A plus 18 mL of normal saline was given at 5 cc in total, the patient underwent whole-body plain CT scan and head plain MRI, which showed no apparent abnormalities. The patient was considered to have delirium, unrest, and disturbed consciousness due to pyrexia but was hospitalized for follow-up, considering the possibility of meningitis. The patient did not receive any antimicrobial or antiviral medication. Lumbar puncture was not performed due to oral administration of edoxaban tosilate hydrate. On 24-Mar-2022, around 09:00, the patient was awake and alert. BT: 37.4 degrees Celsius. On 25-Mar-2022, around 09:00, the patient was awake and alert. BT: 36.3 degrees Celsius. The patient did not have pyrexia. Blood was obtained for culture. Mild enlargement of the ventricle was revealed by head MRI, and brain hypertension and papilloedema were shown on image; therefore, lumbar puncture was not performed while the patient was in the hospital. On 26-Mar-2022, around 09:00, the patient was awake and alert with no pyrexia. The symptoms resolved, and the patient was discharged from the hospital. On 28-Mar-2022, around 09:00, the patient returned to the reporting outpatient department. The patient was awake and alert and did not have pyrexia. Lumbar puncture was performed at the patient's request. The initial pressure was 12.5 cmH2O with final pressure of 11.0 cmH2O. There were no abnormal findings in the cerebrospinal fluid. The culture of herpes DNA was submitted. On 31-Mar-2022, the blood culture result was negative. On 05-Apr-2022, at 10:00, the patient returned to the reporting outpatient department again. The patient was awake and alert and did not have pyrexia. The patient was given an explanation about the result of lumbar puncture, and treatment and follow-up at the reporting department were completed. The outcome of convulsion, disturbed consciousness, pyrexia, delirium, unrest, and possibility of meningitis was reported as resolved. The outcome of papilloedema, cerebral ventriculomegaly, and left renal cyst was unknown. No follow-up investigation will be made. [Head plain CT] (Date of exam: 23-Mar-2022) No intracranial hemorrhage or hematoma was shown. No apparent abnormality was seen in the brain morphology. [Thoracoabdominal plain CT] (Date of exam: 23-Mar-2022) No ground-glass opacity and no infiltrative shadow were found in both lungs. No pleural effusion. Left renal cyst was found. There were no abnormalities in the liver, gallbladder, pancreas, spleen, right kidney, urinary bladder, and prostate gland. No ascitic fluid. Arteriosclerosis was slightly noted, but no dissection or mass formation was unable to be found. Enlarged lymph nodes were not found. Image diagnosis: The cause of the symptoms was unable to be identified. [Head plain MRI] (Date of exam: 23-Mar-2022) No intracranial infarction, hemorrhage, or space occupying lesion was shown. No apparent abnormality was seen in the brain morphology. MRA showed no severe stenosis, dilation, or aneurysm. Hypoplasia was seen in the proximal part of left anterior cerebral artery. No abnormalities were found in bilateral eyeballs or orbits. Pneumatization in each paranasal cavity and both mastoid air cells was maintained. Image diagnosis: The cause of the symptoms was unable to be identified. Reporter comments continuation: Since the patient had no complications that were suspected to be obviously related, the occurrence of adverse events is not related to pathological factors of underlying diseases and complications. The symptoms are considered to have been caused by the transient deliria and unrest due to post-vaccination pyrexia rather than by this vaccine itself; however, this case was reported as the patient hoped it. Follow-up received on 18-MAY-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information,

Case ID	WW Identifier	Narrative (Complete)
		Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 14-Apr-2022 and was forwarded to Moderna on 20-Apr-2022. This case, initially reported to the 4.1(b) by a physician, was received via the 4.1(b) (Ref, 4.1(b)). Tonic convulsion was assessed as serious by the MAH. On 11-Jul-2021, the patient received 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 01-Aug-2021, the patient received 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unspecified date in Jan-2022, the patient occasionally experienced seizure but did not receive detailed examinations in a medical institution. On an unspecified date, body temperature before the vaccination: 36.2 degrees Celsius. On 02-Apr-2022, at 15:00, the patient received 3rd vaccination with this vaccine. The patient received 0.3 mL, which was overdose. At 15:10, the patient fell into a state of excitation during observation and repeatedly experienced multiple episodes of tonic convulsion. The patient became mentally stable, and at the same time convulsion developed less frequently. The symptoms were resolving. The outcome of state of excitation and tonic convulsion was reported as resolving. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (fainted 2 times / then she step up to fast and faint again/ she woke up on the floor/second fainting occurred a few minutes later) in a 57-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (batch no. 037M21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Product used for unknown indication: Pfizer (Dose 1) in October 2021 and Pfizer (Dose 2:) on 26-Nov-2021. Past adverse reactions to the above products included No adverse event with Pfizer and Pfizer. Concurrent medical conditions included Myasthenia gravis (since the end of the MAY (before the administration of the Moderna COVID-19 vaccine).) since 30-May-2021. Concomitant products included PYRIDOSTIGMINE BROMIDE (MESTINON) for Myasthenia gravis. On 17-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (unknown route) .5 milliliter. On 08-Apr-2022 at 8:42 AM, received fourth dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (unknown route) dosage was changed to .5 milliliter. On 17-Dec-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (received the 1st series of Pfizer, the first one like in October and the second one within the 3 weeks approximately the 26Nov2021). On 08-Apr-2022, the patient experienced ACCIDENTAL OVERDOSE (4th dose of Moderna was of 0.5mL). 08-Apr-2022, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (3rd dose of Moderna, at the middle of December like the 17 Dec 2021and the 4th dose of Moderna was the 08 Apr 2022).). On 10-Apr-2022, the patient experienced HEADACHE (on Sunday she began to feel headache, but only one side, on the left/ the next day, Monday,11-Apr-2022, she woke up with a headache, but on the other side, the right/like a migraine). On 11-Apr-2022, the patient experienced SYNCOPE (fainted 2 times / then she step up to fast and faint again/ she woke up on the floor/second fainting occurred a few minutes later) (seriousness criterion medically significant), WOUND (A little cut, consequence of the blow when she fainted), FEELING ABNORMAL (Began to feel very bad), DIZZINESS (Feeling dizzy) and VOMITING (Vomiting). 11-Apr-2022, the patient experienced HYPOTENSION (blood pressure and it was a little low, approximately of 92). 11-Apr-2022, the patient experienced NAUSEA (Nausea). The patient was treated with ACETAMINOPHEN (oral) from 08-Apr-2021 to 11-Apr-2021 for Headache, at a dose of 1 dosage form every six hours. On 17-Dec-2021, INTERCHANGE OF VACCINE PRODUCTS (received the 1st series of Pfizer, the first one like in October and the second one within the 3 weeks approximately the 26Nov2021) had resolved.

Case ID	WW Identifier	Narrative (Complete)
		On 11-Apr-2022, SYNCOPE (fainted 2 times / then she step up to fast and faint again/ she woke up on the floor/second fainting occurred a few minutes later) and HYPOTENSION (blood pressure and it was a little low, approximately of 92) had resolved. On 11-Apr-2022 at 12:00 PM, VOMITING (Vomiting) and NAUSEA (Nausea) had resolved. At the time of the report, WOUND (A little cut, consequence of the blow when she fainted), FEELING ABNORMAL (Began to feel very bad), DIZZINESS (Feeling dizzy), ACCIDENTAL OVERDOSE (4th dose of Moderna was of 0.5mL) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (3rd dose of Moderna, at the middle of December like the 17 Dec 2021and the 4th dose of Moderna was the 08 Apr 2022).) outcome was unknown and HEADACHE (on Sunday she began to feel headache, but only one side, on the left/ the next day, Monday,11-Apr-2022, she woke up with a headache, but on the other side, the right/like a migraine) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Apr-2022, Blood pressure measurement: 92 (Low) 92 A little low. On 11-Apr-2022, Oxygen saturation: fine (normal) fine. The patient did not had history of anaphylaxis, hypersensitivity reaction, rash/urticaria, asthma and high fever. There was no previous history of allergy/hypersensitivity reactions to vaccine. On 10-Apr-2022, patient began to feel a headache, but on only one side, on the left. On 11-Apr-2022, she woke up with a headache, but on the other side, the right. She came out of shower and began to feel very bad and at the moment she fainted for the first time, after she reacted, she stood up again and a second fainting occurred a few minute later. After she reacted, she began to feel very dizzy and vomited. Due to low blood pressure, she had a hot chocolate. The reported wanted to confirm the expiry date of the vaccine and wanted to know if the symptoms of his mother were consequence of the vaccine being expire. The event did not lead patient to seek medical care. Company comment: This is a spontaneous case reported by a consumer. A 57-year-old female patient, previously vaccinated with 2 doses of Pfizer, received fourth dose of mRNA-1273 vaccine (0.5mL) and 2 days later she experienced non serious event of headache that was treated with Acetaminophen. Three days after vaccination patient came out of the shower and began to feel bad, she fainted, then she stood up and faint again and suffered a little cut outside the eye, consequence of the blow when she fainted. After she reacted, she began to feel very dizzy and vomited. Her blood pressure was low. Relevant concurrent medical conditions included Myasthenia gravis which represents a risk factor for autonomic dysfunction including orthostatic dizziness and gastrointestinal symptoms. Additionally, treatment with Mestinon could be a contributory factor for nausea and vomiting. The patient did not seek medical care. Reporter assessed the events headache, vomiting and nausea as not related to the vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-May-2022: Patient demographics added, Suspect coding updated, medical history- myasthenia updated to myasthenia gravis with start date 30-May-2022, lab data added, suspect product start date time updated, treatment medication indication updated, Events added, for the event hypotension outcome updated.
4.1(b)	4.1 (b) 4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of DEAFNESS (lost hearing in right ear) in an adult male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 054C21A, 016M20A and 025L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Blood pressure (he was taking blood pressure medication.) and Cholesterosis (he was taking cholesterol medications.). On 14-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.

Case ID	WW Identifier	Narrative (Complete)
		On 11-Feb-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 23-Aug-2021, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced DEAFNESS (lost hearing in right ear) (seriousness criterion medically significant), INFLUENZA LIKE ILLNESS (pretty severe flu like reaction), POOR QUALITY SLEEP (waking in the middle of the night) and ACCIDENTAL OVERDOSE (may have received the full dose instead of the half dose). The patient was treated with IBUPROFEN (ADVIL [IBUPROFEN]) ongoing since an unknown date at an unspecified dose and frequency. At the time of the report, DEAFNESS (lost hearing in right ear), INFLUENZA LIKE ILLNESS (pretty severe flu like reaction), POOR QUALITY SLEEP (waking in the middle of the night) and ACCIDENTAL OVERDOSE (may have received the full dose instead of the half dose) outcome was unknown. No concomitant medication information was provided. It was reported that, it did not list on the card the dosage level for the booster of Moderna. They did not list the mL amount. They felt like because of his age and artery condition that was strange, hard to explain and undiagnosed, he wanted to be aggressive about getting the booster and the doctor agreed with him getting the dose at the time. They thought they may had received the full dose instead of the half dose because the booster dose was not out yet when he got the 3rd shot Company comment: This case concerns a male patient, of unknown age, with no reported relevant medical history, who experienced unexpected, serious (medically significant) event of Deafness, unspecified days after receiving mRNA-1273 vaccine as a third dose. Dose 1 and Dose 2 were given with a 28-day interval, with the second dose given approximately 6 months before receiving the third dose of mRNA-1273 vaccine. The patient was started with Ibuprofen on an unspecified date, of unknown dose and frequency. The outcome of the event was unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report Most recent FOLLOW-UP information incorporated above includes: On 04-May-2022: Follow up information was received on include no new information.
4.1(b)	4.1 (b) 4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of VENTRICULAR EXTRASYSTOLES (PVC's (premature ventricular contractions)/ gives you a bad feeling/ feel like going to pass out/ makes you feel dizzy) and ARRHYTHMIA (Arrhythmias/feels like you heart is stopping) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 01421A, 038A21A and 028L20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Patient never had COVID + test or diagnosis. Previously administered products included for Product used for unknown indication: Shingles vaccine on 04-Apr-2021; for Drug use for unknown indication: 4.1(b) Past adverse reactions to the above products included No adverse event with Shingles vaccine; and Withdrawal reaction with 4.1(b) Concurrent medical conditions included Allergy to antibiotic (fluoroquinolones, various antibiotics, sulfa), Pre-diabetic and Premature ventricular contractions (A long time ago started,One episode lasted two weeks and resolved; Has a history of PVC's). On 08-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form.

Case ID	WW Identifier	Narrative (Complete)
		On 05-Oct-2021, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 05-Oct-2021, the patient experienced VENTRICULAR EXTRASYSTOLES (PVC's (premature ventricular contractions)/ gives you a bad feeling/ feel like going to pass out/ makes you feel dizzy) (seriousness criterion medically significant), ARRHYTHMIA (Arrhythmias/feels like you heart is stopping) (seriousness criterion medically significant) and ACCIDENTAL OVERDOSE (Full dose given for booster dose). The patient was treated with METOPROLOL for Adverse event, at an unspecified dose and frequency and PROPRANOLOL for Adverse event, at an unspecified dose and frequency. At the time of the report, VENTRICULAR EXTRASYSTOLES (PVC's (premature ventricular contractions)/ gives you a bad feeling/ feel like going to pass out/ makes you feel dizzy) and ARRHYTHMIA (Arrhythmias/feels like you heart is stopping) had not resolved and ACCIDENTAL OVERDOSE (Full dose given for booster dose) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood pressure measurement: remains low (Low) remains low. On an unknown date, Heart rate: remains low (Low) remains low. No concomitant medications were reported. CC: This spontaneous case concerns an 73-year-old female patient, with a relevant history of premature ventricular contractions, who experienced the unexpected, serious (medically significant) Adverse Events of Special Interest of ARRHYTHMIA, and VENTRICULAR EXTRASYSTOLES, that occurred on the same day after the third dose of mRNA-1273 vaccine administration. Additionally, Accidental overdose was also reported. Patient reported that right after getting the 1st booster dose she started experiencing PVC's (premature ventricular contractions) and arrhythmias. Patient felt abnormal and experienced dizziness. Patient consulted with a cardiologist, underwent diagnostics and was prescribed propranolol and metoprolol. Underlying history of premature ventricular contractions, and the patient's age could be the risk factor. Outcome of the event was reported as not resolved. Previously patient had received the primary series of mRNA-1273 vaccine as dose 1 and 2 with sore arm as the event reported. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	4.1(b) 4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of CARDIAC ARREST (Cardiac arrest / Heart stopped), RIB FRACTURE (7 fractured ribs), CHEST PAIN (Severe chest pain) and ARTERIOSCLEROSIS (Plaques in the arteries / blockages in 2 arteries/ Fair bit of plaque build up.) in a 43-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3002538) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Overweight (Patient lost extra weight.), Hyperglycemia (Lowered blood sugar to normal levels without having to do very much except maintain a bit better of diet.), 4.1(b) use (Little 4.1(b) and alcohol) and Alcohol use (Little 4.1(b) and alcohol). Family history included Heart disorder (There are heart problems in patients family they don't affect anyone until they were into there mid 60s or older.). Concurrent medical conditions included Non-smoker (Patient do not smoke cigarettes.). Concomitant products included METOPROLOL, ROSUVASTATIN, ASPIRIN [ACETYLSALICYLIC ACID], CALCIUM, RAMIPRIL and TICAGRELOR for an unknown indication.

Case ID	WW Identifier	Narrative (Complete)
		On 08-Jun-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 12-Jun-2021, the patient experienced RIB FRACTURE (7 fractured ribs) (seriousness criterion hospitalization). On 12-Jun-2021 at 10:00 PM, the patient experienced CARDIAC ARREST (Cardiac arrest / Heart stopped) (seriousness criteria hospitalization, medically significant and life threatening). In June 2021, the patient experienced CHEST PAIN (Severe chest pain) (seriousness criterion hospitalization), ARTERIOSCLEROSIS (Plaques in the arteries / blockages in 2 arteries/ Fair bit of plaque build up.) (seriousness criterion hospitalization), MEMORY IMPAIRMENT (memory is really fuzzy) and OVERDOSE (tested positive for opioids (because of morphine)). The patient was hospitalized on 12-Jun-2021 due to ARTERIOSCLEROSIS and CARDIAC ARREST. The patient was treated with MORPHINE for Chest pain, at an unspecified dose and frequency and Surgery (stent was placed) for Arteriosclerosis. In June 2021, CARDIAC ARREST (Cardiac arrest / Heart stopped) had resolved. At the time of the report, RIB FRACTURE (7 fractured ribs), CHEST PAIN (Severe chest pain), ARTERIOSCLEROSIS (Plaques in the arteries / blockages in 2 arteries/ Fair bit of plaque build up.), MEMORY IMPAIRMENT (memory is really fuzzy) and OVERDOSE (tested positive for opioids (because of morphine)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In June 2021, Opiates: positive (Positive) tested positive for opioids. mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) dosing remained unchanged. Reported that on 12Jun2021 patient went to bed and at 10pm, patient experienced cardiac arrest. CPR was administered and a total of 5 AED shocks were given over the course of 50ish minutes. During the course of chest compressions, patient ended up with 7 fractured ribs. Patient was hospitalized and treatment was provided. Patient hike daily and always bike or walk to work and lead a pretty active lifestyle. There are heart problems (unspecified) in the patient's family but it didn't affect anyone until they were into there mid 60s or older. Patient had an opioid overdose and made no report about a possible vaccine adverse effect. Patient was little bitter about that because patient do not use opioids or any drugs besides a little 4.1(b) and alcohol. Also reported after testing found that patient had 2 arteries blockages and one artery had corrected itself by rerouting around the blockage and other artery had a fair bit of plaque build up. Patient reported that the general consensus was the cardiac arrest was caused by the plaque build up which was clearly a safe call to make. This case was linked to 4.1(b) (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 16-Jun-2022: Significant Follow Up Appended includes Medical history added and Events updated. Company Comment: This spontaneous case concerns a 43-year-old, male patient with relevant medical history of Obesity (BMI: 30.81), who experienced the unexpected, serious (life-threatening, hospitalization and medically significant) event of cardiac arrest; the unexpected, serious (hospitalization) events of rib fracture, chest pain and arteriosclerosis; and an associated unexpected, non-serious event. The events

Case ID	WW Identifier	Narrative (Complete)
		cardiac arrest and rib fracture occurred 4 days after receiving the first dose of the mRNA-1273 vaccine. The start dates of the other events were not provided. Additionally, drug overdose was also reported. It was reported that at around 10 pm of 12Jun2021 (4 days after vaccination), the patient went into cardiac arrest. Cardiopulmonary resuscitation was administered by the patient's wife until the paramedics arrived. The patient's heart had stopped for an unspecified number of times and a total five automated external defibrillator (AED) shocks were delivered over the course of about 50 minutes. During this time, the chest compressions resulted in seven fractured ribs. The patient was brought to the hospital. The patient complained of severe chest pains and he was given morphine. The patient's memory was fuzzy and he was not sure what was going on at that time. The patient was then transferred to another hospital. A drug test was done which was positive for opioids. The physician was under the assumption that the patient had an opioid overdose. An unspecified diagnostic test was also done which revealed blockages in two arteries. It was reported that one artery had corrected by rerouting the blood supply around the blockage while the other artery had plaque build up. The patient then underwent stent placement. No further clinical information (including details about hospitalization) was available for medical review. It was reported that the patient took metoprolol, rosuvastatin, aspirin, calcium, ramipril and ticagrelor (unspecified dose, frequency and duration) after the adverse event. The event cardiac arrest had resolved while the outcomes of the other events were unknown at the time of the report. The medical history of Obesity remains a confounder for the events cardiac arrest, chest pain and arteriosclerosis. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	4.1 (b) 4.1(b)	This spontaneous case was reported by an other health care professional and describes the occurrence of HERPES OPHTHALMIC (Herpes in the left eye/Corneal scarring on the left/ Corneal scarring on the left, accompanied by worsening of vision on the left (currently: 10%)) in an adult female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product OCRELIZUMAB (OCREVUS) for Secondary progressive multiple sclerosis. The patient's past medical history included SARS-CoV-2 infection (moved 6. Maintenance dose (regular: 30-Nov-2021), Caught up on 26-Apr-2022 (abbreviated infusion duration)), Surgery (Trigeminal neuropathy right surgery) on 16-Jul-2020 and Surgery (Trigeminal neuropathy left surgery: 22-Feb/24-Feb-2021.) in February 2021. Concurrent medical conditions included Trigeminal neuropathy, Secondary progressive multiple sclerosis (Ocrevus maintenance for the treatment of their SPMS, spasticity in the right hand, limited ability to walk.), Numbness in face since 22-Feb-2021, Dacryostenosis acquired since 22-Feb-2021, Loss of smell (Patient sees relationship to surgery (22/02/24.02.2021, due to pre-existing therapy Trigeminal neuropathy)) since February 2021 and Hearing impaired (Patient sees relationship to surgery (22/02/24.02.2021, due to pre-existing therapyTrigeminal neuropathy)) since February 2021. Concomitant products included ALLANTOIN, HYALURONATE SODIUM (HYLO VISION HD PLUS) and DEXPANTHENOL (BEPANTHENE) for Dacryostenosis acquired, DIMETINDENE MALEATE (FENISTIL) from 26-Apr-2022 to an unknown date, DRONABINOL, DIENOGEST, ESTRADIOL VALERATE (QLAIRA), COLECALCIFEROL (DEKRISTOL) and GABAPENTIN for an unknown indication. On 20-Sep-2018, the patient started OCRELIZUMAB (OCREVUS) (Intravenous) 600 milligram. On 30-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 30-Dec-2021, the patient experienced PAIN (pain throughout the body), FATIGUE (generalized fatigue/tiredness) and ACCIDENTAL OVERDOSE (double vaccine dose of Spikevax). In January 2022, the patient experienced HERPES OPHTHALMIC (Herpes in the left eye/Corneal scarring on the left/ Corneal scarring on the left, accompanied by worsening of vision on the left (currently: 10%)) (seriousness criterion medically significant), GAIT INABILITY (Worsening of her limited ability to walk (pre-existing therapy)) and MUSCLE SPASTICITY (increased spasticity in the right hand). On 26-Apr-2022, the patient experienced FATIGUE (Fatigue). On 03-Jan-2022, PAIN (pain throughout the body) and FATIGUE (generalized fatigue/tiredness) had resolved. At the time of the report, HERPES OPHTHALMIC (Herpes in the left eye/Corneal scarring on the left/ Corneal scarring on the left, accompanied by worsening of vision

Case ID	WW Identifier	Narrative (Complete)
		on the left (currently: 10%)) and FATIGUE (Fatigue) had resolved, GAIT INABILITY (Worsening of her limited ability to walk (pre-existing therapy)) and MUSCLE SPASTICITY (increased spasticity in the right hand) had not resolved and ACCIDENTAL OVERDOSE (double vaccine dose of Spikevax) outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Patient date of birth reported as 1977. It was reported that Ocrevus was given for maintenance for the treatment of SPMS and recognized as off label use. ~ On 30-Dec-2021, Patient had generalized fatigue, tiredness and pain throughout the body and resolved on 03-Jan-2022. Patient felt relationship to the double vaccine dose of Spikevax. On early Jan-2022, Patient experienced herpes in the left eye, patient felt association with SARS-CoV-2 infection. Patient had corneal scarring on the left, accompanied by worsening of vision on the left (currently: 10%) and done ophthalmological check-up. Patient felt relationship to herpes in the left, according to physician, this was not treatable. Insidious since early Jan-2022, Patient experienced worsening of her limited ability to walk (pre-existing therapy) and increased spasticity in the right hand (pre-existing therapy), Patient felt relationship to SARS-CoV-2 Infection. On 26-Apr-2022. Patient had fatigue for 2-3 days and patient felt this as a connection to premedication (fenistil) of the 6th maintenance dose. For generalized fatigue, tiredness and pain throughout the body patient not taken treatment. Company Comment: This spontaneous case concerns an adult, female patient of unknown age with relevant concurrent condition of Secondary progressive multiple sclerosis treated with Ocrelizumab who experienced the unexpected, serious (medically significant) event of Herpes ophthalmic which occurred approximately within a month after receiving an unknown dose number of mRNA-1273. Accidental overdose was reported as additional event as patient received double vaccine dose of mRNA-1273. Patient was diagnosed to have herpes ophthalmic by an ophthalmologist after presenting with corneal scarring and worsening vision of the left eye. The clinical course, diagnostic investigations and treatment details were not reported in the case. Concomitant use of Ocrelizumab remain as confounders for the event herpes ophthalmic. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Appendix 11.25c Overdose: Literature Search Methodology

(((((((overdose) OR (overdoses)) OR (drug overdose)) OR (drug misuse)) OR (prescription drug misuse)) OR (overdose, drug)) OR (overdoses, drug)) AND ((("2019-nCoV Vaccine mRNA-1273"[21] OR "COVID-19 Vaccines/adverse effects"[21] OR "COVID-19 Vaccines"[21] OR "SARS-CoV-2"[21] OR "COVID-19"[21] OR "COVID-19 Vaccines"[21] OR "mRNA Vaccines"[21] OR mRNA COVID vaccination [tw] OR mRNA-1273 [tw] OR "mRNA 1273" [tw] OR mRNA1273 [tw] OR "modernatx 1273" [tw] OR "Moderna Covid19 Vaccine" [tw] OR "Moderna Covid-19 Vaccine" [tw] OR SPIKEVAX [tw] OR "2019 nCoV Vaccine mRNA 1273" [tw] OR "mRNA-1273, 2019-nCoV Vaccine" [tw] OR "Moderna COVID-19 Vaccine" [tw] OR "COVID-19 Vaccine, Moderna" [tw] OR "Moderna COVID 19 Vaccine" [tw] OR "Moderna COVID 19 Vaccine" [tw] OR "Vaccine, Moderna COVID-19" [tw] OR Elasomeran [tw] OR "Moderna COVID-19 Vaccine RNA" [tw] OR "Moderna COVID 19 Vaccine RNA" [tw] OR "COVID-19 Vaccine Moderna" [tw] OR "COVID 19 Vaccine Moderna" [tw] OR "Moderna, COVID-19 Vaccine" [tw] OR "mRNA-1273" [tw] OR "mRNA 1273" [tw] OR TAK-919 [tw] OR "TAK 919" [tw] OR TAK919 [tw] OR M-1273 [tw] OR "M 1273" [tw] OR M1273 [tw] OR mRNA-1273.211 [tw] OR "mRNA 1273.211" [tw] OR COVID-19[tw] OR SARS-CoV-2[tw] OR "COVID-19 vaccines"[tw] OR "mRNA Vaccines"[tw] or vaccin*[tw])) AND ("2022/01/01"[Date - Publication] : "2022/06/18"[Date - Publication])))

Appendix 11.26a Off-label use: Reporting Period Case Listing

Case ID	Country	Report Type	ALL PT'S	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	WW Identifier	Batch/Lot Number
4.1(b)	4.1(b)	Regulatory Authority	COVID-19, Immunisation, Interchange of vaccine products, Off label use, Vaccination failure	Serious	64.00	768.00	Male	0	0	COMIRNATY, COMIRNATY	4.1(b)	0
	4.1(b)	Regulatory Authority	Asthenia, Bacterial test positive, Confusional state, Coronavirus infection, Drug ineffective, Fatigue, Gait disturbance, Off label use, Pain in extremity	Serious	0.00	0.00	Female	Gait disturbance(C); Balance disorder(C)	D-MANNOSE	OCREVUS		0
	4.1(b)	Spontaneous	Abnormal loss of weight, Cardiac failure congestive, Decreased appetite, Feeling abnormal, Hypersomnia, Illness, Immunisation reaction, Intentional dose omission	Serious	0.00	0.00	Female	0	0	0		0
	4.1(b)	Regulatory Authority	Drug ineffective, Interchange of vaccine products, Off label use, Suspected COVID-19	Serious	0.00	0.00	Male	0	0	COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	Asymptomatic COVID-19, Immunisation, Interchange of vaccine products, Off label use, Vaccination failure	Serious	58.00	696.00	Male	0	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		214019
	4.1(b)	Spontaneous	Neoplasm malignant, Off label use	Serious	0.00	0.00	Male	0	0	0		0
	4.1(b)	Regulatory Authority	Asthenia, Balance disorder, Bladder disorder, Fall, Fatigue, Headache, Ligament sprain, Muscular weakness, Off label use, Osteitis, Pulpitis dental, Skeletal injury, Trigeminal neuralgia, Urinary incontinence, Urinary tract infection, Uveitis, White blood cells urine	Serious	45.00	540.00	Female	Raynaud's phenomenon(C); Barrett's oesophagus(C); Osteopenia(C); Gastrooesophageal sphincter insufficiency(H); Asthma(C); Dysuria(H); Fatigue(C)	DEKRISTOL; IKERVIS; OXYBUTYNIN; GABAPENTIN; RIVOTRIL; ESOMEPRAZOLE; FOSTER [BECLOMETASONE DIPROPIONATE;FORMOTEROL FUMARATE]	OCREVUS		0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	0.00	0.00	Female	0	0	COMIRNATY; COMIRNATY, COMIRNATY; COMIRNATY, COMIRNATY; COMIRNATY, COMIRNATY; COMIRNATY		0
	4.1(b)	Regulatory Authority	COVID-19, Interchange of vaccine products, Off label use, Vaccination failure	Serious	48.00	576.00	Female	0	0	BNT162B2; BNT162B2, BNT162B2; BNT162B2, BNT162B2; BNT162B2, BNT162B2; BNT162B2		0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Immunisation, Interchange of vaccine products, Off label use	Serious	33.00	396.00	Female	Food allergy	CITALOPRAM; SPIRONOLACTONE	BNT162B2; BNT162B2, BNT162B2; BNT162B2, BNT162B2; BNT162B2, BNT162B2; BNT162B2, BNT162B2; BNT162B2		000040A
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Immunisation, Interchange of vaccine products, Off label use	Serious	41.00	492.00	Male	0	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	Deep vein thrombosis, Interchange of vaccine products, Off label use, Tendonitis, Venous thrombosis limb	Serious	55.00	660.00	Male	Obesity(C); Tobacco user(C); HEPATITIS B VACCINE; TETANUS VACCINE; TETANUS VACCINE; HEPATITIS A VACCINE; HEPATITIS B VACCINE; HEPATITIS B VACCINE; PERTUSSIS VACCINE; TETANUS VACCINE; TETANUS VACCINE; TYPHOID VACCIN; HEPATITIS A VACCINE; COMIRNATY; TETANUS VACCINE; TETANUS VACCINE; TETANUS VACCINE	0	COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	Alanine aminotransferase increased, Antinuclear antibody positive, Aspartate aminotransferase increased, Blood thyroid stimulating hormone increased, Cytomegalovirus test positive, Epstein-Barr virus antibody positive, Fatigue, Haemangioma of liver, Hepatic enzyme increased, Hepatitis A antibody positive, Interchange of vaccine products, Myalgia, Off label use, Peripheral swelling, Raynaud's phenomenon	Serious	46.00	552.00	Male	COMIRNATY(H)	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	COVID-19, Interchange of vaccine products, Off label use, Vaccination failure	Serious	0.00	0.00	Female	0	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	Asymptomatic COVID-19, Interchange of vaccine products, Off label use, Vaccination failure	Serious	41.00	492.00	Male	0	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		030G21A
	4.1(b)	Regulatory Authority	Asthenia, Balance disorder, Burning sensation, Coccydynia, Dizziness, Eye disorder, Feeling abnormal, Gait disturbance, General physical health deterioration, Interchange of vaccine products, Memory impairment, Migraine, Musculoskeletal stiffness, Myalgia, Off label use, Pain, Pain in extremity, Paralysis, Spinal pain	Serious	68.00	816.00	Female	Leukaemia(C); Allogenic stem cell transplantation; Migraine(H); Dizziness(H); Limb injury(H); Transplant; Skeletal injury(H); Chemotherapy; Tenoplasty; Somnolence(H)	BLOOD; EUTHYROX; LOSARTAN	ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE		017621A
	4.1(b)	Regulatory Authority	COVID-19, Interchange of vaccine products, Off label use, Vaccination failure	Serious	40.00	480.00	Female	NICKEL(H); KETOPROFENE [KETOPROFEN](H); AMOXICILLIN(H)	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		030G21A
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	35.00	420.00	Male	0	0	COMIRNATY; COMIRNATY, COMIRNATY; COMIRNATY, COMIRNATY; COMIRNATY, COMIRNATY; COMIRNATY		0
	SWEDEN	Regulatory Authority	Death, Interchange of vaccine products, Off label use	Serious	95.00	1140.00	Female	0	0	COMIRNATY, COMIRNATY, COMIRNATY		016G21A
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Nasopharyngitis, Off label use, Pyrexia	Serious	40.00	480.00	Male	Glucose-6-phosphate dehydrogenase deficiency(H)	0	COMIRNATY, COMIRNATY		3005698
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	50.00	600.00	Female	0	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0

Case ID	Country	Report Type	ALL PT'S	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	WW Identifier	Batch/Lot Number
4.1(b)	4.1(b)	Regulatory Authority	Affective disorder, Arthralgia, Back pain, Fatigue, Inflammation, Interchange of vaccine products, Movement disorder, Off label use, Pain, Pyrexia, Somnolence	Serious	70.00	840.00	Female	INFLUENZA VACCINE	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY	4.1(b)	0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Immunisation, Interchange of vaccine products, Off label use	Serious	32.00	384.00	Male	COVID-19(H)	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		3001531; 3001531
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Fatigue, Headache, Nasopharyngitis, Nausea, Off label use	Serious	39.00	468.00	Male	Mite allergy; Interchange of vaccine products(H)	0	COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	25.00	300.00	Male	Hypersensitivity	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	Drug ineffective, Interchange of vaccine products, Off label use, Suspected COVID-19	Serious	49.00	588.00	Female	0	0	COMIRNATY; COVID-19 VACCINE ASTRAZENECA, COMIRNATY; COVID-19 VACCINE ASTRAZENECA, COMIRNATY; COVID-19 VACCINE ASTRAZENECA, COMIRNATY; COVID-19 VACCINE ASTRAZENECA		0
	4.1(b)	Regulatory Authority	Illness, Interchange of vaccine products, Off label use, Pericarditis	Serious	66.00	792.00	Male	0	4.1(b) ; AVAMYS; BETAMETHASONE DIPROPIONATE; CODEINE; EZETIMIBE; GLICLAZIDE; METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE; PANTOPRAZOLE SODIUM; ROSUVASTATIN CALCIUM; SALBUTAMOL; TRAMADOL; ZOPICLONE	VAXZEVRIA; SILIQ; SILIQ, VAXZEVRIA; SILIQ; SILIQ, VAXZEVRIA; SILIQ; SILIQ, VAXZEVRIA; SILIQ; SILIQ		0
	4.1(b)	Regulatory Authority	Colitis ulcerative, Contusion, Cystitis, Muscular weakness, Off label use	Serious	36.00	432.00	Female	0	MEZAVANT; PREDNISONE	ENTYVIO, ENTYVIO, ENTYVIO, ENTYVIO, ENTYVIO		0
	4.1(b)	Regulatory Authority	Arthralgia, Chills, Exposure during pregnancy, Fatigue, Intentional product use issue, Interchange of vaccine products, Malaise, Off label use, Pain in extremity, Placenta praevia, Premature delivery	Serious	39.00	468.00	Female	0	TYLENOL [PARACETAMOL]	VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA		0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	0.00	0.00	Female	0	0	COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	Angina pectoris, Headache, Inappropriate schedule of product administration, Interchange of vaccine products, Off label use, Pain in extremity, Phlebitis	Serious	54.00	648.00	Unknown	0	TOZINAMERAN	COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)		0
	4.1(b)	Regulatory Authority	Drug ineffective, Interchange of vaccine products, Off label use, Suspected COVID-19	Serious	47.00	564.00	Male	0	0	COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	Cough, COVID-19, Drug ineffective, Headache, Interchange of vaccine products, Off label use, Pain in extremity	Serious	39.00	468.00	Female	0	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	0.00	0.00	Male	0	0	COVID-19 VACCINE ASTRAZENECA; COMIRNATY, COVID-19 VACCINE ASTRAZENECA; COMIRNATY, COVID-19 VACCINE ASTRAZENECA; COMIRNATY, COVID-19 VACCINE ASTRAZENECA; COMIRNATY		0
	4.1(b)	Literature-Non-Study	Atrial fibrillation, Intentional dose omission, Syncope	Serious	20.00	240.00	Female	0	0	0		0
	4.1(b)	Regulatory Authority	Burning sensation, Interchange of vaccine products, Neuropathy peripheral, Off label use, Pain in extremity	Serious	57.00	684.00	Female	0	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	0.00	0.00	Male	0	0	COMIRNATY; COVID-19 VACCINE ASTRAZENECA, COMIRNATY; COVID-19 VACCINE ASTRAZENECA, COMIRNATY; COVID-19 VACCINE ASTRAZENECA, COMIRNATY; COVID-19 VACCINE ASTRAZENECA		0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	35.00	420.00	Male	0	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use, Pericardial effusion, Pericarditis, Sinus tachycardia, Supraventricular extrasystoles, Ventricular extrasystoles	Serious	22.00	264.00	Female	0	ORAL CONTRACEPTIVE NOS; IBUPROFEN	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	27.00	324.00	Female	Addison's disease(C)	BOOSTRIX; ASTONIN H 4.1(b) ; INFLUVAC TETRA; HYDROCORTISON 4.1(b) ; QLAIRA	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		214007; 3002614
	4.1(b)	Regulatory Authority	Apathy, Aphasia, Ataxia, Bacterial infection, Body temperature increased, Burning sensation, Cystitis noninfective, Dermatitis contact, Dizziness, Erythema, Fall, Fatigue, Feeling hot, Fluid retention, Gait disturbance, Haematoma, Haemorrhoids, Headache, Heart rate increased, Hemiparesis, Hyperhidrosis, Hypoaesthesia, Hypoaesthesia oral, Insomnia, Joint swelling, Muscular weakness, Myalgia, Neuralgia, Ocular discomfort, Off label use, Pain in extremity, Pruritus, Tinea pedis	Serious	50.00	600.00	Female	Aphasia(C); Anxiety(H); Seasonal allergy; Fatigue(C); Depression(H); Disturbance in attention(C); Allergy to metals; Gait disturbance(C); Progressive relapsing multiple sclerosis(C); Secondary progressive multiple sclerosis(C)	FAMPYRA; MAGNESIUM; CLOMIPRAMIN; SATIVEX; DEKRISTOL; CITALOPRAM	COMIRNATY; OCREVUS, COMIRNATY; OCREVUS, COMIRNATY; OCREVUS, COMIRNATY; OCREVUS, COMIRNATY; OCREVUS, COMIRNATY; OCREVUS, COMIRNATY; OCREVUS		0

Case ID	Country	Report Type	ALL PT'S	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	WW Identifier	Batch/Lot Number
4.1(b)	4.1(b)	Regulatory Authority	Blood lactate dehydrogenase increased, Ear pain, Headache, Hypoacusis, Interchange of vaccine products, Lymphadenitis, Lymphadenopathy, Malaise, Off label use, Oropharyngeal pain, Pain, Pyrexia, Tinnitus	Serious	0.33	3.95	Male	Lymphadenopathy(H); Drug hypersensitivity	PARACETAMOL; 4.1(b) ACICLOVIR MK; PREGABALINE; AMOXICILINA GI; FOLIDEX	VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA	4.1(b)	0
	4.1(b)	Regulatory Authority	Acute kidney injury, Asthma, Blood cholesterol increased, Blood glucose increased, Blood triglycerides increased, Chills, Condition aggravated, Decreased appetite, Dyspnoea, Essential hypertension, Guillain-Barre syndrome, High density lipoprotein decreased, Hypersensitivity, Hypertension, Interchange of vaccine products, Mycoplasma test positive, Myelopathy, Off label use, Platelet count increased, Pruritus, Pyrexia, Rash, Tubulointerstitial nephritis, Upper respiratory tract infection, Urticaria, Vitamin D deficiency, Vomiting	Serious	62.00	744.00	Male	0	DEKRISTOL; RAMIPRIL	VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE, VAXZEVRIA; PFIZER BIONTECH COVID-19 VACCINE		000117A
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	60.00	720.00	Male	Intraocular pressure increased(H); Relapsing-remitting multiple sclerosis(H)	VITAMIN K2 [MENAQUINONE]; DEKRISTOL; FIXAPROST; TAMSULOSIN; OCREVUS	COVID-19 VACCINE ASTRAZENECA; COMIRNATY, COVID-19 VACCINE ASTRAZENECA; COMIRNATY, COVID-19 VACCINE ASTRAZENECA; COMIRNATY, COVID-19 VACCINE ASTRAZENECA; COMIRNATY		0
	4.1(b)	Regulatory Authority	Arthralgia, Cystitis bacterial, Decreased immune responsiveness, Fatigue, Gait disturbance, Headache, Lymphadenopathy, Myalgia, Off label use, Pain in extremity	Serious	55.00	660.00	Female	Hypothyroidism(H); Hypertension(H); Uhthoff's phenomenon(H)	GABAPENTIN; AMLODIPIN [AMLODIPINE]; TIZANIDIN; L-THYROXINE [LEVOTHYROXINE]; SATIVEX	COMIRNATY; OCREVUS		0
	4.1(b)	Regulatory Authority	Abdominal pain upper, Alopecia, Alopecia areata, Alopecia universalis, Asthenia, Balance disorder, Bedridden, Blood immunoglobulin G decreased, Burning sensation, CD4 lymphocytes increased, Chills, COVID-19, Drug ineffective, Drug intolerance, Erythema, Fatigue, Gait disturbance, Gastrointestinal infection, Headache, Hypoaesthesia, Inappropriate schedule of product administration, Influenza, Infusion related reaction, Listless, Macular degeneration, Macular hole, Malaise, Medication error, Multiple sclerosis, Multiple sclerosis relapse, Muscle spasms, Muscular weakness, Nail bed inflammation, Nausea, Neurodermatitis, Off label use, Optic nerve disorder, Oral disorder, Oropharyngeal pain, Pain of skin, Paraesthesia, Polyneuropathy, Product preparation issue, Rash erythematous, SARS-CoV-2 antibody test negative, Sensory disturbance, Stomatitis, T-lymphocyte count increased, Tongue exfoliation, Vitreous opacities	Serious	46.00	552.00	Female	Viral test positive; Allergy to arthropod sting; Ovarian cancer(H); Balance disorder(C); Endocarditis(H); Fatigue(C); Hypersensitivity; Paraesthesia(C); Hypoaesthesia(C); Allergy to arthropod sting; Allergy to arthropod sting; Alopecia(C); Limb discomfort(C); Nail bed inflammation(H); Paraesthesia(C); Drug hypersensitivity; Oophorectomy; Multiple sclerosis(H); TYSABRI(H); Blindness(H)	4.1(b) [ESTRADIOL]; PARACETAMOL; KENTERA; ESTRIOL; NACL; CETIRIZIN; 4.1(b) ; VITAMIN D3	COMIRNATY; OCRELIZUMAB; REMDESIVIR, COMIRNATY; OCRELIZUMAB; REMDESIVIR, COMIRNATY; OCRELIZUMAB; REMDESIVIR, COMIRNATY; OCRELIZUMAB; REMDESIVIR, COMIRNATY; OCRELIZUMAB; REMDESIVIR, COMIRNATY; OCRELIZUMAB; REMDESIVIR		0
	4.1(b)	Spontaneous	Abdominal discomfort, Depressed mood, Gastrooesophageal reflux disease, Herpes ophthalmic, Ocular discomfort, Off label use, Throat irritation, Vision blurred	Serious	0.00	0.00	Male	Gastrooesophageal reflux disease(C)	0	0		0
	4.1(b)	Regulatory Authority	COVID-19, Interchange of vaccine products, Off label use, Urticaria, Vaccination failure	Serious	0.00	0.00	Female	Intermenstrual bleeding(H); Autoimmune thyroiditis(C); Uterine leiomyoma(H); Hypertension(C); Post procedural hypothyroidism(H); Thyroidectomy; Pregnancy(H); Abortion spontaneous(H)	4.1(b) EUTIROX	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		214019

Case ID	Country	Report Type	ALL PT'S	Case Seriousness	Patient Age (Years)	Patient Age (Months)	Patient Gender	Medical History	Concomitant Medications	Co-suspects	WW Identifier	Batch/Lot Number
4.1(b)	4.1(b)	Regulatory Authority	Anxiety disorder, Asthenia, Burning sensation, Cerebrovascular accident, Chills, Coronary artery disease, Depressed mood, Depression, Discouragement, Disturbance in attention, Dizziness, Dyspnoea, Dyspnoea exertional, Embolism, Fall, Fatigue, Feeling abnormal, Feeling guilty, Feelings of worthlessness, Glial scar, Headache, Hot flush, Hypersensitivity, Hypoaesthesia, Inferiority complex, Interchange of vaccine products, Intervertebral disc protrusion, Ischaemia, Lacunar stroke, Mental disorder, Motor dysfunction, Movement disorder, Off label use, Otolithiasis, Palpitations, Paralysis, Peripheral coldness, Self esteem decreased, Sensory disturbance, Sinus tachycardia, Sleep disorder, Somnolence, Thalamic infarction, Vertebral end plate impression, Vertigo positional	Serious	40.00	480.00	Female	Hernia(C); Chronic gastritis(C); Coronary artery disease(C)	ROSUVASTATIN; EPICRISINE; ACETYLSALICYLIC ACID; ESOMEPRAZOLE	VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA	4.1(b)	3002542
	4.1(b)	Regulatory Authority	Carpal tunnel syndrome, Cerebrovascular accident, Chest discomfort, Deafness, Depressed level of consciousness, Depression, Diarrhoea, Interchange of vaccine products, Meniere's disease, Off label use, Paraesthesia, Syncope, Taste disorder	Serious	0.00	0.00	Male	Asthma(H)	TILIDINE; AMOXICILINA GI; TAMSULOSIN; ROSUVASTATIN; EDOXABAN; CANDESARTAN CILEXETIL; TRAMADOL HYDROCHLORIDE; FOSTERA; DULOXETINA TEVA; AMLODIPINE 4.1(b) ATENOLOL/CHLORTALIDONE EG	VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA, VAXZEVRIA		092F21A; 3002542
	4.1(b)	Literature-Non-Study	Anaphylactic reaction, Off label use	Serious	31.00	372.00	Female	0	0	0		0
	4.1(b)	Literature-Non-Study	Anaphylactic reaction, Inappropriate schedule of product administration, Off label use	Serious	57.00	684.00	Female	0	0	0		0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	27.00	324.00	Male	Addison's disease(H); SARS-CoV-2 test positive(H)	QLAIRA; HYDROCORTISON [HYDROCORTISONE]; ASTONIN-H; 4.1(b)	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		214007; 3002614
	4.1(b)	Regulatory Authority	Alopecia, Immunisation reaction, Off label use, Thrombocytopenia	Serious	61.00	732.00	Female	Crohn's disease(C)	0	ENTYVIO; ENTYVIO; ENTYVIO, ENTYVIO; ENTYVIO; ENTYVIO, ENTYVIO; ENTYVIO, ENTYVIO, ENTYVIO; ENTYVIO; ENTYVIO		0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	61.00	732.00	Female	Psoriatic arthropathy(H)	CERTOLIZUMAB	VAXZEVRIA; COMIRNATY, VAXZEVRIA; COMIRNATY, VAXZEVRIA; COMIRNATY, VAXZEVRIA; COMIRNATY		0
	4.1(b)	Regulatory Authority	Drug ineffective, Interchange of vaccine products, Off label use, Suspected COVID-19	Serious	0.00	0.00	Female	0	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	Drug ineffective, Interchange of vaccine products, Off label use, Suspected COVID-19	Serious	0.00	0.00	Female	0	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	Drug ineffective, Interchange of vaccine products, Off label use, Suspected COVID-19	Serious	54.00	648.00	Female	0	0	VAXZEVRIA; COMIRNATY, VAXZEVRIA; COMIRNATY, VAXZEVRIA; COMIRNATY, VAXZEVRIA; COMIRNATY		0
	4.1(b)	Regulatory Authority	Drug ineffective, Interchange of vaccine products, Off label use, Suspected COVID-19	Serious	36.00	432.00	Female	0	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	COVID-19, Drug interaction, Hypogammaglobulinaemia, Off label use, Vaccination failure	Serious	47.00	564.00	Male	Congestive cardiomyopathy(H); PREDNISOLONE(H); DOXORUBICIN(H); CYCLOPHOSPHAMIDE(H); VINCRISTINE(H)	0	RITUXIMAB; TOCILIZUMAB		0
	4.1(b)	Regulatory Authority	COVID-19, Drug ineffective, Interchange of vaccine products, Off label use	Serious	0.00	0.00	Female	0	0	COMIRNATY, COMIRNATY, COMIRNATY, COMIRNATY		0
	4.1(b)	Regulatory Authority	Interchange of vaccine products, Myocarditis, Off label use	Serious	30.00	360.00	Male	0	0	VAXZEVRIA		0
	4.1(b)	Spontaneous	Autoimmune disorder, Off label use	Serious	61.00	732.00	Male	0	0	HUMIRA		0
	4.1(b)	Spontaneous	Bronchiectasis, Hepatic pain, Hypersensitivity, Off label use, Traumatic lung injury	Serious	54.00	648.00	Female	Diabetes mellitus(C); Food allergy; MELOXICAM(H); IODINE(H); EPINEPHRINE(H); HYDROCODONE BITARTRATE(H); ASPIRIN [ACETYLSALICYLIC ACID](H); Rubber sensitivity; Food allergy; Allergy to animal; Food allergy	4.1(b) PRAVASTATIN SODIUM	HUMIRA		0

Appendix 11.26b Off-label use: Reporting Period Case Narratives

Case ID	WW Identifier	Narrative (Complete)
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Jan-2022 and was forwarded to Moderna on 07-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of VACCINATION FAILURE (infected with COVID-19/started with symptoms on 09Dec (PCR positive on 10Dec)) and COVID-19 (infected with COVID-19/started with symptoms on 09Dec (PCR positive on 10Dec)) in a 64-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. No Medical History information was reported. On 13-Jan-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (unknown route) DOSE 1, SINGLE. On 03-Feb-2021, received dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to DOSE 2, SINGLE. On 03-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Dec-2021, the patient experienced IMMUNISATION (He received the third dose of Moderna vaccine), OFF LABEL USE (He received the third dose of Moderna vaccine) and INTERCHANGE OF VACCINE PRODUCTS (He received the third dose of Moderna vaccine). On 09-Dec-2021, the patient experienced VACCINATION FAILURE (infected with COVID-19/started with symptoms on 09Dec (PCR positive on 10Dec)) (seriousness criterion medically significant) and COVID-19 (infected with COVID-19/started with symptoms on 09Dec (PCR positive on 10Dec)) (seriousness criterion medically significant). At the time of the report, VACCINATION FAILURE (infected with COVID-19/started with symptoms on 09Dec (PCR positive on 10Dec)) and COVID-19 (infected with COVID-19/started with symptoms on 09Dec (PCR positive on 10Dec)) had not resolved and IMMUNISATION (He received the third dose of Moderna vaccine), OFF LABEL USE (He received the third dose of Moderna vaccine) and INTERCHANGE OF VACCINE PRODUCTS (He received the third dose of Moderna vaccine) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Dec-2021, SARS-CoV-2 test: positive (Positive) Positive. No concomitant medications were reported. No Treatment medications were reported. Company comment: This is a regulatory authority case concerning a 64-year-old male patient with no medical history reported, who experienced unexpected events of COVID-19 (AESI) and vaccination failure (seriousness criterion of medically significant assessed as per Regulatory Authority reporting). The events occurred 6 days after the third dose of mRNA-1273 vaccine. Clinical course and treatment details were not provided. Patient completed primary vaccination with Tozinameran vaccine (Corminaty). The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 14-Jan-2022. The most recent information was received on 14-Jan-2022 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by a consumer and describes the occurrence of BACTERIAL TEST POSITIVE (BACTERIA IN URINE IDENTIFIED) in a female patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below.

Case ID	WW Identifier	Narrative (Complete)
		Co-suspect product included non-company product OCRELIZUMAB (OCREVUS) for Secondary progressive multiple sclerosis. Concurrent medical conditions included Difficulty in walking and Balance disorder. Concomitant products included D-MANNOSE for an unknown indication. On 05-Jul-2018, the patient started OCRELIZUMAB (OCREVUS) (Intravenous) 300 mg. On 08-Jan-2019, OCRELIZUMAB (OCREVUS) (Intravenous) dosage was changed to 600 mg. On 14-Jan-2020, OCRELIZUMAB (OCREVUS) (Intravenous) dosage was changed to 600 mg. On 05-Jan-2021, OCRELIZUMAB (OCREVUS) (Intravenous) dosage was changed to 600 mg. On 06-May-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Jun-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 21-Aug-2018, the patient experienced ASTHENIA (PROGRESSIVE WEAKNESS). On 06-Jun-2019, the patient experienced BACTERIAL TEST POSITIVE (BACTERIA IN URINE IDENTIFIED) (seriousness criterion medically significant). On 01-Aug-2019, the patient experienced DRUG INEFFECTIVE (FEELING OF LACK OF EFFICACY) and GAIT DISTURBANCE (WORSENING OF RESTRICTED WALKING ABILITY). In November 2021, the patient experienced CORONAVIRUS INFECTION (CORONAVIRUS INFECTION). On an unknown date, the patient experienced PAIN IN EXTREMITY (TENDERNESS IN RIGHT UPPER ARM), CONFUSIONAL STATE (MENTAL CONFUSION), OFF LABEL USE (OCREVUS USED AS OFF LABEL FOR UNLABELED INDICATION) and FATIGUE (FATIGUE). At the time of the report, DRUG INEFFECTIVE (FEELING OF LACK OF EFFICACY) and OFF LABEL USE (OCREVUS USED AS OFF LABEL FOR UNLABELED INDICATION) outcome was unknown, PAIN IN EXTREMITY (TENDERNESS IN RIGHT UPPER ARM), CONFUSIONAL STATE (MENTAL CONFUSION), BACTERIAL TEST POSITIVE (BACTERIA IN URINE IDENTIFIED), CORONAVIRUS INFECTION (CORONAVIRUS INFECTION) and FATIGUE (FATIGUE) had resolved and GAIT DISTURBANCE (WORSENING OF RESTRICTED WALKING ABILITY) and ASTHENIA (PROGRESSIVE WEAKNESS) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Sep-2019, Urine analysis: no bacteria (normal) No bacteria. No Treatment medications were provided. Company Comment: This is a regulatory case concerning a female patient of unknown age with concurrent condition of Secondary progressive multiple sclerosis treated with ocrelizumab (reported as co-suspect), who experienced the unexpected serious (medically significant) event of Bacterial test positive (Bacteria urine identified) 2 years before vaccination with mRNA-1273 vaccine (outcome was reported as recovered without disclosing date). She also experienced the unexpected non-serious AESI of Coronavirus infection, approximately 5 months after the second dose of mRNA-1273 vaccine (first dose of mRNA-1273 within correct interval). Drug ineffective could be considered for the case. The medical history of Secondary progressive multiple sclerosis treated with ocrelizumab remains as a confounder for Bacteria urine identified, while ocrelizumab treatment could be a contributory factor for drug ineffective and Coronavirus infection. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events´ seriousness assessed as reported.

Case ID	WW Identifier	Narrative (Complete)
		Most recent FOLLOW-UP information incorporated above includes: On 14-Jan-2022: Upon internal review on 16-Mar-2022, significant correction was performed. The MAH causality was updated from not applicable to related for the events Bacteria in urine identified, mental confusion, fatigue, worsening of restricted walking ability and progressive weakness. And the MAH causality was updated from not related to Not applicable for the event Corona virus infection. The event ranking was updated.
4.1(b)	4.1(b) 4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of CARDIAC FAILURE CONGESTIVE (conjunctive heart failure) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 27-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Jul-2021, the patient experienced INTENTIONAL DOSE OMISSION (She didn't want to get the second dose). On an unknown date, the patient experienced CARDIAC FAILURE CONGESTIVE (conjunctive heart failure) (seriousness criteria hospitalization and medically significant), HYPERSOMNIA (slept all the time), ILLNESS (wound up very very sick), VACCINATION COMPLICATION (many side effects, next day I had a lot of side effects), ABNORMAL LOSS OF WEIGHT (lost 40 pounds), DECREASED APPETITE (didn't eat food for 6 weeks) and FEELING ABNORMAL (upset, next day I was not myself anymore). The patient was hospitalized for 6 days due to CARDIAC FAILURE CONGESTIVE. On 27-Jul-2021, INTENTIONAL DOSE OMISSION (She didn't want to get the second dose) had resolved. At the time of the report, CARDIAC FAILURE CONGESTIVE (conjunctive heart failure) had not resolved and HYPERSOMNIA (slept all the time), ILLNESS (wound up very very sick), VACCINATION COMPLICATION (many side effects, next day I had a lot of side effects), ABNORMAL LOSS OF WEIGHT (lost 40 pounds), DECREASED APPETITE (didn't eat food for 6 weeks) and FEELING ABNORMAL (upset, next day I was not myself anymore) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Symptoms: It was reported that the patient did not wanted second dose of vaccine because she was affected by first one, She was undergone many tests, she had many side effects, she was healthy and her immune system was good, her doctor did not warned her with ingredients and possible side effects of vaccine. She felt like she was being poisoned, and was continued treatment for heart condition. No concomitant medications were reported No treatment medications were reported Company comment: This is a spontaneous case concerning a female patient of unknown age, with no reported medical history, who experienced the serious (due to hospitalization and medically important condition) unexpected, AESI of Cardiac failure congestive. The event occurred on an unknown date after the first dose of mRNA-1273 vaccine. The outcome of the event was reported as not recovered. The patient was hospitalized for 6 days. Additionally, Intentional dose omission was reported in this case. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	WW Identifier	Narrative (Complete)
		Reporter did not allow further contact
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 20-Jan-2022. The most recent information was received on 11-Apr-2022 and was forwarded to Moderna on 11-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DRUG INEFFECTIVE (Coronavirus infection) and SUSPECTED COVID-19 (Coronavirus infection) in a male patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. No Medical History information was reported. On an unknown date, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form and second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On an unknown date, received first dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced OFF LABEL USE (off label), DRUG INEFFECTIVE (Coronavirus infection) (seriousness criterion medically significant), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) and SUSPECTED COVID-19 (Coronavirus infection) (seriousness criterion medically significant). At the time of the report, OFF LABEL USE (off label), DRUG INEFFECTIVE (Coronavirus infection), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) and SUSPECTED COVID-19 (Coronavirus infection) outcome was unknown. Concomitant medication was not reported. Treatment information was not reported. Company comment: This regulatory case concerns a male patient of an unknown age, with no reported medical history, who experienced the unexpected serious (medically significant) AESI of Suspected COVID-19 that occurred on an unknown time after receiving the booster dose of mRNA-1273 vaccine. Drug ineffective was also reported. Patient had previously received 2 doses of Tozinameran vaccine on unknown dates. There was Interchange of vaccine products, therefore lack of efficacy cannot be concluded for this case. Clinical course, treatment details and lab data were not reported. At the time of reporting, the outcome of event was unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 11-Apr-2022: Follow-up received wherein event vaccination failure updated to drug ineffective, Indication as reported by the primary source updated.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 21-Jan-2022. The most recent information was received on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of IMMUNISATION (COVID-19 vaccine MODERNA , 3rd dose BOOSTER administered on 02Dec2021), ASYMPTOMATIC COVID-19 (sars-cov 2 nasal swab was positive), OFF LABEL USE (COVID-19 vaccine MODERNA , 3rd dose BOOSTER administered on 02Dec2021), INTERCHANGE OF VACCINE PRODUCTS (COVID-19 vaccine MODERNA , 3rd dose BOOSTER administered on

Case ID	WW Identifier	Narrative (Complete)
		02Dec2021) and VACCINATION FAILURE (sars-cov 2 nasal swab was positive) in a 58-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214019) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. No Medical History information was reported. On 13-May-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 03-Jun-2021, received second dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to 1 dosage form. On 02-Dec-2021 at 9:45 AM, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Dec-2021, the patient experienced IMMUNISATION (COVID-19 vaccine MODERNA , 3rd dose BOOSTER administered on 02Dec2021) (seriousness criterion medically significant), OFF LABEL USE (COVID-19 vaccine MODERNA , 3rd dose BOOSTER administered on 02Dec2021) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (COVID-19 vaccine MODERNA , 3rd dose BOOSTER administered on 02Dec2021) (seriousness criterion medically significant). On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced ASYMPTOMATIC COVID-19 (sars-cov 2 nasal swab was positive) (seriousness criterion medically significant) and VACCINATION FAILURE (sars-cov 2 nasal swab was positive) (seriousness criterion medically significant). At the time of the report, IMMUNISATION (COVID-19 vaccine MODERNA , 3rd dose BOOSTER administered on 02Dec2021), OFF LABEL USE (COVID-19 vaccine MODERNA , 3rd dose BOOSTER administered on 02Dec2021) and INTERCHANGE OF VACCINE PRODUCTS (COVID-19 vaccine MODERNA , 3rd dose BOOSTER administered on 02Dec2021) outcome was unknown and ASYMPTOMATIC COVID-19 (sars-cov 2 nasal swab was positive) and VACCINATION FAILURE (sars-cov 2 nasal swab was positive) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Dec-2021, SARS-CoV-2 test: positive (Positive) Test Result: Positive. On 04-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative. No Concomitant drugs were reported. No Treatment information were reported. It was reported that, the relevant past drug history was not applicable. Company comment: This regulatory authority case concerns a 58-year-old male patient with no medical history reported, who experienced the unexpected serious events of Asymptomatic COVID (AESI) after mRNA- 1273 vaccine, booster dose of the vaccination schedule. Interchange of vaccine products was considered since the patient had received initial schedule of vaccination with Comirnarty vaccine. Additionally, vaccination failure and off label use were also reported by the regulatory authority. The event Asymptomatic COVID occurred approximately 25 days after the booster dose of mRNA- 1273 vaccine. At the time of the report, Asymptomatic COVID and vaccination failure have resolved. The seriousness criteria of the events was assessed as per regulatory authority report. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 02-Feb-2022: Follow up contains significant information as events asymptomatic COVID-19 and Vaccination failure updated the outcome from not recovered to recovered. Added lab dat SARS-CoV-2 test on 4-Jan-2022.

Case ID	WW Identifier	Narrative (Complete)
		On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b)	4.1(b) 4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of NEOPLASM MALIGNANT (has since had chemotherapy) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. In January 2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In February 2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 21-Jan-2022, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 21-Jan-2022, the patient experienced OFF LABEL USE (Off label dosing frequency). On an unknown date, the patient experienced NEOPLASM MALIGNANT (has since had chemotherapy) (seriousness criterion medically significant). On 21-Jan-2022, OFF LABEL USE (Off label dosing frequency) had resolved. At the time of the report, NEOPLASM MALIGNANT (has since had chemotherapy) outcome was unknown. Concomitant medication was not reported. Patient received 2 doses of the vaccine and He had since chemotherapy under the direction of his gynecologist. He received an additional primary dose. He was recommended by his HCPs to completely restart the vaccination series a period after completing chemotherapy. Company Comment: This spontaneous case concerns a male patient with unknown age with history of Cancer (unknown type and location) with history of chemotherapy date of treatment and drugs used not reported , who experienced Serious , unexpected event of Neoplasm malignant and non-serious , unexpected event of LLT off label dosing frequency , PT Off label use which occurred on an unknown date after vaccination with the 3rd dose of mRNA-1273 vaccine. This patient has already received his primary series vaccine using mRNA-1273 vaccine for two doses and this Jan 21, 2022 received another primary dose as reported , it was stated that the HCP instructed this patient to receive another two doses after the chemotherapy. Per Guidance in patients who are considered immunocompromised e.g. Post transplant patients , patients with Cancer and undergoing chemotherapy , CKD patient and among others with possible depressed immune system as deemed by the HCP a third dose (full dose) after 1 month after the 2nd dose can be given and can be followed by the 1/2 booster dose after 6 months , but no recommendation as re-starting the primary series. The re-challenge for this case is not applicable . The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Jan-2022 and was forwarded to Moderna on 27-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of UVEITIS (UVEITIS) in a 45-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product OCRELIZUMAB (OCREVUS) injection, solution for Secondary progressive multiple sclerosis and Relapsing-remitting multiple sclerosis.

Case ID	WW Identifier	Narrative (Complete)
		Reflux. The patient's past medical history included Incompetent cardia and Difficulty voiding. Concurrent medical conditions included Raynaud's syndrome, Barrett's esophagus, Osteopenia, Asthma and Fatigue. Concomitant products included COLECALCIFEROL (DEKRISTOL), CICLOSPORIN (IKERVIS), OXYBUTYNIN, GABAPENTIN, CLONAZEPAM (RIVOTRIL), ESOMEPRAZOLE and BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE (FOSTER [BECLOMETASONE DIPROPIONATE;FORMOTEROL FUMARATE]) for an unknown indication. On 30-Jul-2018, the patient started OCRELIZUMAB (OCREVUS) (Intravenous) 300 milligram. On 13-Feb-2019, OCRELIZUMAB (OCREVUS) (Intravenous) dosage was changed to 600 milligram. On 13-Jan-2021, OCRELIZUMAB (OCREVUS) (Intravenous) dosage was changed to 600 milligram. In 2021, received dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 4 drop. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 2.5 milligram. On 10-Mar-2019, the patient experienced FALL (FALL). On 20-Aug-2019, the patient experienced ASTHENIA (WEAKNESS). In September 2019, the patient experienced BALANCE DISORDER (EQUILIBRIUM TROUBLES) and BALANCE DISORDER (BALANCE PROBLEMS (UNK DIAFNOSIS)). On 30-Sep-2019, the patient experienced MUSCULAR WEAKNESS (DECREASED WALKING DISTANCE (LEG MUSCLE WEAKNESS)). In September 2020, the patient experienced HEADACHE (HEADACHE). In February 2021, the patient experienced OFF LABEL USE (OFF LABEL USE FOR UNLABELED INDICATION). In May 2021, the patient experienced URINARY INCONTINENCE (WORSENING OF INCONTINENCE (URINARY INCONTINENCE)). On an unknown date, the patient experienced LIGAMENT SPRAIN (LEFT FOOT LIGAMENT SPRAIN), TRIGEMINAL NEURALGIA (TRIGEMINAL NEURALGIA), UVEITIS (UVEITIS) (seriousness criterion medically significant), SKELETAL INJURY (BONE TEAR LEFT INSTEP (BONE INJURY)), OSTEITIS (JAW INFLAMMATION), WHITE BLOOD CELLS URINE (WHITE BLOOD CELLS URINE), PULPITIS DENTAL (DENTAL ROOT INFLAMMATION), BLADDER DISORDER (BLADDER DISORDER), URINARY TRACT INFECTION (URINARY TRACT INFECTION) and FATIGUE (EPISODE OF TIREDNESS). In August 2019, ASTHENIA (WEAKNESS) had resolved. At the time of the report, LIGAMENT SPRAIN (LEFT FOOT LIGAMENT SPRAIN), TRIGEMINAL NEURALGIA (TRIGEMINAL NEURALGIA), UVEITIS (UVEITIS), SKELETAL INJURY (BONE TEAR LEFT INSTEP (BONE INJURY)), OSTEITIS (JAW INFLAMMATION), PULPITIS DENTAL (DENTAL ROOT INFLAMMATION), BLADDER DISORDER (BLADDER DISORDER), URINARY TRACT INFECTION (URINARY TRACT INFECTION) and FATIGUE (EPISODE OF TIREDNESS) had resolved, HEADACHE (HEADACHE), URINARY INCONTINENCE (WORSENING OF INCONTINENCE (URINARY INCONTINENCE)), BALANCE DISORDER (EQUILIBRIUM TROUBLES), MUSCULAR WEAKNESS (DECREASED WALKING DISTANCE (LEG MUSCLE WEAKNESS)) and BALANCE DISORDER (BALANCE PROBLEMS (UNK DIAFNOSIS)) had not resolved and WHITE BLOOD CELLS URINE (WHITE BLOOD CELLS URINE), FALL (FALL) and OFF LABEL USE (OFF LABEL USE FOR UNLABELED INDICATION) outcome was unknown. Past medical history also includes Reflux Company Comment - This regulatory authority case concerns a 45 year old female patient with medical history of secondary progressive multiple sclerosis, who experienced the serious unexpected event of uveitis. The event occurred on an unknown date

Case ID	WW Identifier	Narrative (Complete)
		after a dose of mRNA-1273 vaccine. Patient's medical history of secondary progressive multiple sclerosis remains a confounder. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 18-May-2022: Follow up Received: Contains No New Information
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b)) on 03-Feb-2022. The most recent information was received on 13-Feb-2022 and was forwarded to Moderna on 13-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of OFF LABEL USE (Off label use), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), DRUG INEFFECTIVE (Drug Ineffective) and COVID-19 (Covid positive test on Lateral flow 22Jan2022) in a female patient of an unknown age who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 immunization. Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for an unknown indication and TOZINAMERAN (COMIRNATY) for COVID-19 immunization. No Medical History information was reported. In May 2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. In June 2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On an unknown date, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 22-Jan-2022, the patient experienced DRUG INEFFECTIVE (Drug Ineffective) (seriousness criterion medically significant) and COVID-19 (Covid positive test on Lateral flow 22Jan2022) (seriousness criterion medically significant). On an unknown date, the patient experienced OFF LABEL USE (Off label use) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criterion medically significant). At the time of the report, OFF LABEL USE (Off label use), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), DRUG INEFFECTIVE (Drug Ineffective) and COVID-19 (Covid positive test on Lateral flow 22Jan2022) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Jan-2022, SARS-CoV-2 test: covid positive test on lateral flow (Positive) Covid positive test on Lateral flow. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. No concomitant medication was provided by the reporter. A female patient received bnt162b2 (COMIRNATY), administration date Jun2021 (Batch/Lot number: unknown) as dose 2, single and administration date May2021 as dose 1, single for covid-19 immunisation; covid-19 vaccine mrna (mrna 1273) (MODERNA COVID-19 VACCINE) as dose 3 (booster), single for covid-19 immunisation. No treatment medication was provided by the reporter. Product quality investigation request Investigations for events LOE and COVID-19 test positive: for Lot Numbers: EP9598 and ER7812 female, 92 years old, vaccination failure (tested positive for COVID) associated with the use of Comirnaty (batch EP9598 and ER7812). The Adverse Drug Reaction (ADR) appeared 8 days after the 2nd administration of the vaccine. There

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		was no suspicion of interactions. Specific treatment of RAMs unknown. Additional data: clinical history of malignant neoplasm of the ascending colon, HTA; Osteoarthritis; Ferropenic anemia; Cholecystectomized. Diagnosis confirmed by RT-PCR method. Additional information: Lot number ER7812 Expiry date:30sep2021 and ET1831 Expiry date:30Jun2021 Company comment: This case concerns a 92-year-old female patient with relevant medical history of malignant neoplasm of the ascending colon who experienced the unexpected, serious (medically significant) AESI event of COVID-19 (with a positive SARS-CoV-2 test) at an unknown time after the booster dose of mRNA-1273 (vaccination date not provided). The patient had received initial schedule of vaccination with COMIRNATY (TOZINAMERAN) (interchange of vaccine products was reported). Additionally, off-label and drug ineffective have been reported. The current pandemic situation of COVID 19 and the medical history of malignant neoplasm of the ascending colon may remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report. Most recent FOLLOW-UP information incorporated above includes: On 13-Feb-2022: Significant Follow up - Additional information: Lot number ER7812 Expiry date:30sep2021 added- Narrative updated
4.1(b)	4.1(b)	This case was initially received via 4.1(b) (Reference number: 4.1(b)) on 04-Feb-2022. The most recent information was received on 11-Feb-2022 and was forwarded to Moderna on 11-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of OFF LABEL USE (Off label use), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), VACCINATION FAILURE (I have COVID 19 symptoms and tested positive by PCR) and COVID-19 (I have COVID 19 symptoms and tested positive by PCR) in a 48-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. Co-suspect products included non-company products TOZINAMERAN (BNT162B2) for an unknown indication and TOZINAMERAN (BNT162B2) for COVID-19 immunisation. No Medical History information was reported. On 13-May-2021, the patient received first dose of TOZINAMERAN (BNT162B2) (unknown route) 1 dosage form. On 03-Jun-2021, the patient received second dose of TOZINAMERAN (BNT162B2) (unknown route) 1 dosage form. On 08-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 08-Dec-2021, the patient experienced OFF LABEL USE (Off label use) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criterion medically significant). On 29-Dec-2021, the patient experienced VACCINATION FAILURE (I have COVID 19 symptoms and tested positive by PCR) (seriousness criterion medically significant) and COVID-19 (I have COVID 19 symptoms and tested positive by PCR) (seriousness criterion medically significant). At the time of the report, OFF LABEL USE (Off label use), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) and COVID-19 (I have COVID 19 symptoms and tested positive by PCR) outcome was unknown and VACCINATION FAILURE (I have COVID 19 symptoms and tested positive by PCR) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Dec-2021, Polymerase chain reaction: positive (Positive) Positive. Polymerase chain reaction (31-DEC-2021):Nasal Swab.. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.

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		No concomitant and treatment use was provided by the reporter. Active drug substance name of Moderna Vaccine was given as CX-024414. Reporter mentioned that Pfizer Product Quality Group provided investigation results on 04Feb2022.The investigation of the referenced PR ID resulted in the following include the complaint for PFIZER BIONTECH COVID-19 VACCINE was investigated which included reviewing the involved batch records, deviation investigation and an analysis of the complaint history for the reported lot and product type. The final scope was determined to be the reported lots include ET1831 and ER7812. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation and stability. PGS Manufacturing site concludes that the reported defect is not representative of the quality of the batch and the batch remains acceptable. The NTM process determined that no regulatory notification was required.No root cause or CAPA were identified as the complaint was not confirmed. Company comment include This is a regulatory authority case concerning a 48-year-old, female patient with no reported medical history and with vaccine history of receiving another brand of Covid-19 vaccine (Covid-19 vaccine Tozinameran) as first and second dose of Covid-19 vaccine, who experienced the unexpected, serious (medically significant according to Regulatory authority report), AESI event of Covid-19. Vaccination failure and off label use were also reported. The event Covid-19 and reported vaccination failure occurred 21 days after the third dose of mRNA-1273 vaccine administration in Covid-19 dose series with positive unspecified PCR test result. No reported treatment information. The outcome of the event Covid-19 was unknown. The vaccine history of receiving another brand of Covid-19 vaccine (Covid-19 vaccine Tozinameran) as first and second dose of Covid-19 vaccine remain confounder. The benefit-risk This case was linked to 4.1(b) (E2B Linked Report). Most recent FOLLOW-UP information incorporated above includes: On 11-Feb-2022: Follow up document received and includes expiration date of BNT162B2 vaccine added. On 29-May-2022: Non-significant follow-up received on 29-May-2022 contains reporter's information and Moderna vaccine active drug substance updated.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 08-Feb-2022 and was forwarded to Moderna on 08-Feb-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of IMMUNISATION (booster), OFF LABEL USE (off label use), INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine product), DRUG INEFFECTIVE (Drug ineffective) and COVID-19 (Covid Positive in Jan2022) in a 33-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000040A) for COVID-19 immunisation. Co-suspect products included non-company products BNT162B2 for an unknown indication and BNT162B2 for COVID-19 immunisation. Concurrent medical conditions included Shellfish allergy (Shellfish-iodine). Concomitant products included CITALOPRAM and SPIRONOLACTONE for an unknown indication. On 10-May-2021, the patient received first dose of BNT162B2 (unknown route) 1 dosage form. On 01-Jun-2021, the patient received second dose of BNT162B2 (unknown route) 1 dosage form. On 12-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 12-Jan-2022, the patient experienced IMMUNISATION (booster) (seriousness criterion medically significant), OFF LABEL USE (off label use) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (interchange

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		of vaccine product) (seriousness criterion medically significant). On 22-Jan-2022, the patient experienced DRUG INEFFECTIVE (Drug ineffective) (seriousness criterion medically significant) and COVID-19 (Covid Positive in Jan2022) (seriousness criterion medically significant). At the time of the report, IMMUNISATION (booster), OFF LABEL USE (off label use), INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine product) and DRUG INEFFECTIVE (Drug ineffective) outcome was unknown and COVID-19 (Covid Positive in Jan2022) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive, Nasal Swab. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment medication information was not provided by reporter. Company Comment: This is a regulatory case of interchange of vaccine products and off label use for this 33-year-old, female patient with history of co-suspect administration of two doses of the BNT162b2 mRNA COVID-19 vaccine, who experienced the unexpected, serious (medically significant) AESI of COVID-19, drug ineffective and immunisation. The patient received two doses of the BNT162b2 mRNA COVID-19 vaccine: the first dose on 10May2021 and the second dose on 01Jun2021. The patient later received the booster dose of the Moderna mRNA-1273 vaccine on 12Jan2022. The events COVID-19 and drug ineffective occurred approximately 7 months after administration of the second dose of the BNT162b2 mRNA COVID-19 vaccine and 10 days after administration of the booster dose of the Moderna mRNA-1273 vaccine. Treatment information was not provided. The event COVID-19 had not resolved at the time of the report. The history of co-suspect administration of the BNT162b2 mRNA COVID-19 vaccines remains a confounder. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) (E2B Linked Report).
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (he developed fever and malaise and was tested positive for SARS-COV-2 (antigen test)), DRUG INEFFECTIVE (he developed fever and malaise and was tested positive for SARS-COV-2 (antigen test)), OFF LABEL USE (Off label use), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) and IMMUNISATION (booster) in a 41-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 immunization. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. No Medical History information was reported. On 10-May-2021, the patient received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 07-Jun-2021, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 11-Jan-2022, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 16-Jan-2022, the patient experienced COVID-19 (he developed fever and malaise and was tested positive for SARS-COV-2 (antigen test)) (seriousness criterion medically significant), DRUG INEFFECTIVE (he developed fever and malaise and was tested positive for SARS-COV-2 (antigen test)) (seriousness criterion medically significant), OFF LABEL USE (Off label use)

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		(seriousness criterion medically significant), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criterion medically significant) and IMMUNISATION (booster) (seriousness criterion medically significant). At the time of the report, COVID-19 (he developed fever and malaise and was tested positive for SARS-COV-2 (antigen test)) had not resolved and DRUG INEFFECTIVE (he developed fever and malaise and was tested positive for SARS-COV-2 (antigen test)), OFF LABEL USE (Off label use), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) and IMMUNISATION (booster) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive. Concomitant medications were not provided by the reporter. Treatment information was not provided. On 16 Jan 2022 patient developed fever and malaise and was tested positive for SARS-COV-2 (antigen test) the same day. He was still positive for SARS-COV-2. Company comment: This is a regulatory case concerning 41-year-old male patient with no medical history reported, received booster dose of Comirnaty, who experienced the serious, due to medically significant, unexpected event of COVID-19 (AESI). Drug ineffective, off label use, interchange of vaccine products, immunisation (verbatim: booster) were considered additional events. The event COVID-19 occurred approximately 7 months and 9 days after the 2nd dose of mRNA-1273 and 5 days after the 3rd dose of Comirnaty. No further information was provided regarding the clinical course, the events off label, immunsation, and treatment of the event. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 14-Feb-2022. The most recent information was received on 24-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEEP VEIN THROMBOSIS (DVT), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine product) and OFF LABEL USE (Off label use) in a 55-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. Previously administered products included for Product used for unknown indication: TETANUS VACCINE on 14-Sep-1967, TETANUS VACCINE on 05-Oct-1967, TETANUS VACCINE on 15-Mar-1972, TETANUS VACCINE on 27-Sep-1976, TETANUS VACCINE on 16-Sep-1978, HEPATITIS B VACCINE on 26-May-1998, TETANUS VACCINE on 26-May-1998, TYPHOID VACCIN on 27-May-1998, HEPATITIS B VACCINE on 08-Jul-1998, HEPATITIS A VACCINE on 23-Jun-1999, HEPATITIS B VACCINE on 23-Jun-1999, HEPATITIS A VACCINE on 12-Jul-2000, TETANUS VACCINE on 24-Jul-2014 and PERTUSSIS VACCINE on 24-Jul-2014; for COVID-19 vaccination: COMIRNATY on 27-Jun-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY, HEPATITIS A VACCINE, HEPATITIS A VACCINE, HEPATITIS B VACCINE, HEPATITIS B VACCINE, HEPATITIS B VACCINE, PERTUSSIS VACCINE, TETANUS VACCINE, TETANUS VACCINE, TETANUS VACCINE, TETANUS VACCINE, TETANUS VACCINE, TETANUS VACCINE, TETANUS VACCINE and TYPHOID VACCIN. Concurrent medical conditions included Obesity since 2018 and Smoker since 1986.

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		On 02-Aug-2021 at 9:50 AM, the patient received second dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 17-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 10-Aug-2021, the patient experienced TENDONITIS (Tendonitis), DEEP VEIN THROMBOSIS (DVT) (seriousness criterion medically significant) and VENOUS THROMBOSIS LIMB (Peripheral venous thrombosis). On 17-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine product) (seriousness criterion medically significant) and OFF LABEL USE (Off label use) (seriousness criterion medically significant). At the time of the report, TENDONITIS (Tendonitis), DEEP VEIN THROMBOSIS (DVT) and VENOUS THROMBOSIS LIMB (Peripheral venous thrombosis) was resolving and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine product) and OFF LABEL USE (Off label use) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Laboratory test: negative (Negative) Negative. On 10-Aug-2021, Ultrasound Doppler: abnormal (abnormal) Test Result:right leg sural twin venous thrombosis. On 12-Aug-2021, Activated partial thromboplastin time: 1.23 Test Result:1.23. On 12-Aug-2021, Haematocrit: 42.2 Test Result:42.2. On 12-Aug-2021, Haemoglobin (140-180): 0% (Low) 0%. On 12-Aug-2021, International normalised ratio: 1.11 Test Result:1.11. On 12-Aug-2021, Platelet count (130-400): 0% (Low) 0%. On 12-Jan-2022, Investigation: abnormal (abnormal) Test Result:DVT ongoing. On 12-Jan-2022, Ultrasound Doppler: abnormal (abnormal) Test Result:DVT ongoing. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant drug information provided. Previously administered products included for Product used for unknown indication: DIPHTHERIA VACCINES on 14-Sep-1967, 05-Oct-1967, 15-Mar-1972 and 24-Jul-2014. Past adverse reactions to the DIPHTHERIA VACCINES included No adverse event. No treatment drug information provided. Sender's comments- Based on the information in the case report, a causal association between reported events deep vein thrombosis, venous thrombosis limb and the suspect BNT162b2 cannot be excluded.The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Company comment: This regulatory case concerns a 55-year-old male patient, with history of interchange of vaccine products and relevant medical history of Obesity, smoking and, who experienced the unexpected serious (medically significant) AESI Deep vein thrombosis, in association with mRNA-1273. Additionally, interchange of vaccine products and off label use were also reported. It is to be noted that the event occurred approximately 4 months prior to vaccination with mRNA-1273 and 8 days after the second dose of Comirnaty covid19 vaccine. Medical history of obesity and smoking could be confounders. Second dose of Comirnaty covid 19 vaccine could be a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per Regulatory Authority’s report.

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		Most recent FOLLOW-UP information incorporated above includes: On 24-Mar-2022: Follow up contains significant information. Lab data added. Event outcome updated.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of ASPARTATE AMINOTRANSFERASE INCREASED (aspartate aminotransferase: 236), HAEMANGIOMA OF LIVER (heamangioma liver/ two haemangiomas in right liver lobe), ALANINE AMINOTRANSFERASE INCREASED (alanine aminotransferase: 190) and HEPATIC ENZYME INCREASED (liver enzymes increased) in a 46-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. Previously administered products included for COVID-19 immunization: COMIRNATY on 11-Jun-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY. On 16-Jul-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 03-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In August 2021, the patient experienced PERIPHERAL SWELLING (Swollen hands and fingers), RAYNAUD'S PHENOMENON (Raynaud's phenomenon), FATIGUE (fatigue), HAEMANGIOMA OF LIVER (heamangioma liver/ two haemangiomas in right liver lobe) (seriousness criterion medically significant), MYALGIA (myalgia (especially legs)) and HEPATIC ENZYME INCREASED (liver enzymes increased) (seriousness criterion medically significant). On 03-Nov-2021, the patient experienced ASPARTATE AMINOTRANSFERASE INCREASED (aspartate aminotransferase: 236) (seriousness criterion medically significant) and ALANINE AMINOTRANSFERASE INCREASED (alanine aminotransferase: 190) (seriousness criterion medically significant). On 10-Nov-2021, the patient experienced HEPATITIS A ANTIBODY POSITIVE (Hepatitis A antibodies total positive), CYTOMEGALOVIRUS TEST POSITIVE (CMV IgG antibody: positive/positive) and EPSTEIN-BARR VIRUS ANTIBODY POSITIVE (Epstein-Barr virus IgG antibody positive). On 01-Dec-2021, the patient experienced BLOOD THYROID STIMULATING HORMONE INCREASED (TSH: 4.3) and ANTINUCLEAR ANTIBODY POSITIVE (antinuclear antibody: positive). On 03-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced OFF LABEL USE (Received vaccine with Comirnaty and COVID-19 VACCINE MODERNA) and INTERCHANGE OF VACCINE PRODUCTS (Received vaccine with Comirnaty and COVID-19 VACCINE MODERNA). At the time of the report, HEPATITIS A ANTIBODY POSITIVE (Hepatitis A antibodies total positive), BLOOD THYROID STIMULATING HORMONE INCREASED (TSH: 4.3), ASPARTATE AMINOTRANSFERASE INCREASED (aspartate aminotransferase: 236), CYTOMEGALOVIRUS TEST POSITIVE (CMV IgG antibody: positive/positive), OFF LABEL USE (Received vaccine with Comirnaty and COVID-19 VACCINE MODERNA), ANTINUCLEAR ANTIBODY POSITIVE (antinuclear antibody: positive), ALANINE AMINOTRANSFERASE INCREASED (alanine aminotransferase: 190), INTERCHANGE OF VACCINE PRODUCTS (Received vaccine with Comirnaty and COVID-19 VACCINE MODERNA) and EPSTEIN-BARR VIRUS ANTIBODY POSITIVE (Epstein-Barr virus IgG antibody positive) outcome was unknown and PERIPHERAL SWELLING (Swollen hands and fingers), RAYNAUD'S PHENOMENON (Raynaud's phenomenon), FATIGUE (fatigue), HAEMANGIOMA OF LIVER (heamangioma liver/ two haemangiomas in right liver lobe), MYALGIA (myalgia (especially legs)) and HEPATIC ENZYME INCREASED (liver enzymes increased) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Hepatic enzyme: increased Test Result:increased. On 03-Nov-2021, Alanine aminotransferase (Unknown-45): 190 Test Result:190 Test Range Normal High : 45.

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		On 03-Nov-2021, Aspartate aminotransferase (Unknown-45): 236 Test Result:236. Test Range Normal High : 45. On 03-Nov-2021, Blood alkaline phosphatase (Unknown-125): 71 Test Result:71. Test Range Normal High: 125. On 03-Nov-2021, Blood bilirubin (4-24): 12 (normal) Test Result:12. Test Range Normal Low: 4 Test Range Normal High: 24. On 03-Nov-2021, Blood creatinine (61-113): 74 (normal) Test Result:74 Test Range Normal Low : 61. Test Range Normal High : 113. On 03-Nov-2021, Blood glucose (4-7.8): 7.1 (normal) Test Result:7.1. Test Range Normal Low : 4 Test Range Normal High : 7.8. On 03-Nov-2021, Blood thyroid stimulating hormone (0.27-4.2): 3.12 Test Result:3.12 Test Range Normal Low : 0.27 Test Range Normal High : 4.2. On 03-Nov-2021, C-reactive protein (Unknown-10): less than 4 Test Result:less than 4 Test Range Normal High :10.. On 03-Nov-2021, Glomerular filtration rate (60-Unknown): 105 Test Result:105 Test Range Normal Low : 60. On 03-Nov-2021, Haemoglobin (8.5-11): 9.8 Test Result:9.8 Test Range Normal Low : 8.5 Test Range Normal High :11. On 03-Nov-2021, Mean cell volume (80-100): 94 Test Result:94 Test Range Normal Low : 80 Test Range Normal High : 100. On 03-Nov-2021, Red blood cell sedimentation rate (1-15): 2 Test Result:2 Test Range Normal Low : 1 Test Range Normal High : 15. On 03-Nov-2021, Vitamin B12 (148-548): 358 Test Result:358 Test Range Normal Low :148 Test Range Normal High :548. On 03-Nov-2021, Vitamin D (50-150): 70 Test Result:70 Test Range Normal Low : 50 Test Range Normal High :150. On 10-Nov-2021, Alanine aminotransferase (Unknown-45): 170 Test Result:170. Test Range Normal High 45. On 10-Nov-2021, Aspartate aminotransferase (Unknown-45): 213 Test Result:213 Test Range Normal High : 45. On 10-Nov-2021, Blood alkaline phosphatase (Unknown-125): 70 Test Result:70 Test Range Normal High :125.. On 10-Nov-2021, Blood bilirubin (4-24): 11 (normal) Test Result:11 Test Range Normal Low : 4 Test Range Normal High : 24. On 10-Nov-2021, Cytomegalovirus test: positive (Positive) Test Result: Positive and negative (Negative) Test Result: negative. On 10-Nov-2021, Epstein-Barr virus antibody: caps antigen negative (Negative) Test Result:caps antigen negative, nuclear antigen positive (Positive) Test Result:nuclear antigen positive and negative (Negative) Test Result:negative (caps Ag). On 10-Nov-2021, Gamma-glutamyltransferase (Unknown-55): 23 Test Result:23 Test Range Normal High : 55. On 10-Nov-2021, Hepatitis A antibody: positive (Positive) Positive and negative (Negative) Negative. On 10-Nov-2021, Hepatitis B antibody: negative (Negative) Negative. On 10-Nov-2021, Hepatitis B core antibody: negative (Negative) Negative. On 10-Nov-2021, Hepatitis B surface antibody (10-Unknown): less than 2 Test Result:less than 2 Test Range Normal Low : 10. On 10-Nov-2021, Hepatitis B surface antigen: negative (Negative) Negative. On 10-Nov-2021, Hepatitis C antibody: negative (Negative) Test Result: negative. On 10-Nov-2021, Hepatitis E antibody: negative (Negative) Test Result: negative and negative (Negative) Test Result: negative. On 10-Nov-2021, Ultrasound abdomen: small cyst Test Result:small cyst. On 01-Dec-2021, Alanine aminotransferase (Unknown-45): 190 Test Result:190 Test Range Normal High 45. On 01-Dec-2021, Alpha-1 anti-trypsin: 1.6 Test Result:1.6. On 01-Dec-2021, Angiotensin converting enzyme: 62 Test Result:62. On 01-Dec-2021, Anti-cyclic citrullinated peptide antibody: 3.4 Test Result:3.4. On 01-Dec-2021, Anti-transglutaminase antibody: 0.3 Test Result:0.3. On 01-Dec-2021, Antimitochondrial antibody: 3 Test Result:3. On 01-Dec-2021, Antineutrophil cytoplasmic antibody: .2 Test Result:less than 0.2 and 0.2 Test Result:less than 0.2. On 01-Dec-2021, Antinuclear antibody: positive (Positive) Positive, negative (Negative) Negative, negative (Negative) Negative, negative (Negative) Negative, negative (Negative) Negative, ro52 (Negative) Test Result:Ro52: negative, r060 (Positive) Test Result:Ro60: positive, negative (Negative) Negative and negative (Negative) Negative. On 01-Dec-2021, Aspartate aminotransferase (Unknown-45): 264 Test Result:264 Test Range Normal High :45.

Case ID	WW Identifier	Narrative (Complete)
		On 01-Dec-2021, Autoantibody test: negative (Negative) Negative, 1 Test Result:1, negative (Negative) Negative and unknown Test Result:unknown results. On 01-Dec-2021, Bilirubin conjugated: 3 Test Result:less th
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 16-Feb-2022. The most recent information was received on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (Became sick, Covid-19), INTERCHANGE OF VACCINE PRODUCTS (Taken three doses of Pfizer/ Moderna covid vaccine), OFF LABEL USE (Taken three doses of Pfizer/ Moderna covid vaccine) and VACCINATION FAILURE (Became sick, Covid-19) in a female patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 immunisation. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. No Medical History information was reported. On 05-May-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. In May 2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-May-2021, received second dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. On 17-Jan-2022, the patient experienced COVID-19 (Became sick, Covid-19) (seriousness criterion medically significant) and VACCINATION FAILURE (Became sick, Covid-19) (seriousness criterion medically significant). On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Taken three doses of Pfizer/ Moderna covid vaccine) (seriousness criterion medically significant) and OFF LABEL USE (Taken three doses of Pfizer/ Moderna covid vaccine) (seriousness criterion medically significant). At the time of the report, COVID-19 (Became sick, Covid-19) had not resolved and INTERCHANGE OF VACCINE PRODUCTS (Taken three doses of Pfizer/ Moderna covid vaccine), OFF LABEL USE (Taken three doses of Pfizer/ Moderna covid vaccine) and VACCINATION FAILURE (Became sick, Covid-19) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive. Concomitant medication was not provided. Treatment information was not provided. Company Comment: This is a regulatory case of interchange of vaccine products and off label use for this female patient, of unknown age, with history of co-suspect administration of two doses of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine), who experienced the unexpected, serious (medically significant) AESI of COVID-19. Additionally, vaccination failure was also reported. The event occurred approximately 8 months after administration of an unspecified dose of the mRNA-1273 vaccine on an unspecified date in May2021. The patient tested positive for SARS-CoV-2 on 17Jan2022. Treatment information was not provided. The event COVID-19 had not resolved at the time of the report. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.

Case ID	WW Identifier	Narrative (Complete)
		Most recent FOLLOW-UP information incorporated above includes: On 28-Apr-2022: Follow up received that contains information includes suspect product indication updated and co-suspect product additional information on drug added.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 21-Feb-2022. The most recent information was received on 09-Mar-2022 and was forwarded to Moderna on 09-Mar-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of INTERCHANGE OF VACCINE PRODUCTS (Off-Label use + Interchange of vaccine products), VACCINATION FAILURE (Asymptomatic COVID-19), OFF LABEL USE (Off-Label use + Interchange of vaccine products) and ASYMPTOMATIC COVID-19 (Asymptomatic COVID-19) in a 41-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 030G21A) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. No Medical History information was reported. On 10-Jun-2021 at 4:30 PM, the patient received first dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 15-Jul-2021 at 3:45 AM, received second dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to 1 dosage form. On 31-Dec-2021 at 11:00 AM, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 31-Dec-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Off-Label use + Interchange of vaccine products) (seriousness criterion medically significant) and OFF LABEL USE (Off-Label use + Interchange of vaccine products) (seriousness criterion medically significant). On 26-Jan-2022, the patient experienced VACCINATION FAILURE (Asymptomatic COVID-19) (seriousness criterion medically significant). On an unknown date, the patient experienced ASYMPTOMATIC COVID-19 (Asymptomatic COVID-19) (seriousness criterion medically significant). At the time of the report, INTERCHANGE OF VACCINE PRODUCTS (Off-Label use + Interchange of vaccine products), VACCINATION FAILURE (Asymptomatic COVID-19) and OFF LABEL USE (Off-Label use + Interchange of vaccine products) outcome was unknown and ASYMPTOMATIC COVID-19 (Asymptomatic COVID-19) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Jan-2022, SARS-CoV-2 test: positive (Positive) Test Result: Positive Rapid Antigen Nasal Swab. On 02-Feb-2022, SARS-CoV-2 test: negative (Negative) Test Result: Negative Rapid Antigen test. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Additional information for co-suspect reported: Expiry Date=30-SEP-2021. Concomitant medications were not provided by the reporter. Treatment information was not provided. Company comment:This regulatory authority case concerns a 41-year-old male patient, with no medical history reported, previously vaccinated with two doses of Comirnaty, who experienced the unexpected AESI of asymptomatic COVID 19. Additional events reported were vaccination failure, off-label use and interchange of vaccine products. There was no rationale provided for the off-label use. Time to onset for the event of asymptomatic COVID 19 was not provided however, based on the onset of vaccination failure and positive SARS-COV2 test, the event occurred 26 days after the dose of mRNA-1273. The

Case ID	WW Identifier	Narrative (Complete)
		benefit-risk relationship of mRNA-1273 is not affected by this report. The events were considered as medically significant by the regulatory authority. Most recent FOLLOW-UP information incorporated above includes: On 01-Mar-2022: Follow-up received is non significant. On 09-Mar-2022: Significant follow up received, lab data, expiry date for co-suspect added. Updated event outcome and removed start date for event Asymptomatic COVID-19.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 18-Feb-2022 and was forwarded to Moderna on 18-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PARALYSIS (THE MUSCLES ARE BECOMING MORE PARALYZED AND WEIRD/ PARALYZED FINGERS, ESPECIALLY ON THE RIGHT SIDE (IT STARTED FROM THE ARM AND ON)/ VERY STRANGE FEELING THAT SEEMED LIKE IT PARALYZED) in a 68-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 017621A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) for an unknown indication and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) for an unknown indication. The patient's past medical history included Migraine (for a few years and was medicated for it.), Dizziness (some years ago), Arm injury (She had more or less managed to recover) in 2016, Bone injury in 2016, Sleepy (she sat on a subway bench and passed out. She had then gone to the hospital and everything was fine at the time.), Allogeneic peripheral haematopoietic stem cell transplant, Transplant, Chemotherapy and Tendon repair. Concurrent medical conditions included Leukemia. Concomitant products included BLOOD, WHOLE (BLOOD) for Blood pressure, LOSARTAN for Hypertensive, LEVOTHYROXINE SODIUM (EUTHYROX) for Thyroid disorder. On 08-May-2021, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) (Intramuscular) 1 dosage form. On 08-Jul-2021, the patient received second dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) (Intramuscular) 1 dosage form. On 12-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced BALANCE DISORDER (LOSING HER BALANCE (IN THE MORNING, SHE FALLS TO THE FLOOR BECAUSE SHE HAS NO BALANCE)/ IMBALANCE), GENERAL PHYSICAL HEALTH DETERIORATION (GETTING WORRIED BECAUSE EVERY DAY THERE IS SOMETHING DIFFERENT), PAIN IN EXTREMITY (PAIN ON HER HAND), COCCYDYNIA (IN THE PART OF THE COCCYX SHE ALREADY HAD SOME PAIN), PAIN IN EXTREMITY (VERY WEIRD PAIN ON HER LEGS, SHE WAS ONE DAY IN BED BUT DID NOT HAVE A FEVER), MUSCULOSKELETAL STIFFNESS (DIFFICULTY MOVING THE FINGERS OF HER RIGHT HAND), MYALGIA (A LOT OF MUSCLE PAIN), FEELING ABNORMAL (SHE NOTICES WITH EACH DAY THAT GOES BY THERE IS A WEIRD FEELING/ FEELING VERY BAD/ UNPLEASANT SENSATION), PAIN (SHE NOTICES WITH EACH DAY THAT GOES BY THERE IS ONE MORE PAIN), BURNING SENSATION (SOMETHING WAS BURNING INSIDE THE BODY, VERY WEIRD FEELING, ESPECIALLY ON A PART OF THE LEGS, SOME MUSCLE PAIN), OFF LABEL USE (THE THIRD DOSE SHE RECEIVED WAS MODERNA ON 12DEC2021.), DIZZINESS (DIZZINESS), MEMORY IMPAIRMENT (GETTING A LITTLE FORGOTTEN), SPINAL PAIN (EVEN IN THE SPINE IT SEEMS LIKE IT HURTS EVERYWHERE, IT STARTS SOMEWHERE, IN THE MIDDLE, IN THE END), GAIT DISTURBANCE (SHE DOES NOT

Case ID	WW Identifier	Narrative (Complete)
		FEEL THAT SHE WALKS NORMALLY), PARALYSIS (THE MUSCLES ARE BECOMING MORE PARALYZED AND WEIRD/ PARALYZED FINGERS, ESPECIALLY ON THE RIGHT SIDE (IT STARTED FROM THE ARM AND ON)/ VERY STRANGE FEELING THAT SEEMED LIKE IT PARALYZED) (seriousness criterion medically significant), MIGRAINE (MIGRAINES), ASTHENIA (WEAKNESS), INTERCHANGE OF VACCINE PRODUCTS (THE THIRD DOSE SHE RECEIVED WAS MODERNA ON 12DEC2021) and EYE DISORDER (SOMETHING (UNINTELLIGIBLE) IN HER EYES AS IF IT WERE VERTIGO)). At the time of the report, BALANCE DISORDER (LOSING HER BALANCE (IN THE MORNING, SHE FALLS TO THE FLOOR BECAUSE SHE HAS NO BALANCE)/ IMBALANCE), GENERAL PHYSICAL HEALTH DETERIORATION (GETTING WORRIED BECAUSE EVERY DAY THERE IS SOMETHING DIFFERENT), PAIN IN EXTREMITY (PAIN ON HER HAND), COCCYDYNIA (IN THE PART OF THE COCCYX SHE ALREADY HAD SOME PAIN), PAIN IN EXTREMITY (VERY WEIRD PAIN ON HER LEGS, SHE WAS ONE DAY IN BED BUT DID NOT HAVE A FEVER), MUSCULOSKELETAL STIFFNESS (DIFFICULTY MOVING THE FINGERS OF HER RIGHT HAND), MYALGIA (A LOT OF MUSCLE PAIN), FEELING ABNORMAL (SHE NOTICES WITH EACH DAY THAT GOES BY THERE IS A WEIRD FEELING/ FEELING VERY BAD/ UNPLEASANT SENSATION), PAIN (SHE NOTICES WITH EACH DAY THAT GOES BY THERE IS ONE MORE PAIN), BURNING SENSATION (SOMETHING WAS BURNING INSIDE THE BODY, VERY WEIRD FEELING, ESPECIALLY ON A PART OF THE LEGS, SOME MUSCLE PAIN), OFF LABEL USE (THE THIRD DOSE SHE RECEIVED WAS MODERNA ON 12DEC2021.), DIZZINESS (DIZZINESS), MEMORY IMPAIRMENT (GETTING A LITTLE FORGOTTEN), SPINAL PAIN (EVEN IN THE SPINE IT SEEMS LIKE IT HURTS EVERYWHERE, IT STARTS SOMEWHERE, IN THE MIDDLE, IN THE END), GAIT DISTURBANCE (SHE DOES NOT FEEL THAT SHE WALKS NORMALLY), PARALYSIS (THE MUSCLES ARE BECOMING MORE PARALYZED AND WEIRD/ PARALYZED FINGERS, ESPECIALLY ON THE RIGHT SIDE (IT STARTED FROM THE ARM AND ON)/ VERY STRANGE FEELING THAT SEEMED LIKE IT PARALYZED), MIGRAINE (MIGRAINES), ASTHENIA (WEAKNESS), INTERCHANGE OF VACCINE PRODUCTS (THE THIRD DOSE SHE RECEIVED WAS MODERNA ON 12DEC2021) and EYE DISORDER (SOMETHING (UNINTELLIGIBLE) IN HER EYES AS IF IT WERE VERTIGO)) outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Additional Information on drug (ASTRAZENECA COVID-19 VACCINE, ASTRAZENECA COVID-19 VACCINE and Spikevax) included off label use. Treatment medications was not reported. Paralysis was not listed in the company core data sheet for AZD1222. Due to limited information on the baseline health characteristics of the patient before vaccination and further clarification of the event, circumstances leading to the event, relevant medical and family history of the patient, concurrent diseases (Neurological disorder, Degenerative disorder, Autoimmune disease), concomitant medications, specific risk factors (lifestyle, diet, stress), etiological and complete diagnostic work-up (Magnetic resonance imaging, immunoglobulin titer, blood panel test, cranial computed tomography scan, nerve conduction study), the evaluation did not find evidence to suggest a causal relationship between the event and AZD1222. Company Comment- This is a regulatory authority case concerning a 68-year-old, female patient with relevant medical history of leukemia, chemotherapy, migraine, dizziness, arm injury, bone injury, tendon repair and concurrent medical conditions of thyroid disorder

Case ID	WW Identifier	Narrative (Complete)
		and hypertension and with the vaccine history of receiving 2 doses of another brand of Covid-19 vaccine (Covid-19 vaccine AstraZeneca) as previous doses, who experienced the unexpected serious (medically significant according to regulatory authority) event of the muscles are becoming more paralyzed and weird/ paralyzed fingers, especially on the right side (it started from the arm and on)/ very strange feeling that seemed like it paralyzed, the unexpected non-serious events of balance disorder, general physical health deterioration, hand pain, coccyx pain, pain in legs, fingers stiffness right hand, feeling abnormal, pain, burning sensation, memory impairment, spinal pain, gait disturbance, migraines, asthenia, eye disorder and the expected non-serious events of myalgia and dizziness. The RA SD also reported off label use and interchanged of vaccine product. The occurrence of the events were unknown with respect to the third dose of mRNA-1273 vaccine in Covid-19 vaccination in series. No reported treatment information. The outcome of the events were unknown. The medical history of leukemia, chemotherapy, migraine, dizziness, arm injury, bone injury, tendon repair and concurrent medical conditions of thyroid disorder and hypertension and with the vaccine history of receiving 2 doses of another brand of Covid-19 vaccine (Covid-19 vaccine AstraZeneca) as previous doses remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 21-Feb-2022. The most recent information was received on 09-Mar-2022 and was forwarded to Moderna on 09-Mar-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of COVID-19 (covid 19, symptoms: sore throat, cold, fever, headache), OFF LABEL USE (Off-Label use + Interchange of vaccine products), INTERCHANGE OF VACCINE PRODUCTS (Off-Label use + Interchange of vaccine products) and VACCINATION FAILURE (covid 19, symptoms: sore throat, cold, fever, headache) in a 40-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 030G21A) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. Previously administered products included for Product used for unknown indication: KETOPROFENE [KETOPROFEN], NICKEL and AMOXICILLIN. Past adverse reactions to the above products included Drug allergy with AMOXICILLIN, KETOPROFENE [KETOPROFEN] and NICKEL. On 10-Jun-2021 at 4:30 PM, the patient received first dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 15-Jul-2021 at 3:45 PM, received second dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to 1 dosage form. On 31-Dec-2021 at 11:00 AM, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 31-Dec-2021, the patient experienced OFF LABEL USE (Off-Label use + Interchange of vaccine products) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (Off-Label use + Interchange of vaccine products) (seriousness criterion medically significant). On 26-Jan-2022, the patient experienced VACCINATION FAILURE (covid 19, symptoms: sore throat, cold, fever, headache) (seriousness criterion medically significant). On an unknown date, the patient experienced COVID-19 (covid 19, symptoms: sore throat, cold, fever, headache) (seriousness criterion medically significant). At the time of the report, COVID-19 (covid 19, symptoms: sore throat, cold, fever, headache) had resolved and OFF LABEL USE (Off-Label use + Interchange of vaccine products), INTERCHANGE OF VACCINE PRODUCTS (Off-Label use + Interchange of vaccine products) and VACCINATION FAILURE (covid 19, symptoms: sore throat, cold, fever, headache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 26-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive.

Case ID	WW Identifier	Narrative (Complete)
		On 02-Feb-2022, SARS-CoV-2 test: negative (Negative) Negative. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No Concomitant medication provided. No treatment medication reported. Comirnaty Expiry Date reported as 31-OCT-2021 Company comment: This regulatory authority case concerns a 40 year old female patient with no relevant medical history who experienced the unexpected serious (important medical event) event of COVID-19(AESI), about 194 days after receiving the booster dose with mRNA-1273 vaccine. Additionally, Interchange of vaccine products, Off label use and Vaccination failure were reported. The patient had earlier received two doses of Comirnaty vaccine. COVID-19 antigen test was positive about 26 days after the booster dose. At the time of the report, the patient had recovered from covid 19. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness retained as per Regulatory Authority reporting. Based on available information a contributory role of BNT162B2 to the reported events Covid-19 and vaccination failure cannot be totally excluded as efficacy of a drug varies from individual to individual depending upon the immune status. As with any vaccine, vaccination with BNT162B2 may not protect all vaccine recipients, so the expectedness of covid-19 and vaccination failure is : expected. The case will be reassessed further upon receipt of additional information. Most recent FOLLOW-UP information incorporated above includes: On 09-Mar-2022: Significant follow-up : Test result added, event outcome for COVID-19 updated.
4.1(b)	4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b)) on 27-Feb-2022 and was forwarded to Moderna on 27-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of OFF LABEL USE (Off label use), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), DRUG INEFFECTIVE (Drug ineffective) and COVID-19 (positive PCR for Covid test last week) in a 35-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 immunisation. Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for an unknown indication and TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. No Medical History information was reported. In 2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form and first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. In December 2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. In 2021, the patient experienced DRUG INEFFECTIVE (Drug ineffective) (seriousness criterion medically significant) and COVID-19 (positive PCR for Covid test last week) (seriousness criterion medically significant). In December 2021, the patient experienced OFF LABEL USE (Off label use) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criterion medically significant). At the time of the

Case ID	WW Identifier	Narrative (Complete)
		report, OFF LABEL USE (Off label use), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), DRUG INEFFECTIVE (Drug ineffective) and COVID-19 (positive PCR for Covid test last week) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: positive (Positive) Positive. No concomitant medications were reported. No treatment information was provided. Date of last administration for COMIRNATY (DOSE 1and DOSE 2) and Moderna CoviD-19 Vaccine BOOSTER DOSE was reported as 2021 and Dec-2021 respectively. The patient has received Comirnaty for his Dose 1 and 2 in the summer of 2021 but received the Moderna C-19 vaccine as booster in Dec-2021. He said he had received a positive PCR for Covid test last week. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information was expected. Company comment: This is a regulatory authority case concerning a 35-year-old male patient with no medical history reported, who experienced the serious(seriousness criterion medically significant) unexpected AESI event of COVID-19 and serious(seriousness criterion medically significant) unexpected events of drug ineffective, off label use, and interchange of vaccine products after the third dose of the mRNA -1273 vaccine. The patient's COVID-19 PCR test was positive. At the time of report outcome of the events was unknown. The benefit-risk relationship of the vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 25-Feb-2022. The most recent information was received on 17-Mar-2022 and was forwarded to Moderna on 17-Mar-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of OFF LABEL USE (dose 1 and 2 comirnaty, dose 3 Moderna), INTERCHANGE OF VACCINE PRODUCTS (Moderna vaccine during autumn 2021) and DEATH (died on 18Jan2022) in a 95-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 016G21A) for COVID-19 immunisation. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. No Medical History information was reported. On 04-Jun-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 21-Jul-2021, received second dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. On 28-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 28-Dec-2021, the patient experienced OFF LABEL USE (dose 1 and 2 comirnaty, dose 3 Moderna) (seriousness criteria death and medically significant). 28-Dec-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Moderna vaccine during autumn 2021) (seriousness criteria death and medically significant). The patient died on 18-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed.

Case ID	WW Identifier	Narrative (Complete)
		For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided. Dosage text for suspect product Spikevax was reported as DOSE 3 (BOOSTER), SINGLE and for co-suspect product Dosage text was reported as DOSE 1, SINGLE and DOSE 2, SINGLE. No treatment medication was reported. Company comment: This regulatory case concerns a 95-year-old, female patient with history of interchange of vaccine products (two doses of Pfizer BioNTech covid19 vaccine), who experienced unexpected fatal event of Death approximately 7 months after receiving third dose (booster) of mRNA-1273 vaccine. Interchange of vaccine products and Off label use are also reported in the case with a fatal outcome. It is unknown if an autopsy was done, and the cause of death was reported as unknown. Advanced age of the patient could be a risk factor. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting. This case was linked to 4.1(b) (E2B Linked Report). Most recent FOLLOW-UP information incorporated above includes: On 17-Mar-2022: Significant Follow Up: Spikevax start date and batch number updated, Comirnaty start date of two doses updated. Interchange of vaccine products and off label use start date was updated as 28-Dec-2021. Narrative updated.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 28-Feb-2022. The most recent information was received on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of DRUG INEFFECTIVE (COVID-19 symptoms: fever and cold) and COVID-19 (COVID-19 symptoms: fever and cold) in a 40-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005698) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. The patient's past medical history included Favism. On 10-May-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 31-May-2021, received second dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to 1 dosage form. On 13-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 24-Jan-2022, the patient experienced NASOPHARYNGITIS (COVID-19 symptoms: fever and cold), DRUG INEFFECTIVE (COVID-19 symptoms: fever and cold) (seriousness criterion medically significant), PYREXIA (COVID-19 symptoms: fever and cold) and COVID-19 (COVID-19 symptoms: fever and cold) (seriousness criterion medically significant). On an unknown date, the patient experienced OFF LABEL USE (Off label use) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). At the time of the report, NASOPHARYNGITIS (COVID-19 symptoms: fever and cold), PYREXIA (COVID-19 symptoms: fever and cold) and COVID-19 (COVID-19 symptoms: fever and cold) had resolved and DRUG INEFFECTIVE (COVID-19 symptoms: fever and cold), OFF LABEL USE (Off label use) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):

Case ID	WW Identifier	Narrative (Complete)
		On 25-Jan-2022, SARS-CoV-2 test: positive (Positive) Test Result:Positive. On 04-Feb-2022, SARS-CoV-2 test: negative (Negative) Test Result:Negative. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitants were reported. No treatment information was reported. Company Comment: This is a regulatory authority case of interchange of vaccine products, concerning a 40-year-old male patient, with no relevant medical history reported, who experienced the serious (medically significant) unexpected AESI of COVID-19, 1 month and 11 days after the third dose of mRNA-1273 (reported as booster dose). Additionally drug ineffective and off label use were also reported. COVID-19 outcome was resolved. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Mar-2022: Updated lab data, additional information on drug and event outcome.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 01-Mar-2022 and was forwarded to Moderna on 01-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (Vaccine break with positive covid19 infection with symptoms), OFF LABEL USE (Dose 1 and 2: comirnaty vaccine; Dose 3: spikevax vaccine), INTERCHANGE OF VACCINE PRODUCTS (Dose 1 and 2: comirnaty vaccine; Dose 3: spikevax vaccine) and DRUG INEFFECTIVE (Vaccine break with positive covid19 infection with symptoms) in a 50-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. Patient had no medical history. On 05-May-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 27-May-2021, received second dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. On 17-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Dec-2021, the patient experienced OFF LABEL USE (Dose 1 and 2: comirnaty vaccine; Dose 3: spikevax vaccine) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (Dose 1 and 2: comirnaty vaccine; Dose 3: spikevax vaccine) (seriousness criterion medically significant). On 01-Feb-2022, the patient experienced COVID-19 (Vaccine break with positive covid19 infection with symptoms) (seriousness criterion medically significant) and DRUG INEFFECTIVE (Vaccine break with positive covid19 infection with symptoms) (seriousness criterion medically significant). At the time of the report, COVID-19 (Vaccine break with positive covid19 infection with symptoms) and DRUG INEFFECTIVE (Vaccine break with positive covid19 infection with symptoms) had resolved and OFF LABEL USE (Dose 1 and 2: comirnaty vaccine; Dose 3: spikevax vaccine) and INTERCHANGE OF VACCINE PRODUCTS (Dose 1 and 2: comirnaty vaccine; Dose 3: spikevax vaccine) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):

Case ID	WW Identifier	Narrative (Complete)
		On 01-Feb-2022, SARS-CoV-2 test: positive (Positive) Positive Nasal Swab. No concomitant medication was reported. No treatment medications was reported. Company comment: This is a regulatory case concerning a 50-year-old, female patient medical history of concomitant products included Comirnaty (two doses), who experienced the unexpected serious (medically significant) events of Off Label Use, Interchange of Vaccine Products, Drug Ineffective and COVID-19 (AESI). The events of Off Label Use & Interchange of Vaccine Products started on the same day and the events of Drug Ineffective & COVID-19 started approximately 1 months & 15 days after the patient received third dose of mRNA-1273 vaccine. There was an inappropriate schedule of vaccine administration as the first and second doses where concomitant products Comirnaty and only the third dose was mRNA-1273 vaccine and not as indicated in the RSI at the time; and that could be a confounder for the event of COVID-19. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 09-Mar-2022: Follow-up document received 09-Mar-2022 with no new significant information.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Feb-2022 and was forwarded to Moderna on 28-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MOVEMENT DISORDER (impossibility to move), FATIGUE (she is always very tired / intense fatigue), ARTHRALGIA (very violent pain, mainly in the back, shoulders, hips, that were constantly moving), INFLAMMATION (lot of inflammation), BACK PAIN (very violent pain, mainly in the back, shoulders, hips, that were constantly moving), SOMNOLENCE (felt like sleeping), PAIN (she had moving pains/ very violent pain, mainly in the back, shoulders, hips, that were constantly moving) and AFFECTIVE DISORDER (she wanted nothing / was not like before Ihave not retrieved my personality) in a 70-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. Previously administered products included for Immunization: INFLUENZA VACCINE. Past adverse reactions to the above products included Adverse event NOS with INFLUENZA VACCINE. On 28-Apr-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 15-Oct-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Nov-2021, received third dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 29-Apr-2021, the patient experienced MOVEMENT DISORDER (impossibility to move) (seriousness criterion disability), ARTHRALGIA (very violent pain, mainly in the back, shoulders, hips, that were constantly moving) (seriousness criterion disability), BACK PAIN (very violent pain, mainly in the back, shoulders, hips, that were constantly moving) (seriousness criterion disability), SOMNOLENCE (felt like sleeping) (seriousness criterion disability), PAIN (she had moving pains/ very violent pain, mainly in the back, shoulders, hips, that were constantly moving) (seriousness criterion disability) and AFFECTIVE DISORDER (she wanted nothing / was not like before Ihave not retrieved my personality) (seriousness criterion disability). In 2021, the patient experienced INFLAMMATION (lot of inflammation) (seriousness criterion disability). On 15-

Case ID	WW Identifier	Narrative (Complete)
		Oct-2021, the patient experienced OFF LABEL USE (first dose COMRINATY, received COVID-19 vaccine Moderna with booster) and INTERCHANGE OF VACCINE PRODUCTS (first dose COMRINATY, received COVID-19 vaccine Moderna with booster). On an unknown date, the patient experienced FATIGUE (she is always very tired / intense fatigue) (seriousness criterion disability) and PYREXIA (fever/emperature/between 37.8 and 38 centigrade). In 2021, MOVEMENT DISORDER (impossibility to move), ARTHRALGIA (very violent pain, mainly in the back, shoulders, hips, that were constantly moving), INFLAMMATION (lot of inflammation), BACK PAIN (very violent pain, mainly in the back, shoulders, hips, that were constantly moving) and SOMNOLENCE (felt like sleeping) had resolved, AFFECTIVE DISORDER (she wanted nothing / was not like before Ihave not retrieved my personality) had resolved with sequelae. At the time of the report, FATIGUE (she is always very tired / intense fatigue) had resolved with sequelae, PYREXIA (fever/emperature/between 37.8 and 38 centigrade) and PAIN (she had moving pains/ very violent pain, mainly in the back, shoulders, hips, that were constantly moving) had resolved and OFF LABEL USE (first dose COMRINATY, received COVID-19 vaccine Moderna with booster) and INTERCHANGE OF VACCINE PRODUCTS (first dose COMRINATY, received COVID-19 vaccine Moderna with booster) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 29-Apr-2021, Body temperature: between 37.8 and 38 centigrade. (High) between 37.8 and 38 Centigrade. fever. In 2021, Blood test: lot of inflammation lot of inflammation, but the physician did not find where., 3 blood tests and all normal (normal) 3 blood tests and all normal and nothing specific has been found. (normal) nothing specific has been found.. In 2021, Scan: normal (normal) normal. In 2021, X-ray: did not find anything (normal) did not find anything. On 29-Sep-2021, Serology test: negative (Negative) Negative. Concomitant medication of the patient was not reported. No treatment information was provided by the reporter. Company comment: This regulatory authority case concerns a 70-year-old female patient with no medical history provided, who experienced serious (due to disability) unexpected events of Movement disorder, Arthralgia, Back pain, Somnolence, Pain and Affective disorder, Inflammation and Fatigue, as well as non serious expected event of Pyrexia. The events of Movement disorder, Arthralgia, Back pain, Somnolence, Pain and Affective disorder occurred prior to administration of the mRNA-1273 vaccine (the events occurred the day after administration of the Tozinameran vaccine), therefore, the company causality for these events is assessed as not related to the mRNA-1273 vaccine. The exact start dates for the events of Inflammation, Pyrexia and Fatigue were not provided, therefore, the causal relationship cannot be excluded and the company causality for these events is assessed as related. It was stated that blood tests showed "a lot of inflammation", however, no additional details were provided. X-ray and scan were normal. In addition, the events of Off label use and Interchange of vaccine products was also coded as non serious unexpected events as per Regulatory Authority and were retained as such, having in mind that the patient received one dose of Tozinameran vaccine and afterwards she received the mRNA-1273 vaccine. The company causality for these two events is not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.
4.1(b) [redacted]	4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 01-Mar-2022. The most recent information was received on 08-Mar-2022 and was forwarded to Moderna on 08-Mar-2022.

Case ID	WW Identifier	Narrative (Complete)
		This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (performed COVID-19 antigen tests both with positive results), OFF LABEL USE (Previous COVID-19 vaccination with Moderna), INTERCHANGE OF VACCINE PRODUCTS (Previous COVID-19 vaccination with Moderna), IMMUNISATION (dose 3 COMIRNATY) and DRUG INEFFECTIVE (performed COVID-19 antigen tests both with positive results) in a 32-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3001531 and 3001531) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. The patient's past medical history included COVID-19 (Recovered after hospitalization) in September 2020. On 09-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-May-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 04-Jan-2022, the patient received third dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 04-Jan-2022, the patient experienced OFF LABEL USE (Previous COVID-19 vaccination with Moderna) (seriousness criterion medically significant), INTERCHANGE OF VACCINE PRODUCTS (Previous COVID-19 vaccination with Moderna) (seriousness criterion medically significant) and IMMUNISATION (dose 3 COMIRNATY) (seriousness criterion medically significant). On 02-Feb-2022, the patient experienced DRUG INEFFECTIVE (performed COVID-19 antigen tests both with positive results) (seriousness criterion medically significant). On an unknown date, the patient experienced COVID-19 (performed COVID-19 antigen tests both with positive results) (seriousness criterion medically significant). At the time of the report, COVID-19 (performed COVID-19 antigen tests both with positive results) had resolved and OFF LABEL USE (Previous COVID-19 vaccination with Moderna), INTERCHANGE OF VACCINE PRODUCTS (Previous COVID-19 vaccination with Moderna), IMMUNISATION (dose 3 COMIRNATY) and DRUG INEFFECTIVE (performed COVID-19 antigen tests both with positive results) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Feb-2022, SARS-CoV-2 test: positive (Positive) Positive. On 03-Feb-2022, SARS-CoV-2 test: positive (Positive) Positive. On 08-Feb-2022, SARS-CoV-2 test: negative (Negative) Negative. No concomitant product was provided. No treatment information was provided. Spikevax Expiry Date reported as 28-SEP-2021. Comirnaty Expiry Date reported as 31-MAY-2022. Company Comment: This regulatory case concerns a 32-year-old male patient with history of interchange of vaccine products (one dose of Comirnaty Covid19 vaccine), who experienced the unexpected serious (medically significant) AESI event of COVID-19, eight months twenty-six days after a second dose of mRNA-1273 vaccine and twenty-nine days after a dose of Comirnaty COVID-19 vaccine. Additionally, Off label use, Interchange of vaccine products, Immunization, and Drug ineffective were also reported. SARS-CoV-2 test was reported to be positive. The patient had taken a third dose (Comirnaty COVID-19) more than eight months after the mRNA-1273 vaccine. At the time of reporting, the outcome of event was

Case ID	WW Identifier	Narrative (Complete)
		unknown. Off label use, Inappropriate schedule and interchange of vaccine could be confounding for the event of COVID-19. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 08-Mar-2022: Significant follow-up received with updated event details and Lab data.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 02-Mar-2022. The most recent information was received on 09-Mar-2022 and was forwarded to Moderna on 09-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (Corona infection was confirmed by quick-test on 29-Jan-2022 and PCR test on 31-JAN-2022), DRUG INEFFECTIVE (Corona infection was confirmed by quick-test on 29-Jan-2022 and PCR test on 31-JAN-2022) and OFF LABEL USE (Comirnaty was vaccinated on December 10, 2021 after two previous vaccinations with Moderna (02 May 2021 and 13 June 2021).) in a 39-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. The patient's past medical history included Interchange of vaccine products on 10-Dec-2021. Concurrent medical conditions included House dust allergy since 1994. On 02-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 13-Jun-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 10-Dec-2021, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 10-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced OFF LABEL USE (Comirnaty was vaccinated on December 10, 2021 after two previous vaccinations with Moderna (02 May 2021 and 13 June 2021).) (seriousness criterion medically significant). On 27-Jan-2022, the patient experienced DRUG INEFFECTIVE (Corona infection was confirmed by quick-test on 29-Jan-2022 and PCR test on 31-JAN-2022) (seriousness criterion medically significant). On an unknown date, the patient experienced COVID-19 (Corona infection was confirmed by quick-test on 29-Jan-2022 and PCR test on 31-JAN-2022) (seriousness criterion medically significant), NAUSEA (Nausea), FATIGUE (tiredness/exhaustion), NASOPHARYNGITIS (cold) and HEADACHE (Headache). At the time of the report, COVID-19 (Corona infection was confirmed by quick-test on 29-Jan-2022 and PCR test on 31-JAN-2022), NAUSEA (Nausea), FATIGUE (tiredness/exhaustion), NASOPHARYNGITIS (cold) and HEADACHE (Headache) had resolved and DRUG INEFFECTIVE (Corona infection was confirmed by quick-test on 29-Jan-2022 and PCR test on 31-JAN-2022) and OFF LABEL USE (Comirnaty was vaccinated on December 10, 2021 after two previous vaccinations with Moderna (02 May 2021 and 13 June 2021).) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 29-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive. colloidal gold. On 31-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive. Ct value=24. Concomitant medication was not provided. Treatment information was not provided. Company comment: This regulatory case concerns a 39-year-old, male patient with relevant history of Interchange of vaccine products wherein patient received Tozinameran as third dose of COVID-19 vaccine approximately 6 months after the mRNA-1273 primary series, who experienced the unexpected, serious (medically significant) AESI COVID-19. Drug ineffective and

Case ID	WW Identifier	Narrative (Complete)
		Off label use were reported as additional events. The event of COVID-19 was confirmed through PCR test 7 months after the second dose of mRNA-1273 vaccine with occurence of non-serious events of Nasopharyngitis, Headache, Nausea and Fatigue. It should be noted that the patient received the second dose 42 days after the first dose of mRNA-1273 which is outside the recommended dosing interval (Inappropriate schedule of product administration). Administration of Tozinameran COVID-19 vaccine, reported as co-suspect drug, remains a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 09-Mar-2022: Follow up contains significant information. Patient demographics, medical history, route of administration, events added. On 23-Mar-2022: Follow-up document received contain no new information.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 02-Mar-2022 and was forwarded to Moderna on 02-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (First dose Comirnaty, second dose SpikeVax - got COVID-19), INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine products), DRUG INEFFECTIVE (First dose Comirnaty, second dose SpikeVax - got COVID-19) and OFF LABEL USE (off label use) in a 25-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunization. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. Concurrent medical conditions included Allergy. In 2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form and first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. In 2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine products) (seriousness criterion medically significant) and OFF LABEL USE (off label use) (seriousness criterion medically significant). On 01-Jan-2022, the patient experienced COVID-19 (First dose Comirnaty, second dose SpikeVax - got COVID-19) (seriousness criterion medically significant) and DRUG INEFFECTIVE (First dose Comirnaty, second dose SpikeVax - got COVID-19) (seriousness criterion medically significant). At the time of the report, COVID-19 (First dose Comirnaty, second dose SpikeVax - got COVID-19) and DRUG INEFFECTIVE (First dose Comirnaty, second dose SpikeVax - got COVID-19) had resolved and INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine products) and OFF LABEL USE (off label use) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 01-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive. No concomitant medication was provided. No treatment information was mentioned. Company comment: This is a regulatory case concerning a 25-year-old, male patient with medical history of Allergy and concomitant non-company product of Tozinameran, who experienced the unexpected serious (medically significant) events of COVID-19 (AESI), Interchange of Vaccine Products, Drug Ineffective and Off Label Use. The events started after an unknown interval after the

Case ID	WW Identifier	Narrative (Complete)
		administration of the second dose of mRNA-1273 vaccine. There was an inappropriate schedule of vaccine administration as the first dose was a noncompany product of Tozinameran (unknown date) & second doses of mRNA-1273 were administered on an unknown date and not as indicated in the RSI at the time; and that could be a confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Mar-2022 and was forwarded to Moderna on 04-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of OFF LABEL USE (I got vaccines from AstraZeneca, Moderna and BionTech), INTERCHANGE OF VACCINE PRODUCTS (I got vaccines from AstraZeneca, Moderna and BionTech), SUSPECTED COVID-19 (I caught Omicron (presumably)) and DRUG INEFFECTIVE (I caught Omicron (presumably)) in a 49-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for COVID-19 immunisation and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for COVID-19 immunisation. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form, third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form and first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (unknown route) 1 dosage form. On an unknown date, the patient experienced OFF LABEL USE (I got vaccines from AstraZeneca, Moderna and BionTech) (seriousness criterion medically significant), INTERCHANGE OF VACCINE PRODUCTS (I got vaccines from AstraZeneca, Moderna and BionTech) (seriousness criterion medically significant), SUSPECTED COVID-19 (I caught Omicron (presumably)) (seriousness criterion medically significant) and DRUG INEFFECTIVE (I caught Omicron (presumably)) (seriousness criterion medically significant). At the time of the report, OFF LABEL USE (I got vaccines from AstraZeneca, Moderna and BionTech), INTERCHANGE OF VACCINE PRODUCTS (I got vaccines from AstraZeneca, Moderna and BionTech), SUSPECTED COVID-19 (I caught Omicron (presumably)) and DRUG INEFFECTIVE (I caught Omicron (presumably)) outcome was unknown. Concomitant medication was not provided. Treatment information was not provided. Company Comment: This regulatory case concerns a 49-year-old female patient, with no reported medical history, who received one dose of mRNA-1273 vaccine on an unknown date and reportedly experienced the serious (medically significant) unexpected event of Suspected COVID-19 (I caught Omicron (presumably)) on an unknown date. On an unspecified date, drug ineffective was also noted in this case. Furthermore, it was reported that interchange of vaccine products occurred on an unknown date wherein the patient received CHADOX1 NCOV-19 as her first dose, mRNA-1273 as her second dose, and TOZINAMERAN as her third dose (reported as off label use). No further information was reported regarding clinical course and treatment details. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events' seriousness assessed per Regulatory Authority reporting.
4.1(b)	4.1(b) 4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022.

Case ID	WW Identifier	Narrative (Complete)
		This regulatory authority case was reported by a consumer and describes the occurrence of ILLNESS (Illness), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), OFF LABEL USE (Off label use) and PERICARDITIS (Pericarditis) in a 66-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for COVID-19 immunisation, BRODALUMAB (SILIQ) for Psoriasis and BRODALUMAB (SILIQ) for Psoriasis. Concomitant products included PERINDOPRIL ARGININE (4.1(b)), FLUTICASONE FUROATE (AVAMYS), BETAMETHASONE DIPROPIONATE, CODEINE, EZETIMIBE, GLICLAZIDE, METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE, PANTOPRAZOLE SODIUM, ROSUVASTATIN CALCIUM, SALBUTAMOL, TRAMADOL and ZOPICLONE for an unknown indication. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form, dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (Intramuscular) 1 dosage form, BRODALUMAB (SILIQ) (Subcutaneous) 210 milligram every two weeks and BRODALUMAB (SILIQ) (Subcutaneous) 210 milligram once a week. On an unknown date, the patient experienced ILLNESS (Illness) (seriousness criterion hospitalization), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criterion hospitalization), OFF LABEL USE (Off label use) (seriousness criterion hospitalization) and PERICARDITIS (Pericarditis) (seriousness criterion hospitalization). At the time of the report, ILLNESS (Illness), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), OFF LABEL USE (Off label use) and PERICARDITIS (Pericarditis) had resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Treatment information was not provided. Company comment: This regulatory authority case concerns a 66-year-old male patient with a history of Polypharmacy and co-suspect use of Brodalumab, who experienced the serious (hospitalization) expected AESI of Pericarditis, among other events, in association with dose of mRNA- 1273 vaccine (unspecified dose number). Temporal association cannot be assessed due to lack of information on the onset date of the event and vaccination date. The patient also received an unspecified dose of Vaxzervria vaccine (reported as Interchange of vaccine products administration) on an unknown date. Additionally, Off label use was also reported. No information is available regarding clinical manifestations, diagnostic work-up performed and treatment provided. At the time of the report, the event had resolved. Use of Brodalumab and Vaxzervria vaccine remain as co-suspects. Polypharmacy might be a confounder. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report.
4.1(b)	4.1(b) 4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of COLITIS ULCERATIVE (Colitis ulcerative), CONTUSION (Contusion), CYSTITIS (Cystitis), MUSCULAR WEAKNESS (Muscular weakness) and OFF LABEL USE (Off label use) in a 36-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication.

Case ID	WW Identifier	Narrative (Complete)
		Co-suspect product included non-company product VEDOLIZUMAB (ENTYVIO) powder for solution for infusion for Colitis ulcerative. Concomitant products included MESALAZINE (MEZAVANT) and PREDNISONE for an unknown indication. On an unknown date, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form and VEDOLIZUMAB (ENTYVIO) (Intravenous) 300 milligram every four weeks. On an unknown date, VEDOLIZUMAB (ENTYVIO) (Intravenous) dosage was changed to 300 milligram every four weeks, VEDOLIZUMAB (ENTYVIO) (Intravenous) dosage was changed to 300 milligram every four weeks, VEDOLIZUMAB (ENTYVIO) (Intravenous) dosage was changed to 300 milligram, VEDOLIZUMAB (ENTYVIO) (Intravenous) dosage was changed to 300 milligram every four weeks, VEDOLIZUMAB (ENTYVIO) (Intravenous) dosage was changed to 300 milligram every four weeks, VEDOLIZUMAB (ENTYVIO) (Intravenous) dosage was changed to 300 milligram every four weeks, VEDOLIZUMAB (ENTYVIO) (Intravenous) dosage was changed to 300 milligram every four weeks and VEDOLIZUMAB (ENTYVIO) (Intravenous) dosage was changed to 300 milligram every four weeks. On an unknown date, the patient experienced COLITIS ULCERATIVE (Colitis ulcerative) (seriousness criterion medically significant), CONTUSION (Contusion) (seriousness criterion medically significant), CYSTITIS (Cystitis) (seriousness criterion medically significant), MUSCULAR WEAKNESS (Muscular weakness) (seriousness criterion medically significant) and OFF LABEL USE (Off label use) (seriousness criterion medically significant). At the time of the report, COLITIS ULCERATIVE (Colitis ulcerative), CONTUSION (Contusion), CYSTITIS (Cystitis), MUSCULAR WEAKNESS (Muscular weakness) and OFF LABEL USE (Off label use) had not resolved. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No medical history was provided by the reporter. Treatment Medication use information was not provided by reporter. Company Comment: This regulatory case concerns a 36-year-old, female patient with no reported medical history, who experienced the unexpected, serious (medically significant) events of Colitis ulcerative, Contusion, Cystitis, and Muscular weakness, which occurred at unknown time after the unknown dose of mRNA-1723. Off label use was also reported in this case. As per RA report patient was receiving Entyvio and Mesalazine for ulcerative colitis as well as Prednisone for unknown indication. At the time of reporting, outcome of the events was reported as not resolved. The benefit-risk relationship of mRNA-1273 is not affected by this report. This case was linked to 4.1(b) (E2B Linked Report).
4.1(b)	4.1(b) 4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority retrospective pregnancy case was reported by a consumer and describes the occurrence of ARTHRALGIA (Arthralgia), CHILLS (Chills), EXPOSURE DURING PREGNANCY (Exposure during pregnancy), FATIGUE (Fatigue), the first episode of INTENTIONAL PRODUCT USE ISSUE (Intentional product use issue), the second episode of INTENTIONAL PRODUCT USE ISSUE (Intentional product use issue), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), MALAISE (Malaise), OFF LABEL USE (Off label use), PAIN IN

Case ID	WW Identifier	Narrative (Complete)
		EXTREMITY (Pain in extremity), PLACENTA PRAEVIA (Placenta praevia) and PREMATURE DELIVERY (Premature delivery) in a 39-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. Co-suspect product included non-company product COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for COVID-19 immunisation. Concomitant products included PARACETAMOL (TYLENOL [PARACETAMOL]) for an unknown indication. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) .5 milliliter and dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (Intramuscular) .5 milliliter. Last menstrual period and estimated date of delivery were not provided. On an unknown date, the patient experienced ARTHRALGIA (Arthralgia) (seriousness criteria hospitalization and medically significant), CHILLS (Chills) (seriousness criteria hospitalization and medically significant), EXPOSURE DURING PREGNANCY (Exposure during pregnancy) (seriousness criteria hospitalization and medically significant), FATIGUE (Fatigue) (seriousness criteria hospitalization and medically significant), the first episode of INTENTIONAL PRODUCT USE ISSUE (Intentional product use issue) (seriousness criteria hospitalization and medically significant), the second episode of INTENTIONAL PRODUCT USE ISSUE (Intentional product use issue) (seriousness criteria hospitalization and medically significant), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criteria hospitalization and medically significant), MALAISE (Malaise) (seriousness criteria hospitalization and medically significant), OFF LABEL USE (Off label use) (seriousness criteria hospitalization and medically significant), PAIN IN EXTREMITY (Pain in extremity) (seriousness criteria hospitalization and medically significant), PLACENTA PRAEVIA (Placenta praevia) (seriousness criteria hospitalization and medically significant) and PREMATURE DELIVERY (Premature delivery) (seriousness criteria hospitalization and medically significant). The delivery occurred on an unknown date, which was reported as Premature. For neonate 1, The outcome was reported as Pre-Term Birth NOS. At the time of the report, ARTHRALGIA (Arthralgia), CHILLS (Chills), EXPOSURE DURING PREGNANCY (Exposure during pregnancy), FATIGUE (Fatigue), the last episode of INTENTIONAL PRODUCT USE ISSUE (Intentional product use issue), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), MALAISE (Malaise), OFF LABEL USE (Off label use), PAIN IN EXTREMITY (Pain in extremity), PLACENTA PRAEVIA (Placenta praevia) and PREMATURE DELIVERY (Premature delivery) outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. It was stated that on an unknown date patient received concomitant medication alpha-carotene/betacarotene/calcium/iron/vitamin c via an unknown route. No treatment medications were reported. Company comment: This regulatory case concerns a 39-year-old female patient with no reported medical history, who experienced unlisted, serious (hospitalization, medically significant) events of Arthralgia, Chills, Fatigue, Malaise, Pain in extremity, Placenta previa and Premature delivery. Exposure during pregnancy, Intentional product use issue (reported twice), Interchange of vaccine products and Off label use were reported as additional events. The events occurred on an unknown date after mRNA-1273 vaccine. Date of vaccination and gestational age were unknown. Outcome of premature delivery was not

Case ID	WW Identifier	Narrative (Complete)
		mentioned. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Mar-2022 and was forwarded to Moderna on 04-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (Despite that I got infected with Omicron B.1.1.529, I felt really bad), INTERCHANGE OF VACCINE PRODUCTS (First and second dose with Moderna, booster dose with Comirnaty), DRUG INEFFECTIVE (Despite that I got infected with Omicron B.1.1.529, I felt really bad) and OFF LABEL USE (First and second dose with Moderna, booster dose with Comirnaty) in a female patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. No Medical History information was reported. On 21-Dec-2021, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced COVID-19 (Despite that I got infected with Omicron B.1.1.529, I felt really bad) (seriousness criterion medically significant), INTERCHANGE OF VACCINE PRODUCTS (First and second dose with Moderna, booster dose with Comirnaty) (seriousness criterion medically significant), DRUG INEFFECTIVE (Despite that I got infected with Omicron B.1.1.529, I felt really bad) (seriousness criterion medically significant) and OFF LABEL USE (First and second dose with Moderna, booster dose with Comirnaty) (seriousness criterion medically significant). At the time of the report, COVID-19 (Despite that I got infected with Omicron B.1.1.529, I felt really bad), INTERCHANGE OF VACCINE PRODUCTS (First and second dose with Moderna, booster dose with Comirnaty), DRUG INEFFECTIVE (Despite that I got infected with Omicron B.1.1.529, I felt really bad) and OFF LABEL USE (First and second dose with Moderna, booster dose with Comirnaty) outcome was unknown. Concomitant medications were not provided by the reporter. Treatment information was not provided. Additional Information on Drug was reported as Off label use for Comirnaty. Company comment: This regulatory authority case concerns a female patient with no medical history reported, who experienced the unexpected AESI of COVID 19, which was considered as medically significant. The patient also experienced events of interchange of vaccine products, drug ineffective and off label use (described as First and second dose with Moderna, booster dose with Comirnaty), which were also reported to be Medically significant. The events occurred on an unknown date after the second dose of mRNA-1273. The Comirnaty vaccine was administered as the third (booster) dose. As reported, the patient got infected with Omicron B.1.1.529, despite the vaccination and felt really bad. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 20-Jun-2022: Follow up received is NNI.

Case ID	WW Identifier	Narrative (Complete)
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Mar-2022 and was forwarded to Moderna on 17-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of HEADACHE (SERIOUS HEADACHES) in a 54-year-old patient of an unknown gender who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) for an unknown indication. Patient concurrent conditions included metabolic disorders, autoimmune disorders, malignancy, haematologic disorders and specific risk factors are infection, coagulopathy. Concomitant products included TOZINAMERAN for an unknown indication. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form and first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (MODERNA AS 2ND (ACTUAL MEDICATION ERROR)), HEADACHE (SERIOUS HEADACHES) (seriousness criterion medically significant), ANGINA PECTORIS (ANGINA), PHLEBITIS (PHLEBILIS), PAIN IN EXTREMITY (SORE ARM), INTERCHANGE OF VACCINE PRODUCTS (MODERNA AS 2ND (INTERCHANGE OF VACCINE)) and OFF LABEL USE (MODERNA AS 2ND). At the time of the report, INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (MODERNA AS 2ND (ACTUAL MEDICATION ERROR)), ANGINA PECTORIS (ANGINA), PHLEBITIS (PHLEBILIS), PAIN IN EXTREMITY (SORE ARM), INTERCHANGE OF VACCINE PRODUCTS (MODERNA AS 2ND (INTERCHANGE OF VACCINE)) and OFF LABEL USE (MODERNA AS 2ND) outcome was unknown and HEADACHE (SERIOUS HEADACHES) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Treatment information was not provided. Lab data includes physical and haematological assessment, complete blood count with platelet count, peripheral smear, basic metabolic profilel, coagulation profile, imaging scans. The evaluation did not find evidence to suggest causal relationship between Event and AZD1222. Company comment: This regulatory authority case concerns a 54-year-old patient of unknown gender, with no reported medical history who experienced the serious unexpected (medically significant) event of Headache unknown days after an unspecified dose of mRNA-1273 vaccine. Interchange of vaccine products, Inappropriate schedule of product administration, and Off label use also reported in the case. Patient has received COVID 19 vaccines from 2 other manufacturers on unknown dates. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event retained serious as per Regulatory Authority reporting.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 18-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DRUG INEFFECTIVE (Developed Covid-19 approximately one week after third dose), INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine

Case ID	WW Identifier	Narrative (Complete)
		products), SUSPECTED COVID-19 (Developed Covid-19 approximately one week after third dose) and OFF LABEL USE (Off label use) in a 47-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. No Medical History information was reported. On an unknown date, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form On an unknown date, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. and first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. In January 2022, the patient experienced DRUG INEFFECTIVE (Developed Covid-19 approximately one week after third dose) (seriousness criterion medically significant) and SUSPECTED COVID-19 (Developed Covid-19 approximately one week after third dose) (seriousness criterion medically significant). On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine products) (seriousness criterion medically significant) and OFF LABEL USE (Off label use) (seriousness criterion medically significant). At the time of the report, DRUG INEFFECTIVE (Developed Covid-19 approximately one week after third dose) and SUSPECTED COVID-19 (Developed Covid-19 approximately one week after third dose) had resolved and INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine products) and OFF LABEL USE (Off label use) outcome was unknown. No concomitant product use was provided. No treatment information was provided. Company Comment: This regulatory case concerns a 47-year-old, male patient with no reported medical history, who experienced the unexpected, serious (medically significant) AESI Suspected COVID-19. Drug ineffective and, Off label use with Interchange of vaccine products were reported as additional events where interchange was described as administration of Tozinameran COVID-19 vaccine as first dose while mRNA-1273 was given as 2nd and booster doses. The event reportedly occurred a week after receiving mRNA-1273 vaccine as booster. Dosing interval is unknown since dates of vaccinations were not specified. Clinical course and treatment details were not provided in the case. The ongoing COVID-19 pandemic remains a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 23-Mar-2022. The most recent information was received on 30-Mar-2022 and was forwarded to Moderna on 30-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of OFF LABEL USE (Off label use), COVID-19 (SARS-COV-2 TEST POSITIVE), INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine products) and DRUG INEFFECTIVE (Drug ineffective) in a 39-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. No Medical History information was reported. On 29-Jan-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form.

Case ID	WW Identifier	Narrative (Complete)
		On 19-Feb-2021, received second dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. On 30-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In February 2022, the patient experienced DRUG INEFFECTIVE (Drug ineffective) (seriousness criterion medically significant). On 20-Feb-2022, the patient experienced COVID-19 (SARS-COV-2 TEST POSITIVE) (seriousness criterion medically significant). On an unknown date, the patient experienced OFF LABEL USE (Off label use) (seriousness criterion medically significant), INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine products) (seriousness criterion medically significant), COUGH (cough), PAIN IN EXTREMITY (limb pain) and HEADACHE (headache). At the time of the report, OFF LABEL USE (Off label use), COVID-19 (SARS-COV-2 TEST POSITIVE), INTERCHANGE OF VACCINE PRODUCTS (interchange of vaccine products), DRUG INEFFECTIVE (Drug ineffective), COUGH (cough), PAIN IN EXTREMITY (limb pain) and HEADACHE (headache) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Feb-2022, SARS-CoV-2 test: positive (Positive) POSITIVE. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. No Concomitant medications were reported. No Treatment information was provided. Additional Information on Drug (COMIRNATY): Expiry Date=30-APR-2021 Company comment: This regulatory authority case concerns a 39-year-old female patient with no medical history reported, who experienced the unexpected, serious (Medically significant) event of COVID-19 (AESI). Interchange of vaccine products was reported in the case described as vaccination with a different COVID-19 vaccine (TOZINAMERAN) unknown days prior to receiving mRNA1273. Off-label use and Drug ineffective were also reported as additional events. The events occurred unknown days after receiving a dose of mRNA 1273 as booster. On 20-Feb-2021, the patient had a positive COVID-19 PCR. The clinical course and treatment details were not reported. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority. Most recent FOLLOW-UP information incorporated above includes: On 30-Mar-2022: Follow-up received contains significant information- Patient details updated, Events and Drug start dates added.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 30-Mar-2022 and was forwarded to Moderna on 30-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (rapid test was positive, and this was confirmed with a PCR test), DRUG INEFFECTIVE (rapid test was positive, and this was confirmed with a PCR test), OFF LABEL USE (Off label use) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) in a male patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 vaccination.

Case ID	WW Identifier	Narrative (Complete)
		Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for COVID-19 immunisation and TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. No Medical History information was reported. On 11-Mar-2021, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (unknown route) 1 dosage form. On 03-Jun-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 01-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Dec-2021, the patient experienced COVID-19 (rapid test was positive, and this was confirmed with a PCR test) (seriousness criterion medically significant) and DRUG INEFFECTIVE (rapid test was positive, and this was confirmed with a PCR test) (seriousness criterion medically significant). On an unknown date, the patient experienced OFF LABEL USE (Off label use) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criterion medically significant). At the time of the report, COVID-19 (rapid test was positive, and this was confirmed with a PCR test), DRUG INEFFECTIVE (rapid test was positive, and this was confirmed with a PCR test), OFF LABEL USE (Off label use) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Dec-2021, SARS-CoV-2 test: positive (Positive) Positive. On 09-Dec-2021, SARS-CoV-2 test: positive (Positive) Positive. No concomitant medication were provided. No treatment information were given. COMPANY COMMENT : This regulatory authority case concerns unspecified age male patient, with no medical history reported, who experienced unexpected serious (seriousness criterion medically significant) AESI event of covid-19 and unexpected serious (seriousness criterion medically significant) event of drug ineffective, which occurred 7 days after third dose of mRNA-1273 vaccine. The patient was noted to have received one dose with COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) was taken 8 months 20 days prior to mRNA-1273 vaccine and one dose with COMIRNATY was taken 5 months 28 days prior to mRNA-1273 vaccine. (Interchange of vaccine products) It is also reported off label use. SARS-CoV-2 test rapid was positive on 8-dec-2021 and SARS-CoV-2 test PCR was positive on 09-DEC-21. Current ongoing pandemia remains as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events were assessed as serious as per Regulatory Authority´s report.
4.1(b) [redacted]	4.1(b) [redacted] 4.1(b)	This literature-non-study case was reported in a literature article and describes the occurrence of ATRIAL FIBRILLATION (Atrial fibrillation) and SYNCOPE (Syncope) in a 20-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE:

Case ID	WW Identifier	Narrative (Complete)
		Parker W, Joseph SJ, Saloni L, Singh T. New atrial fibrillation and syncope in a collegiate athlete immediately following COVID-19 vaccination.. J Am Coll Cardiol. 2022;79(9):2326 No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced ATRIAL FIBRILLATION (Atrial fibrillation) (seriousness criterion medically significant), SYNCOPE (Syncope) (seriousness criterion medically significant) and INTENTIONAL DOSE OMISSION (the patient declined the second dose). At the time of the report, ATRIAL FIBRILLATION (Atrial fibrillation), SYNCOPE (Syncope) and INTENTIONAL DOSE OMISSION (the patient declined the second dose) outcome was unknown. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood iron: normal Normal. On an unknown date, Blood thyroid stimulating hormone: normal Normal. On an unknown date, Cardiac electrophysiologic study: no accessory pathway, though af with rvr recurred no accessory pathway, though AF with RVR recurred during her EPS and required electrical cardioversion. On an unknown date, Cardiopulmonary exercise test: above average peak rate of oxygen uptake(vo2) of 4 revealed above average peak rate of oxygen uptake(VO2) of 48.1 ml/kg/min (134% predicted), appropriate cardiopulmonary response to exercise, and no ECG changes.. On an unknown date, Full blood count: normal Normal. On an unknown date, Myocardial necrosis marker: normal Normal. On an unknown date, Sinus rhythm: af with rapidventricular response (rvr) at 150 bea AF with rapid ventricular response (RVR) at 150 beats per minute. mRNA-1273 (Spikevax) (Unknown) was withdrawn on an unknown date. For mRNA-1273 (Spikevax) (Unknown), the reporter considered ATRIAL FIBRILLATION (Atrial fibrillation), SYNCOPE (Syncope) and INTENTIONAL DOSE OMISSION (the patient declined the second dose) to be related. No concomitant and treatment medications were reported. Patient was reported to be a collegiate long distance runner with no medical history presented with palpitations and syncope 15 minutes after receiving Moderna COVID-19 vaccine dose 1. Patient spontaneously cardioverted to normal sinus rhythm (NSR) shortly thereafter, though developed prolonged exertional intolerance for several months. 2-week ambulatory rhythm monitoring showed NSR with no recurrent AF. Patient was advised a graded exercise protocol for return to sports participation Company comment.

Case ID	WW Identifier	Narrative (Complete)
		This literature non-study case concerns a 20-year-old, female athlete patient with no medical history reported, who experienced the unexpected, serious (medically significant) AESI of Atrial fibrillation, and the unexpected serious (medically significant) event of syncope (listed for USPI), 15 minutes after the administration of the first dose of mRNA-1273 vaccine. The initial rhythm was atrial fibrillation with rapid ventricular response at 150 beats per minute. She spontaneously cardioverted to normal sinus rhythm in a short period of time; however, she developed prolonged exertional intolerance for several months. In an electrophysiological study the atrial fibrillation recurred and required electrical cardioversion. After this, a 2-week ambulatory rhythm monitoring showed normal sinus rhythm with no longer recurrence of atrial fibrillation. A cardiopulmonary stress test revealed above average peak rate of oxygen uptake, appropriate cardiopulmonary response to exercise, and no electrocardiogram changes. Thyroid stimulating hormone, iron studies, complete blood count and cardiac biomarkers were normal. Patient´s athletic condition (collegiate long – distance runner) remains as contributory factor for atrial fibrillation. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 01-Apr-2022: Follow-up received by safety on 04-April-2022 included an Email with FTA received from SARA team contains significant information includes reporters information and authors details.
4.1(b)	4.1(b) 4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 04-Apr-2022 and was forwarded to Moderna on 04-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of BURNING SENSATION (Burning sensation), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), NEUROPATHY PERIPHERAL (Neuropathy peripheral), OFF LABEL USE (Off label use) and PAIN IN EXTREMITY (Pain in extremity) in a 57-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 immunisation. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form and dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On an unknown date, the patient experienced BURNING SENSATION (Burning sensation) (seriousness criterion medically significant), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criterion medically significant), NEUROPATHY PERIPHERAL (Neuropathy peripheral) (seriousness criterion medically significant), OFF LABEL USE (Off label use) (seriousness criterion medically significant) and PAIN IN EXTREMITY (Pain in extremity) (seriousness criterion medically significant). At the time of the report, BURNING SENSATION (Burning sensation), INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), NEUROPATHY PERIPHERAL (Neuropathy peripheral), OFF LABEL USE (Off label use) and PAIN IN EXTREMITY (Pain in extremity) outcome was unknown. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. No concomitant medications reported by reporter. No treatment medications provided by the reporter.

Case ID	WW Identifier	Narrative (Complete)
		Company Comment: This regulatory authority case concerns a 57 year old, female patient with no reported medical history, who experienced unexpected, serious (medically significant) events of burning sensation, neuropathy peripheral and pain in extremity after receiving a dose of mRNA-1273 on an unknown date. Interchange of vaccine products and off label use were also reported. Clinical course, labs and treatment details were not reported. The outcome of events is unknown. Concomitant vaccination with Covid 19 vaccine Comirnaty could be a confounding factor. The benefit risk relationship of mRNA-1273 is not affected by this report. Event seriousness is assessed as per regulatory authority's report.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 22-Apr-2022 and was forwarded to Moderna on 22-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of INTERCHANGE OF VACCINE PRODUCTS (1st Vaccination Astra, 2nd BionTech), DRUG INEFFECTIVE (Infected despite triple vaccination, which is currently "only" having the same effect as a cold/ Vaccine Breakthrough), OFF LABEL USE (1st Vaccination Astra, 2nd BionTech) and COVID-19 (Infected despite triple vaccination, which is currently "only" having the same effect as a cold/ Vaccine Breakthrough) in a male patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for COVID-19 immunisation and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for COVID-19 immunisation. No Medical History information was reported. On an unknown date, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form, second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form and first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (unknown route) 1 dosage form. On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (1st Vaccination Astra, 2nd BionTech) (seriousness criterion medically significant), DRUG INEFFECTIVE (Infected despite triple vaccination, which is currently "only" having the same effect as a cold/ Vaccine Breakthrough) (seriousness criterion medically significant), OFF LABEL USE (1st Vaccination Astra, 2nd BionTech) (seriousness criterion medically significant) and COVID-19 (Infected despite triple vaccination, which is currently "only" having the same effect as a cold/ Vaccine Breakthrough) (seriousness criterion medically significant). At the time of the report, INTERCHANGE OF VACCINE PRODUCTS (1st Vaccination Astra, 2nd BionTech), DRUG INEFFECTIVE (Infected despite triple vaccination, which is currently "only" having the same effect as a cold/ Vaccine Breakthrough), OFF LABEL USE (1st Vaccination Astra, 2nd BionTech) and COVID-19 (Infected despite triple vaccination, which is currently "only" having the same effect as a cold/ Vaccine Breakthrough) outcome was unknown. No concomitant medications were reported. No treatment medications were reported. Company Comment: This regulatory authority case concerns a male patient of unknown age, with no reported medical history, who experienced unexpected, serious (medically significant) AESI Covid-19 on an unknown date after receiving a booster dose of mRNA-1273 (reported as third dose). Interchange of vaccine products, drug ineffective and off label use (1st Vaccination Astra, 2nd BioNTech) were also reported. Clinical course, labs and treatment details were not reported. The outcome of Covid-19 is unknown. The ongoing Covid-19 pandemic could be a contributory factor. The benefit risk relationship of mRNA-1273 is not affected by this report. Event seriousness is assessed as per regulatory authority's report.

Case ID	WW Identifier	Narrative (Complete)
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 26-Apr-2022 and was forwarded to Moderna on 26-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (COVID-19 infection/symptomatic: "chills and sweats"), INTERCHANGE OF VACCINE PRODUCTS (1st and 2nd Moderna and 3rd Biontech), OFF LABEL USE (1st and 2nd Moderna and 3rd Biontech) and DRUG INEFFECTIVE (COVID-19 infection/symptomatic: "chills and sweats") in a 35-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. No Medical History information was reported. On 28-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 29-Jun-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 30-Nov-2021, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 30-Nov-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (1st and 2nd Moderna and 3rd Biontech) (seriousness criterion medically significant) and OFF LABEL USE (1st and 2nd Moderna and 3rd Biontech) (seriousness criterion medically significant). On 27-Mar-2022, the patient experienced COVID-19 (COVID-19 infection/symptomatic: "chills and sweats") (seriousness criterion medically significant) and DRUG INEFFECTIVE (COVID-19 infection/symptomatic: "chills and sweats") (seriousness criterion medically significant). At the time of the report, COVID-19 (COVID-19 infection/symptomatic: "chills and sweats"), INTERCHANGE OF VACCINE PRODUCTS (1st and 2nd Moderna and 3rd Biontech), OFF LABEL USE (1st and 2nd Moderna and 3rd Biontech) and DRUG INEFFECTIVE (COVID-19 infection/symptomatic: "chills and sweats") outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Mar-2022, SARS-CoV-2 test: positive (Positive) Positive. Concomitant drugs were not reported. Treatment medications were not provided. Company Comment: This is a regulatory case of Interchange of vaccine products concerning a 35-year-old male patient with no reported medical history, previously vaccinated with the first dose of mRNA-1273 (dose1 in vaccine series), who experienced the unexpected serious (medically significant) AESI of COVID-19 (symptomatic: "chills and sweats"). The event occurred approximately 8 months 27 days after the second dose of mRNA-1273 vaccine (administered 2 months 1 day after dose 1) and 3 months 27 days after a booster dose (dose 3) of COVID-19 vaccine Comirnaty. COVID-19 virus test (Rapid test) was positive. There was no information about the clinical course and treatment medication. Additional events of Drug ineffective and Off-label use were also reported. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 29-Apr-2022 and was forwarded to Moderna on 29-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of OFF LABEL USE (vaccinated 3 times (2x Moderna, 1x Biontech)), VENTRICULAR EXTRASYSTOLES (Since then daily extrasystoles (heart tripping) VES and SVES.), COVID-19 (Covid-19 positive), SINUS TACHYCARDIA (Sinus tachycardia), SUPRAVENTRICULAR

Case ID	WW Identifier	Narrative (Complete)
		EXTRASYSTOLES (Since then daily extrasystoles (heart tripping) VES and SVES.), INTERCHANGE OF VACCINE PRODUCTS (vaccinated 3 times (2x Moderna, 1x Biontech)), PERICARDIAL EFFUSION (Pericarditis (inflammation of the heart pouch) with pericardial effusion (8mm)), DRUG INEFFECTIVE (Covid-19 positive) and PERICARDITIS (Pericarditis (inflammation of the heart pouch) with pericardial effusion (8mm)) in a 22-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. Concomitant products included ORAL CONTRACEPTIVE NOS and IBUPROFEN for an unknown indication. On 26-Nov-2021 at 12:30 PM, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 06-Dec-2021, the patient experienced VENTRICULAR EXTRASYSTOLES (Since then daily extrasystoles (heart tripping) VES and SVES.) (seriousness criteria hospitalization and disability), SINUS TACHYCARDIA (Sinus tachycardia) (seriousness criteria hospitalization and disability), SUPRAVENTRICULAR EXTRASYSTOLES (Since then daily extrasystoles (heart tripping) VES and SVES.) (seriousness criteria hospitalization and disability), PERICARDIAL EFFUSION (Pericarditis (inflammation of the heart pouch) with pericardial effusion (8mm)) (seriousness criteria hospitalization, disability and medically significant) and PERICARDITIS (Pericarditis (inflammation of the heart pouch) with pericardial effusion (8mm)) (seriousness criteria hospitalization, disability and medically significant). On 11-Mar-2022, the patient experienced COVID-19 (Covid-19 positive) (seriousness criterion medically significant) and DRUG INEFFECTIVE (Covid-19 positive) (seriousness criterion medically significant). On an unknown date, the patient experienced OFF LABEL USE (vaccinated 3 times (2x Moderna, 1x Biontech)) (seriousness criteria hospitalization, disability and medically significant) and INTERCHANGE OF VACCINE PRODUCTS (vaccinated 3 times (2x Moderna, 1x Biontech)) (seriousness criteria hospitalization, disability and medically significant). At the time of the report, OFF LABEL USE (vaccinated 3 times (2x Moderna, 1x Biontech)), COVID-19 (Covid-19 positive), INTERCHANGE OF VACCINE PRODUCTS (vaccinated 3 times (2x Moderna, 1x Biontech)) and DRUG INEFFECTIVE (Covid-19 positive) outcome was unknown and VENTRICULAR EXTRASYSTOLES (Since then daily extrasystoles (heart tripping) VES and SVES.), SINUS TACHYCARDIA (Sinus tachycardia), SUPRAVENTRICULAR EXTRASYSTOLES (Since then daily extrasystoles (heart tripping) VES and SVES.), PERICARDIAL EFFUSION (Pericarditis (inflammation of the heart pouch) with pericardial effusion (8mm)) and PERICARDITIS (Pericarditis (inflammation of the heart pouch) with pericardial effusion (8mm)) had resolved with sequelae. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Mar-2022, SARS-CoV-2 test: positive (Positive) Positive. Company Comment: This regulatory case concerns a 22-year-old, female patient, with no relevant medical history reported, who experienced an expected, disabling & medically significant AESI Pericarditis with an unexpected, disabling & medically significant event of Pericardial effusion, as well as the unexpected, disabling events of AESI Ventricular extrasystoles, AESI Sinus tachycardia & AESI Supraventricular extrasystoles, and lastly, an unexpected, medically significant AESI COVID-19 in association with mRNA-2173 vaccine. Drug ineffective was also reported in this case. Exact onset latency of all the reported events as well as lack of efficacy cannot be established with unknown start dates of both doses of mRNA-1273 vaccine.

Case ID	WW Identifier	Narrative (Complete)
		Interchange of vaccine products & Off label use were reported as she received 2 primary doses of mRNA-1273 vaccine and a booster dose of Pfizer's COVID-19 vaccine. After 10 days upon receiving her booster dose, inflammation of the heart pouch with pericardial effusion (8mm), extrasysoles, & sinus tachycardia occurred and led to the patient's hospitalization. Event COVID-19 was diagnosed with a positive nasal swab SARS-CoV-2 test 3 months later. Outcome of all cardiac related events have resolved with sequalae. Further details on the medical history, concomitant medications, clinical course, diagnostics, & treatment details were not reported. Interchange of vaccine products remains as a confounder to all the events. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed per Regulatory Authority reporting.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 02-May-2022. The most recent information was received on 10-Jun-2022 and was forwarded to Moderna on 10-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (corona infection), DRUG INEFFECTIVE (corona infection), OFF LABEL USE (3rd vaccination with BioNTech (previous with Moderna) on 20-Dec-21) and INTERCHANGE OF VACCINE PRODUCTS (3rd vaccination with BioNTech (previous with Moderna) on 20-Dec-21) in a 27-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 214007 and 3002614) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. Concurrent medical conditions included Addison's disease since 2017. Concomitant products included FLUDROCORTISONE (ASTONIN H), PRASTERONE (4.1(b) and HYDROCORTISONE (HYDROCORTISON 4.1(b) for Addison's disease, DIENOGEST, ESTRADIOL VALERATE (QLAIRA) for Oral contraceptive, DIPHTHERIA VACCINE TOXOID, PERTUSSIS VACCINE ACELLULAR 3-COMPONENT, TETANUS VACCINE TOXOID (BOOSTRIX) from 23-Sep-2021 to 23-Sep-2021 and INFLUENZA VACCINE INACT SAG 4V (INFLUVAC TETRA) from 05-Nov-2021 to 05-Nov-2021 for an unknown indication. On 08-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 14-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 20-Dec-2021, the patient received third dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 20-Dec-2021, the patient experienced OFF LABEL USE (3rd vaccination with BioNTech (previous with Moderna) on 20-Dec-21) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (3rd vaccination with BioNTech (previous with Moderna) on 20-Dec-21) (seriousness criterion medically significant). On 22-Mar-2022, the patient experienced DRUG INEFFECTIVE (corona infection) (seriousness criterion medically significant). On an unknown date, the patient experienced COVID-19 (corona infection) (seriousness criterion medically significant). At the time of the report, COVID-19 (corona infection) had resolved and DRUG INEFFECTIVE (corona infection), OFF LABEL USE (3rd vaccination with BioNTech (previous with Moderna) on 20-Dec-21) and INTERCHANGE OF VACCINE PRODUCTS (3rd vaccination with BioNTech (previous with Moderna) on 20-Dec-21) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Mar-2022, SARS-CoV-2 test: 19.25 Test Result:19.25. On 23-Mar-2022, Pyrexia: 38.5 degrees Test Result:38.5 degrees. In the evening fluctuating fever between 37.5-37.5. On 28-Mar-2022, SARS-CoV-2 test: negative (Negative) Negative. Treatment medication was not provided by the reporter.

Case ID	WW Identifier	Narrative (Complete)
		Company comment: This regulatory case concerns a 27-year-old female patient, with relevant medical history of Addison's disease, who experienced the unexpected serious (medically significant) AESI of COVID-19 after receiving the 2nd dose of mRNA-1273 vaccine. Additionally, Drug ineffective, Off label use, and Interchange of vaccine products were also reported as serious events by Regulatory Authority. The onset date of the event COVID-19 was not reported. Patient received 2 doses of mRNA-1273 vaccine as primary series given at an interval of 38 days, hence, it does not satisfy the dosing regimen criteria for lack of efficacy. SARS-CoV-2 test with result of 19.25 was reported on March 22,2022 (approximately 8 months after the 2nd dose of mRNA-1273 vaccine) and negative result on March 28,2022. Fever of 38.5 degrees was reported. Clinical course and treatment details were not reported. The outcome of event was reported as resolved. Addison's disease could be considered as a risk factor for event COVID-19. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 10-Jun-2022: Follow-up received wherein expiry date of co suspect vaccine added.
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 04-May-2022. The most recent information was received on 30-May-2022 and was forwarded to Moderna on 30-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of HEMIPARESIS (WEAKNESS OF THE LEFT SIDE OF THE BODY), BACTERIAL INFECTION (BACTERIAL INFECTION), DIZZINESS (DIZZINESS), OCULAR DISCOMFORT (FEELING OF PRESSURE IN BOTH EYES), ATAXIA (ATAXIA IN TRUNK), DERMATITIS CONTACT (CONTACT ALLERGY) and HAEMORRHOIDS (HEMORRHOIDS) in a 50-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for COVID-19 prophylaxis and OCRELIZUMAB (OCREVUS) injection, solution for Progressive relapsing multiple sclerosis and Secondary progressive multiple sclerosis. The patient's past medical history included Anxiety and Depression. Concurrent medical conditions included Amnestic aphasia, Birch pollen allergy, Fatigue, Concentration impaired, Nickel sensitivity, Difficulty in walking, Progressive relapsing multiple sclerosis and Secondary progressive multiple sclerosis. Concomitant products included FAMPRIDINE (FAMPYRA), MAGNESIUM, CLOMIPRAMINE HYDROCHLORIDE (CLOMIPRAMIN), CANNABIDIOL, DRONABINOL (SATIVEX), COLECALCIFEROL (DEKRISTOL) and CITALOPRAM for an unknown indication. On 23-May-2018, the patient started OCRELIZUMAB (OCREVUS) (Intravenous) 300 milligram. On 04-Dec-2018, OCRELIZUMAB (OCREVUS) (Intravenous) dosage was changed to 600 milligram. On 03-Jun-2019, OCRELIZUMAB (OCREVUS) (Intravenous) dosage was changed to 600 milligram. On 03-Dec-2019, OCRELIZUMAB (OCREVUS) (Intravenous) dosage was changed to 600 milligram. On 29-Jul-2020, OCRELIZUMAB (OCREVUS) (Intravenous) dosage was changed to 600 milligram. On 31-Mar-2021, OCRELIZUMAB (OCREVUS) (Intravenous) dosage was changed to 600 milligram. On 25-Mar-2022, received fourth dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form and dose of TOZINAMERAN (COMIRNATY) (unknown route) 4th vaccination on 25/Mar/2022. On 23-May-2018, the patient experienced GAIT DISTURBANCE (WORSENING OF IMPAIRED ABILITY TO WALK). On 14-May-2019, the patient

Case ID	WW Identifier	Narrative (Complete)
		experienced ATAXIA (ATAXIA IN TRUNK) (seriousness criterion hospitalization). On 16-May-2019, the patient experienced OCULAR DISCOMFORT (FEELING OF PRESSURE IN BOTH EYES) (seriousness criterion hospitalization). In 2019, the patient experienced APHASIA (WORSENING OF WORD FINDING DIFFICULTY). In October 2019, the patient experienced MYALGIA (MUSCLE PAIN). In 2020, the patient experienced DERMATITIS CONTACT (CONTACT ALLERGY) (seriousness criterion hospitalization). On 19-Oct-2020, the patient experienced HEMIPARESIS (WEAKNESS OF THE LEFT SIDE OF THE BODY) (seriousness criterion medically significant) and HYPOAESTHESIA (NUMBNESS). In November 2020, the patient experienced APATHY (AVOLITION). In March 2021, the patient experienced HAEMORRHOIDS (HEMORRHOIDS) (seriousness criterion hospitalization). In 2021, the patient experienced HYPOAESTHESIA ORAL (NUMBNESS IN THE MIDDLE REGION OF TONGUE). In October 2021, the patient experienced GAIT DISTURBANCE (WORSENING OF PRE-EXISTING LIMITED WALKING ABILITY). In January 2022, the patient experienced ERYTHEMA (REDDENING ON THE OUTER SIDE OF THE RIGHT UPPER ANKLE JOINT) and JOINT SWELLING (SWELLING ON ANKLE JOINT). On 25-Mar-2022, the patient experienced HEADACHE (HEADACHES). On an unknown date, the patient experienced NEURALGIA (NEURALGIA), PAIN IN EXTREMITY (STUBBLE BURNING PAIN IN ENTIRE LEFT LEG), PRURITUS (ITCHING), BACTERIAL INFECTION (BACTERIAL INFECTION) (seriousness criterion medically significant), FLUID RETENTION (WATER RETENTIONS IN FEET), DIZZINESS (DIZZINESS) (seriousness criterion hospitalization), MUSCULAR WEAKNESS (WEAK FOOT DORSIFLEXION (UNK DIAGNOSIS)), OFF LABEL USE (OCREVUS OFF LABEL USE FOR UNLABELED INDICATION), BODY TEMPERATURE INCREASED (INCREASED BODY TEMPERATURE), HEART RATE INCREASED (INCREASED HEART RATE), CYSTITIS NONINFECTIVE (BLADDER INFLAMMATION), TINEA PEDIS (ATHLETE FOOT), FEELING HOT (HEAT SENSATION), INSOMNIA (INSOMNIA), FALL (FALL), HAEMATOMA (HAEMATOMAS), FATIGUE (WORSENING OF FATIGUE), the first episode of FATIGUE (TIREDNESS), BURNING SENSATION (BURNING SENSATION IN FEET AND CALVES), HYPERHIDROSIS (SWEATING), ERYTHEMA (SKIN REDNESS) and the second episode of FATIGUE (TIREDNESS). At the time of the report, NEURALGIA (NEURALGIA), PAIN IN EXTREMITY (STUBBLE BURNING PAIN IN ENTIRE LEFT LEG), PRURITUS (ITCHING), HEMIPARESIS (WEAKNESS OF THE LEFT SIDE OF THE BODY), BACTERIAL INFECTION (BACTERIAL INFECTION), FLUID RETENTION (WATER RETENTIONS IN FEET), DIZZINESS (DIZZINESS), HYPOAESTHESIA (NUMBNESS), APATHY (AVOLITION), BODY TEMPERATURE INCREASED (INCREASED BODY TEMPERATURE), HEART RATE INCREASED (INCREASED HEART RATE), TINEA PEDIS (ATHLETE FOOT), FEELING HOT (HEAT SENSATION), INSOMNIA (INSOMNIA), MYALGIA (MUSCLE PAIN), HAEMATOMA (HAEMATOMAS), FATIGUE (WORSENING OF FATIGUE), BURNING SENSATION (BURNING SENSATION IN FEET AND CALVES), HAEMORRHOIDS (HEMORRHOIDS), HYPERHIDROSIS (SWEATING), ERYTHEMA (SKIN REDNESS) and the last episode of FATIGUE (TIREDNESS) had resolved, APHASIA (WORSENING OF WORD FINDING DIFFICULTY), GAIT DISTURBANCE (WORSENING OF IMPAIRED ABILITY TO WALK), HYPOAESTHESIA ORAL (NUMBNESS IN THE MIDDLE REGION OF TONGUE), GAIT DISTURBANCE (WORSENING OF PRE-EXISTING LIMITED WALKING ABILITY), OCULAR DISCOMFORT (FEELING OF PRESSURE IN BOTH EYES) and CYSTITIS NONINFECTIVE (BLADDER INFLAMMATION) had not resolved, ERYTHEMA (REDDENING ON THE OUTER SIDE OF THE RIGHT UPPER ANKLE JOINT), MUSCULAR WEAKNESS (WEAK FOOT DORSIFLEXION (UNK DIAGNOSIS)), OFF LABEL USE (OCREVUS OFF LABEL USE FOR UNLABELED INDICATION), JOINT SWELLING (SWELLING ON ANKLE JOINT), FALL (FALL) and HEADACHE (HEADACHES) outcome was unknown and ATAXIA (ATAXIA IN TRUNK) and DERMATITIS CONTACT (CONTACT ALLERGY) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-May-2019, Magnetic resonance imaging: ataxia with deterioration in walking ability Ataxia with deterioration in walking ability and pressure in both eyes was diagnosed..

Case ID	WW Identifier	Narrative (Complete)
		The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Treatment information was not provided. Company comment: This regulatory case concerns a 50-year-old, female patient with concurrent multiple sclerosis (progressive relapsing with eventual transition to secondary progressive) with limited ambulation and on polypharmacy, who was hospitalized for the unexpected events of Ataxia, Ocular discomfort, Dermatitis contact, Haemorrhoids and Dizziness; and, experienced the unexpected, serious (medically significant) events of Hemiparesis and Bacterial infection. A number of non-serious events were also reported in the case. Off label use was also reported as an additional event describing the use of Ocrelizumab (Ocrevus) for an unapproved indication. The events of hemiparesis, dermatitis contact and haemorrhoids occurred after receiving mRNA-1273 which was administered on an unknown date; while ataxia and ocular discomfort started and were diagnosed through magnetic resonance imaging prior to the COVID-19 pandemic and mRNA-1273 vaccination. The onset dates of bacterial infection and dizziness were not provided in the case. Details of the course during hospital stay, diagnostic procedures conducted and medical intervention administered were not provided in the case. The serious events of dizziness, hemiparesis and haemorrhoids were resolved on unknown dates. There was also interchange of vaccine products wherein the patient received the co-suspect Tozinameran as fourth COVID-19 vaccine dose and which remains a confounder for the ongoing events. Ocrelizumab (Ocrevus) was also cited as co-suspect in the case and along with polypharmacy could be confounders to the events. Additionally, the patient's progressive m
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-May-2022 and was forwarded to Moderna on 04-May-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of TINNITUS (RINGING IN THE EAR), HEADACHE (HEADACHE), MALAISE (GENERALIZED MALAISE), PYREXIA (FEVER), EAR PAIN (EAR ACHE), LYMPHADENOPATHY (SWOLLEN LYMPH NODES) and OROPHARYNGEAL PAIN (SORE THROAT) in a 120-day-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for an unknown indication. The patient's past medical history included Lymphadenopathy. Concurrent medical conditions included Drug allergy. Concomitant products included PARACETAMOL, KETOPROFEN LYSINE (4.1(b)), ACICLOVIR (ACICLOVIR MK), PREGABALIN (PREGABALINE), AMOXICILLIN TRIHYDRATE (AMOXICILINA GI) and FOLIC ACID (FOLIDEX) for an unknown indication. On 05-Jun-2021, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (Intramuscular) 1 dosage form. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jun-2021, the patient experienced HEADACHE (HEADACHE) (seriousness criteria disability and medically significant), MALAISE (GENERALIZED MALAISE) (seriousness criteria disability and medically significant), EAR PAIN (EAR ACHE) (seriousness criteria disability and medically significant), LYMPHADENOPATHY (SWOLLEN LYMPH NODES) (seriousness criteria disability and medically significant) and OROPHARYNGEAL PAIN (SORE THROAT) (seriousness criteria disability and

Case ID	WW Identifier	Narrative (Complete)
		medically significant). On 20-Feb-2022, the patient experienced TINNITUS (RINGING IN THE EAR) (seriousness criteria disability and medically significant). On an unknown date, the patient experienced OFF LABEL USE (I HAVE TAKEN TWO MORE DOSES OF THE COVID VACCINE, BUT MODERNA, NOT ASTRAZENECA), PAIN (FELT PAIN EVERYWHERE), HYPOACUSIS (I NO LONGER LISTEN AS BEFORE), LYMPHADENITIS (RIGHT LATEROCERVICAL LYMPHADENOMEGALY (RIGHT LATEROCERVICAL TENDER LYMPHADENITIS, PHARYNGEAL AND ISTHMUS HYPEREMIA OF THE MOUTH)), PYREXIA (FEVER) (seriousness criteria disability and medically significant), BLOOD LACTATE DEHYDROGENASE INCREASED (P-LACTATE DEHYDROGENASE (LDH) > 265 U/L) and INTERCHANGE OF VACCINE PRODUCTS (I HAVE TAKEN TWO MORE DOSES OF THE COVID VACCINE, BUT MODERNA, NOT ASTRAZENECA (INTERCHANGE OF VACCINES)). At the time of the report, OFF LABEL USE (I HAVE TAKEN TWO MORE DOSES OF THE COVID VACCINE, BUT MODERNA, NOT ASTRAZENECA), PAIN (FELT PAIN EVERYWHERE), HYPOACUSIS (I NO LONGER LISTEN AS BEFORE), LYMPHADENITIS (RIGHT LATEROCERVICAL LYMPHADENOMEGALY (RIGHT LATEROCERVICAL TENDER LYMPHADENITIS, PHARYNGEAL AND ISTHMUS HYPEREMIA OF THE MOUTH)), BLOOD LACTATE DEHYDROGENASE INCREASED (P-LACTATE DEHYDROGENASE (LDH) > 265 U/L) and INTERCHANGE OF VACCINE PRODUCTS (I HAVE TAKEN TWO MORE DOSES OF THE COVID VACCINE, BUT MODERNA, NOT ASTRAZENECA (INTERCHANGE OF VACCINES)) outcome was unknown, TINNITUS (RINGING IN THE EAR), HEADACHE (HEADACHE), MALAISE (GENERALIZED MALAISE), EAR PAIN (EAR ACHE), LYMPHADENOPATHY (SWOLLEN LYMPH NODES) and OROPHARYNGEAL PAIN (SORE THROAT) had not resolved and PYREXIA (FEVER) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Nov-2021, Magnetic resonance imaging: no signal changes in the context of cerebral There are no signal changes in the context of cerebral parenchyma. There is no restricted proton diffusivity. Normally sized ventricular system on axis with persistence of the pellucid septum cable. Normally, the amplitude of the periencephalic CSF spaces.. On an unknown date, Basophilia: 0.0 x 10^3/ul 0.0 X 10^3/UL and 0.7 % 0.7 %. On an unknown date, Blood creatinine: 1.04 mg/dl 1.04 mg/dL. On an unknown date, Blood immunoglobulin E: 32.4 iu/ml 32.4 IU/ml. On an unknown date, Blood lactate dehydrogenase: 265 265. On an unknown date, Blood test: unknown UNKNOWN. On an unknown date, Blood urea: 21 mg/dl 21 mg/dL. On an unknown date, C-reactive protein increased: 0.6 mg/dl 0.6 mg/dL. On an unknown date, Computerised tomogram: unknown UNKNOWN. On an unknown date, Computerised tomogram neck: short axis equal to or less than 0.9 cm The examination was performed in a multilayer spiral technique, without contrast agent as required by the medical request. In the second and third levels of both sides, lymph node formations of a short axis equal to or less than 0.9 cm, dimensionally non-pathological, are recognized; detailed ultrasound evaluation is required, if not performed. Symmetrical pharyngeal – laryngeal airspace. Thyroid in place, of normal size and morphology.. On an unknown date, Eosinophil count: 3.3 % 3.3 %. On an unknown date, Glomerular filtration rate: 82 ml/min 82 ml/min. On an unknown date, Haematocrit: 44.8 % 44.8 %. On an unknown date, Haemoglobin: 5.3 g/dl 5.3 g/dL. On an unknown date, Hepatitis B surface antibody positive: 827.00 miu/ml 827.00 mIU/ml. On an unknown date, Herpes simplex: positive (Positive) Positive. On an unknown date, Lymphocyte count: 34.4 % 34.4 %. On an unknown date, Magnetic resonance imaging: unknown UNKNOWN.

Case ID	WW Identifier	Narrative (Complete)
		On an unknown date, Mean cell haemoglobin: 31.0 pg/ml 31.0 pg/ml. On an unknown date, Mean cell haemoglobin concentration: 34.2 g/dl 34.2 G/DL. On an unknown date, Mean cell volume: 90.9 fl 90.9 Fl. On an unknown date, Monocyte count: 0.6 x 10^3/ul 0.6 X 10^3/UL and 9.4% 9.4%. On an unknown date, Neutrophil count: 52.2 % 52.2 % and 3.2 x 10^3/ul 3.2 X 10^3/UL. On an unknown date, Platelet disorder: 279 x 10^3/ul 279 X 10^3/UL. On an unknown date, Rectal ultrasound: unknown UNKNOWN. On an unknown date, Red blood cell abnormality: 4.93 x 10^6/ul 4.93 x 10^6/UL and 13.1 % 13.1 %. On an unknown date, Red blood cell count: 0.0 / 100 wbc 0.0 / 100 WBC and 0.00 x 10^3/ul 0.00 X 10^3/UL. On an unknown date, Streptococcus test negative: < 20 iu/ml < 20 IU/ml. On an unknown date, Ultrasound Doppler: all lymph nodes appear avascular All lymph nodes appear avascular. On an unknown date, Ultrasound scan: some lymph node formations with preserved On the right side in the latero-cervical region, there are some lymph node formations with preserved morphology and a well-evident central ilum, measuring a maximum diameter of approximately 7.5 mm; 10 mm; 10.5 mm, 11 mm. In addition, on the right is another hypoecogenic area of 14.5 x 8 mm with net margins (possible inflammatory lymph nodes).. On an unknown date, Varicella zoster virus infection: positive (Positive) Positive. On an unknown date, White blood cell count: 6.14 x 10^3/ul 6.14 X 10^3/UL. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Company comment: This regulatory case concerns a 120-day-old, male patient with medical history of Lymphadenopathy, who experienced the unexpected, serious (Medically significant, Disability) events of Tinnitus, Headache, Malaise, Pyrexia, Ear pain, Lymphadenopathy and Oropharyngeal pain. The exact date of administration of an unknown dose of mRNA-1273 was not specified in respect to the onset of events, hence latency could not be assessed. The patient received the initial dose of Astrazeneca on June 5, 2021. On November 20, 2021, magnetic resonance imaging was done which revealed no signal changes in the context of cerebral There are no signal changes in the context of cerebral parenchyma. There is no restricted proton diffusivity. Normally sized ventricular system on axis with persistence of the pellucid septum cable. Normally, the amplitude of the periencephalic CSF spaces. On an unknown date, computerized tomogram of the neck was done, short axis equal to or less than 0.9 cm The examination was performed in a multilayer spiral technique, without contrast agent as required by the medical request. In the second and third levels of both sides, lymph node formations of a s
4.1(b) [redacted]	4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 05-May-2022. The most recent information was received on 21-Jun-2022 and was forwarded to Moderna on 21-Jun-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHILLS (CHILLS), MYELOPATHY (POST CERVICAL DISC HERNIATION MYELOPATHY), ACUTE KIDNEY INJURY (ACUTE RENAL FAILURE IN THE STATE OF AKI I), URTICARIA (LARGE AREA OF URTICARIA ON THE TORSO AND ISOLATED SITES ON THE BOTH LEGS), VOMITING (VOMITING), VITAMIN D DEFICIENCY (VITAMIN D DEFICIENCY), CONDITION AGGRAVATED (WORSENING OF SYMPTOMS, RENEWED IMMUNE ADSORPTION OVER 7 DAYS), GUILLAIN-BARRE SYNDROME (GUILLAIN-BARRE SYNDROME), ESSENTIAL HYPERTENSION (BENIGN ESSENTIAL HYPERTENSION), PYREXIA (FEVER), PRURITUS (ITCHING), DYSPNOEA (MILD DYSPNEA SYMPTOMS HAD ALREADY EXISTED LONGER), HYPERSENSITIVITY (ALLERGIC REACTION AFTER COVID BOOSTER VACCINATION), HYPERTENSION (ARTERIAL HYPERTENSION), TUBULOINTERSTITIAL NEPHRITIS

Case ID	WW Identifier	Narrative (Complete)
		(INTERSTITIAL NEPHRITIS AFTER COVID-MODERNA VACCINATION), DECREASED APPETITE (LOSS OF APPETITE), UPPER RESPIRATORY TRACT INFECTION (UPPER RESPIRATORY TRACT INFECTION), ASTHMA (SUSPECTED ALLERGIC ASTHMA) and RASH (TWO DAYS LATER, THE ITCHY EXANTHEMA DEVELOPED ON THE TORSO) in a 62-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000117A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for an unknown indication and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for an unknown indication. Concomitant products included COLECALCIFEROL (DEKRISTOL) and RAMIPRIL for an unknown indication. On 06-May-2021, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (Intramuscular) 1 dosage form. On 04-Aug-2021, the patient received dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (Intramuscular) 1 dosage form. On 11-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced CHILLS (CHILLS) (seriousness criterion hospitalization), MYELOPATHY (POST CERVICAL DISC HERNIATION MYELOPATHY) (seriousness criterion hospitalization), ACUTE KIDNEY INJURY (ACUTE RENAL FAILURE IN THE STATE OF AKI I) (seriousness criteria hospitalization and medically significant), URTICARIA (LARGE AREA OF URTICARIA ON THE TORSO AND ISOLATED SITES ON THE BOTH LEGS) (seriousness criterion hospitalization), VOMITING (VOMITING) (seriousness criterion hospitalization), MYCOPLASMA TEST POSITIVE (PARAINFECTIOUS AFTER AN UPPER RESPIRATORY TRACT INFECTION WITH DETECTED MYCOPLASMA ANTIBODIES DD AS A VACCINATION REACTION AFTER COVID-19 PRIMARY VACCINATION WITH ASTRAZENECA 2 WEEKS EARLIER), VITAMIN D DEFICIENCY (VITAMIN D DEFICIENCY) (seriousness criterion hospitalization), HIGH DENSITY LIPOPROTEIN DECREASED (DECREASED HDL CHOLESTEROL LEVEL OF 28 MG/DL), PLATELET COUNT INCREASED (ELEVATED PLATELET COUNT OF 404 G/L,), CONDITION AGGRAVATED (WORSENING OF SYMPTOMS, RENEWED IMMUNE ADSORPTION OVER 7 DAYS) (seriousness criterion hospitalization), GUILLAIN-BARRE SYNDROME (GUILLAIN-BARRE SYNDROME) (seriousness criteria hospitalization and medically significant), ESSENTIAL HYPERTENSION (BENIGN ESSENTIAL HYPERTENSION) (seriousness criterion hospitalization), PYREXIA (FEVER) (seriousness criterion hospitalization), PRURITUS (ITCHING) (seriousness criterion hospitalization), OFF LABEL USE (ANDBIONTECH-PFIZER DOSE2), BLOOD CHOLESTEROL INCREASED (ELEVATED CHOLESTEROL LEVEL OF 206 MG/DL), DYSPNOEA (MILD DYSPNEA SYMPTOMS HAD ALREADY EXISTED LONGER) (seriousness criterion hospitalization), BLOOD GLUCOSE INCREASED (ELEVATED BLOOD SUGAR VALUE OF 105 MG/DL,), HYPERSENSITIVITY (ALLERGIC REACTION AFTER COVID BOOSTER VACCINATION) (seriousness criterion hospitalization), HYPERTENSION (ARTERIAL HYPERTENSION) (seriousness criterion hospitalization), TUBULOINTERSTITIAL NEPHRITIS (INTERSTITIAL NEPHRITIS AFTER COVID-MODERNA VACCINATION) (seriousness criteria hospitalization and medically significant), DECREASED APPETITE (LOSS OF APPETITE) (seriousness criterion hospitalization), UPPER RESPIRATORY TRACT INFECTION (UPPER RESPIRATORY TRACT INFECTION) (seriousness criterion hospitalization), ASTHMA (SUSPECTED ALLERGIC ASTHMA) (seriousness criterion hospitalization), BLOOD TRIGLYCERIDES INCREASED (INCREASED TRIGLYCERIDE LEVEL OF 375 MG/DL), INTERCHANGE OF VACCINE PRODUCTS (ASTRAZENECA COVID-19 VACCINE DOSE1 ANDBIONTECH-PFIZER DOSE2 (INTERCHANGE OF VACCINES)) and RASH (TWO DAYS LATER, THE ITCHY EXANTHEMA DEVELOPED ON THE TORSO) (seriousness criterion hospitalization). At the time of the report, CHILLS (CHILLS), MYELOPATHY (POST CERVICAL DISC HERNIATION MYELOPATHY), ACUTE KIDNEY INJURY (ACUTE RENAL

Case ID	WW Identifier	Narrative (Complete)
		FAILURE IN THE STATE OF AKI I), URTICARIA (LARGE AREA OF URTICARIA ON THE TORSO AND ISOLATED SITES ON THE BOTH LEGS), VOMITING (VOMITING), MYCOPLASMA TEST POSITIVE (PARAINFECTIOUS AFTER AN UPPER RESPIRATORY TRACT INFECTION WITH DETECTED MYCOPLASMA ANTIBODIES DD AS A VACCINATION REACTION AFTER COVID-19 PRIMARY VACCINATION WITH ASTRAZENECA 2 WEEKS EARLIER), VITAMIN D DEFICIENCY (VITAMIN D DEFICIENCY), HIGH DENSITY LIPOPROTEIN DECREASED (DECREASED HDL CHOLESTEROL LEVEL OF 28 MG/DL), PLATELET COUNT INCREASED (ELEVATED PLATELET COUNT OF 404 G/L,), CONDITION AGGRAVATED (WORSENING OF SYMPTOMS, RENEWED IMMUNE ADSORPTION OVER 7 DAYS), GUILLAIN-BARRE SYNDROME (GUILLAIN-BARRE SYNDROME), ESSENTIAL HYPERTENSION (BENIGN ESSENTIAL HYPERTENSION), PYREXIA (FEVER), PRURITUS (ITCHING), OFF LABEL USE (ANDBIONTECH-PFIZER DOSE2), BLOOD CHOLESTEROL INCREASED (ELEVATED CHOLESTEROL LEVEL OF 206 MG/DL), DYSPNOEA (MILD DYSPNEA SYMPTOMS HAD ALREADY EXISTED LONGER), BLOOD GLUCOSE INCREASED (ELEVATED BLOOD SUGAR VALUE OF 105 MG/DL,), HYPERSENSITIVITY (ALLERGIC REACTION AFTER COVID BOOSTER VACCINATION), HYPERTENSION (ARTERIAL HYPERTENSION), TUBULOINTERSTITIAL NEPHRITIS (INTERSTITIAL NEPHRITIS AFTER COVID-MODERNA VACCINATION), DECREASED APPETITE (LOSS OF APPETITE), UPPER RESPIRATORY TRACT INFECTION (UPPER RESPIRATORY TRACT INFECTION), ASTHMA (SUSPECTED ALLERGIC ASTHMA), BLOOD TRIGLYCERIDES INCREASED (INCREASED TRIGLYCERIDE LEVEL OF 375 MG/DL), INTERCHANGE OF VACCINE PRODUCTS (ASTRAZENECA COVID-19 VACCINE DOSE1 ANDBIONTECH-PFIZER DOSE2 (INTERCHANGE OF VACCINES)) and RASH (TWO DAYS LATER, THE ITCHY EXANTHEMA DEVELOPED ON THE TORSO) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-May-2021, Ultrasound scan: sonographically no abnormalities in the visible ar Sonographically no abnormalities in the visible areas of the right femoral nerve, no compression by hematomas or other masses. On 20-Jul-2021, Chest X-ray: no extensive infiltrates No extensive infiltrates. On 20-Jul-2021, SARS-CoV-2 test: negative NEGATIVE. On 21-Jul-2021, Chest X-ray: shaldon catheter properly inserted with no evidenc Shaldon catheter properly inserted with no evidence of complication. Mild cardiopulmonary congestion / overhydration with very prominent hili.. On 22-Jul-2021, Blood sodium: 142 142. On 23-Jul-2021, Blood sodium: 143 143. On 27-Jul-2021, Computerised tomogram thorax: no recognizable emphysematous or fibrotic changes No recognizable emphysematous or fibrotic changes. On 27-Jul-2021, Pulmonary function test: findings to follow. Findings to follow.. On 28-Jul-2021, Blood sodium: 142 142. On 30-Jul-2021, Magnetic resonance imaging: findings to follow. Findings to follow.. On an unknown date, Blood cholesterol increased: 206 206 MG/DL. On an unknown date, Blood creatinine: 1.96 1.02 1.96 1.02. On an unknown date, Blood glucose increased: 105 105 MG/DL. On an unknown date, Blood potassium: 4.35 4.05 4.35 4.05. On an unknown date, Blood sodium: 137.1 141.9 137.1 141.9. On an unknown date, Blood triglycerides increased: 375 375 MG/DL. On an unknown date, C-reactive protein increased: 2.90 0.98 2.90 0.98. On an unknown date, High density lipoprotein: 28 28 MG/DL. On an unknown date, Laboratory test: 121.5 121
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 09-May-2022 and was forwarded to Moderna on 09-May-2022.

Case ID	WW Identifier	Narrative (Complete)
		This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (Covid-19 infection), DRUG INEFFECTIVE (Covid-19 infection), INTERCHANGE OF VACCINE PRODUCTS (1st vaccination with AstraZeneca, 2nd with Biontech, booster with Moderna) and OFF LABEL USE (1st vaccination with AstraZeneca, 2nd with Biontech, booster with Moderna) in a 60-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for an unknown indication and TOZINAMERAN (COMIRNATY) for COVID-19 immunization. The patient's past medical history included Increased intraocular pressure and Relapsing-remitting multiple sclerosis. Concomitant products included OCRELIZUMAB (OCREVUS) from 06-Sep-2019 to an unknown date for Relapsing-remitting multiple sclerosis, MENAQUINONE (VITAMIN K2 [MENAQUINONE]), COLECALCIFEROL (DEKRISTOL), LATANOPROST, TIMOLOL MALEATE (FIXAPROST) and TAMSULOSIN for an unknown indication. In June 2021, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (unknown route) 1 dosage form. On 12-Jul-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On an unknown date, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Jul-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (1st vaccination with AstraZeneca, 2nd with Biontech, booster with Moderna) (seriousness criterion medically significant) and OFF LABEL USE (1st vaccination with AstraZeneca, 2nd with Biontech, booster with Moderna) (seriousness criterion medically significant). In March 2022, the patient experienced COVID-19 (Covid-19 infection) (seriousness criterion medically significant) and DRUG INEFFECTIVE (Covid-19 infection) (seriousness criterion medically significant). At the time of the report, COVID-19 (Covid-19 infection) had resolved and DRUG INEFFECTIVE (Covid-19 infection), INTERCHANGE OF VACCINE PRODUCTS (1st vaccination with AstraZeneca, 2nd with Biontech, booster with Moderna) and OFF LABEL USE (1st vaccination with AstraZeneca, 2nd with Biontech, booster with Moderna) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In August 2021, Pyrexia: 38,8 °c Test Result:38,8 °C Centigrade. In August 2021, SARS-CoV-2 antibody test: missing antibodies Test Result:missing antibodies. In August 2021, SARS-CoV-2 test: negative (Negative) Negative. In March 2022, SARS-CoV-2 test: covid-19 infection Test Result:COVID-19 Infection. No treatment medications were reported. Company Comment: This is a regulatory case concerning a 60-year-old male patient with no relevant medical history, who experienced the unexpected, serious (medically significant) adverse event of special interest of COVID-19 (with a positive test for SARS-CoV-2), after receiving a booster dose of mRNA-1273 vaccine. Drug ineffective, Interchange of vaccine products and Off label use were also reported as an additional event. Date of vaccination, clinical course and treatment details were not provided in the case. The event had resolved at the time of the report. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event retained as serious as per Regulatory Authority.

Case ID	WW Identifier	Narrative (Complete)
4.1(b)	4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of CYSTITIS BACTERIAL (BACTERIAL BLADDER INFECTION) in a 55-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for COVID-19 prophylaxis and OCRELIZUMAB (OCREVUS) solution for injection for Secondary progressive multiple sclerosis. The patient's past medical history included Hypothyroidism, Hypertension and Uhthoff's phenomenon. Concomitant products included GABAPENTIN, AMLODIPINE (AMLODIPIN [AMLODIPINE]), TIZANIDINE HYDROCHLORIDE (TIZANIDIN), LEVOTHYROXINE (L-THYROXINE [LEVOTHYROXINE]) and CANNABIDIOL, DRONABINOL (SATIVEX) for an unknown indication. On 23-Nov-2020, the patient started OCRELIZUMAB (OCREVUS) (Intravenous) 300 milligram. On 14-Mar-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-May-2021, OCRELIZUMAB (OCREVUS) (Intravenous) dosage was changed to 600 milligram every six months. On 09-Sep-2021, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 11-Mar-2022, received fourth dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. On 11-Aug-2021, the patient experienced CYSTITIS BACTERIAL (BACTERIAL BLADDER INFECTION) (seriousness criterion medically significant). On 23-Oct-2021, the patient experienced LYMPHADENOPATHY (SWOLLEN AXILLARY LYMPH NODES). On an unknown date, the patient experienced FATIGUE (TIREDNESS), OFF LABEL USE (OCREVUS USED AS OFF LABEL FOR UNLABELED INDICATION), MYALGIA (MUSCLE PAIN), HEADACHE (HEADACHE), GAIT DISTURBANCE (WORSENING OF ABILITY TO WALK (WALKING DIFFICULTY)), DECREASED IMMUNE RESPONSIVENESS (LACK OF IMMUNE RESPONSE), ARTHRALGIA (JOINT PAIN IN SHOULDER) and PAIN IN EXTREMITY (ARM PAIN). In August 2021, CYSTITIS BACTERIAL (BACTERIAL BLADDER INFECTION) had resolved. At the time of the report, FATIGUE (TIREDNESS), MYALGIA (MUSCLE PAIN), HEADACHE (HEADACHE), GAIT DISTURBANCE (WORSENING OF ABILITY TO WALK (WALKING DIFFICULTY)), ARTHRALGIA (JOINT PAIN IN SHOULDER) and PAIN IN EXTREMITY (ARM PAIN) had resolved and OFF LABEL USE (OCREVUS USED AS OFF LABEL FOR UNLABELED INDICATION), LYMPHADENOPATHY (SWOLLEN AXILLARY LYMPH NODES) and DECREASED IMMUNE RESPONSIVENESS (LACK OF IMMUNE RESPONSE) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Aug-2021, Body temperature: 39-40 degree celsius 39-40 degree celsius. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. No treatment reported. Company Comment: This is a regulatory authority case concerning a 55-year-old, female patient with no relevant medical history, who experienced the unexpected serious (medically significant) event of Cystitis bacterial and unexpected non-serious events of Off label use, gait disturbance, decreased immune response and expected non-serious events of Fatigue, Lymphadenopathy, myalgia, headache, Arthralgia, Pain in extremity. The event Cystitis bacterial occurred 150 days after the

Case ID	WW Identifier	Narrative (Complete)
		unspecified dose of mRNA-1273 COVID 19 Vaccine. The event Lymphadenopathy occurred 44 days after the Cominarty Vaccine. On an unknown date, Fatigue, off label use, myalgia, headache, gait disturbance, decreased immune response, Arthralgia, Pain in extremity occurred. The event outcome was reported as unknown. No treatment reported. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 13-May-2022 and was forwarded to Moderna on 13-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (SARS-COV-2 INFECTION), MACULAR HOLE (MACULAR FORAMEN), OPTIC NERVE DISORDER (AFFECTION OF OPTIC NERVE (UNK DIAGNOSIS)), MULTIPLE SCLEROSIS (WORSENING OF MULTIPLE SCLEROSIS SYMPTOMS), MULTIPLE SCLEROSIS RELAPSE (FLARE UP OF MULTIPLE SCLEROSIS) and MACULAR DEGENERATION (MACULAR DEGENERATION) in a 46-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for COVID-19 vaccination, OCRELIZUMAB solution for infusion for Relapsing-remitting multiple sclerosis and REMDESIVIR for Shortness of breath. Reported 3 breast lumps right (diagnosis in May 2016 and regular monitoring). The patient's past medical history included Ovarian carcinoma (removal of both ovaries, 2015), Endocarditis (as child), Nail bed inflammation, Multiple sclerosis (Flare-up of multiple sclerosis in brain stem with incomplete paraplegia.Rebound flare-up of multiple sclerosis occurred from Tysabri), Blindness (blindness (walking was learned again with wheelchair and walking aid)), Virus antibody test abnormal (very high John Cunningham-Virus Titer (nos)) since an unknown date and Oophorectomy in 2015. Previously administered products included for Product used for unknown indication: TYSABRI (Rebound flare-up of multiple sclerosis occurred from Tysabri). Past adverse reactions to the above products included Multiple sclerosis flare with TYSABRI. Concurrent medical conditions included Allergic reaction to wasp sting, Balance disorder, Fatigue, Allergy NOS (various allergies (including penicillin, bees, wasps),), Paresthesia of limbs (Sensitivity disorders on the left lower leg), Numbness in feet (numbness on soles of the feet), Allergic reaction to wasp sting, Allergic reaction to bee sting, Hair loss (alopecia areata universalis (November 2020)), Foot discomfort (weak foot dorsiflexion), Paresthesia of limbs and Penicillin allergy. Concomitant products included ESTRADIOL (4.1(b) [ESTRADIOL]), PARACETAMOL, OXYBUTYNIN (KENTERA), ESTRIOL, SODIUM CHLORIDE (NACL), CETIRIZINE HYDROCHLORIDE (CETIRIZIN), LORATADINE (4.1(b)) and COLECALCIFEROL (VITAMIN D3) for an unknown indication. On 20-Mar-2018, the patient started OCRELIZUMAB (Intravenous) 300 milligram. On 04-Apr-2018, OCRELIZUMAB (Intravenous) dosage was changed to 300 milligram. On 05-Oct-2018, OCRELIZUMAB (Intravenous) dosage was changed to 600 milligram. On 10-Apr-2019, OCRELIZUMAB (Intravenous) dosage was changed to 600 milligram. On 27-Apr-2020, OCRELIZUMAB (Intravenous) dosage was changed to 600 milligram. On 26-Oct-2020, OCRELIZUMAB (Intravenous) dosage was changed to 600 milligram. On 18-Jan-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 13-Feb-2021, received dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. In March 2021, received dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. On 26-Apr-2021, OCRELIZUMAB (Intravenous) dosage was changed to 600 milligram. On 17-Feb-2022, the patient received fourth dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form.

Case ID	WW Identifier	Narrative (Complete)
		On 10-Apr-2022, the patient started REMDESIVIR (Intravenous) at an unspecified dose. On 20-Mar-2018, the patient experienced PRODUCT PREPARATION ISSUE (OCRELIZUMAB DILUTED INAPPROPRIATELY IN 500 ML NACL INSTEAD OF 250 ML (INAPPROPRIATE DILUTION OF MEDICATION)), ALOPECIA (WORSENING OF HAIR LOSS) and OFF LABEL USE (OCREVUS INTENTIONALLY USED FOR AN OFF LABEL DOSAGE). On 14-Apr-2018, the patient experienced OPTIC NERVE DISORDER (AFFECTION OF OPTIC NERVE (UNK DIAGNOSIS)) (seriousness criterion hospitalization) and MULTIPLE SCLEROSIS RELAPSE (FLARE UP OF MULTIPLE SCLEROSIS) (seriousness criterion hospitalization). In November 2018, the patient experienced VITREOUS OPACITIES (VITREOUS OPACITIES), MACULAR HOLE (MACULAR FORAMEN) (seriousness criterion medically significant) and MACULAR DEGENERATION (MACULAR DEGENERATION) (seriousness criterion medically significant). On 30-Mar-2020, the patient experienced MULTIPLE SCLEROSIS (WORSENING OF MULTIPLE SCLEROSIS SYMPTOMS) (seriousness criterion medically significant). On 13-Sep-2020, the patient experienced ALOPECIA AREATA (ALOPECIA AREATA). In September 2020, the patient experienced CD4 LYMPHOCYTES INCREASED (CD4 LYMPHOCYTES INCREASED) and T-LYMPHOCYTE COUNT INCREASED (T LYMPHOCYTES INCREASED). On 26-Oct-2020, the patient experienced ERYTHEMA (REDNESS ON NECK) and BURNING SENSATION (BURNING NECK). In November 2020, the patient experienced ALOPECIA UNIVERSALIS (ALOPECIA UNIVERSALIS). In February 2021, the patient experienced NEURODERMATITIS (NEURODERMATITIS). In March 2021, the patient experienced DRUG INEFFECTIVE (FEELING OF OCREVUS INEFFECTIVE). On 09-Apr-2022, the patient experienced COVID-19 (SARS-COV-2 INFECTION) (seriousness criterion hospitalization). On an unknown date, the patient experienced NAIL BED INFLAMMATION (WORSENING OF NAILBED INFLAMMATION), PARAESTHESIA (PARESTHESIA IN LEGS), the first episode of FATIGUE (TIREDNESS), HYPOAESTHESIA (NUMBNESS IN LEGS), CHILLS (CHILLS), the second episode of FATIGUE (TIREDNESS), GASTROINTESTINAL INFECTION (GASTROINTESTINAL INFECTION), STOMATITIS (INFLAMMATION OF ORAL MUCOSA), SENSORY DISTURBANCE (WORSENING OF SENSITIVITY DISORDERS ON THE LEFT LOWER LEG (UNK DIAGNOSIS)), INFLUENZA (FLU LIKE INFECTION), INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (THE SECOND INFUSION WAS GIVEN LATER THAN PLANNED BECAUSE OF CAPACITY PROBLEMS OF THE CLINIC), SARS-COV-2 ANTIBODY TEST NEGATIVE (LACK OF ANTIBODY FORMATION AFTER VACCINATION WITH COMIRNATY), INFUSION RELATED REACTION (INFUSION RELATED REACTIONS), PAIN OF SKIN (PAIN OF SKIN), NAUSEA (NAUSEA), HEADACHE (HEADACHE), ASTHENIA (WEAKNESS), LISTLESS (LISTLESSNESS), BLOOD IMMUNOGLOBULIN G DECREASED (IGG VALUE DECREASED), GAIT DISTURBANCE (UNSTEADY GAIT), TONGUE EXFOLIATION (PEELING TONGUE), MEDICATION ERROR (MEDICATION ERROR), MUSCLE SPASMS (MUSCLE CRAMP IN THE LEFT LEG), BALANCE DISORDER (WORSENING OF BALANCE DISORDER), MALAISE (FEELS ILL), DRUG INTOLERANCE (POOR TOLERABILITY AFTER COREVUS INFUSION), BEDRIDDEN (BEDRIDDEN AFTER OCREVUS INFUSION), ABDOMINAL PAIN UPPER (STOMACH CRAMPS), OROPHARYNGEAL PAIN (RECURRENT SORE THROAT), RASH ERYTHEMATOUS (RED RASH ON HER UPPER CHEST), POLYNEUROPATHY (POLYNEUROPATHY LEGS), MUSCULAR WEAKNESS (WORSENING OF WEAK FOOT DORSIFLEXION (UNK DIAGNOSIS)), RASH ERYTHEMATOUS (RED RASH) and ORAL DISORDER (ORAL MUCOSA DETACHMENT (UNK DIAGNOSIS)). On 19-Oct-2018, MUSCULAR WEAKNESS (WORSENING OF WEAK FOOT DORSIFLEXION (UNK DIAGNOSIS)) had resolved. In October 2020, ERYTHEMA (REDNESS ON NECK), GAIT DISTURBANCE (UNSTEADY GAIT) and BURNING SENSATION (BURNING NECK) had resolved. At the time of the report, NAIL BED INFLAMMATION (WORSENING OF NAILBED INFLAMMATION), PARAESTHESIA (PARESTHESIA IN LEGS), HYPOAESTHESIA (NUMBNESS IN LEGS), COVID-19 (SARS-COV-2 INFECTION), CHILLS (CHILLS), the last episode of FATIGUE (TIREDNESS), GASTROINTESTINAL INFECTION (GASTROINTESTINAL INFECTION), STOMATITIS (INFLAMMATION OF ORAL MUCOSA), SENSORY DISTURBANCE (WORSENING OF SENSITIVITY DISORDERS ON THE LEFT LOWER LEG (UNK DIAGNOSIS)), INFLUENZA (FLU LIKE INFECTION), INFUSION RELATED REACTION (INFUSION RELATED REACTIONS), PAIN OF SKIN (PAIN OF SKIN), NAUSEA (NAUSEA), HEADACHE

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		(HEADACHE), ASTHENIA (WEAKNESS), LISTLESS (LISTLESSNESS), MULTIPLE SCLEROSIS (WORSENING OF MULTIPLE SCLEROSIS SYMPTOMS), TONGUE EXFOLIATION (PEELING TONGUE), MUSCLE SPASMS (MUSCLE CRAMP IN THE LEFT LEG), BALANCE DISORDER (WORSENING OF BALANCE DISORDER), MALAISE (FEELS ILL), ABDOMINAL PAIN UPPER (STOMACH CRAMPS), OROPHARYNGEAL PAIN (RECURRENT SORE THROAT), POLYNEUROPATHY (POLYNEUROPATHY LEGS), RASH ERYTHEMATOUS (RED RASH) and ORAL DISORDER (ORAL MUCOSA DETACHMENT (UNK DIAGNOSIS)) had resolved, PRODUCT PREPARATIO
4.1(b)	4.1(b) 4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of HERPES OPHTHALMIC (Vaccines triggered the herpes because when he was vaccinated for the first time his eye bothered him a little/ Herpes in left eye) in a male patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Acid reflux (oesophageal). On 02-Mar-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 30-Aug-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. In May 2021, the patient experienced DEPRESSED MOOD (Felt sad / Felt depresssed). In February 2022, the patient experienced HERPES OPHTHALMIC (Vaccines triggered the herpes because when he was vaccinated for the first time his eye bothered him a little/ Herpes in left eye) (seriousness criterion medically significant). On 12-Apr-2022, the patient experienced GASTROOESOPHAGEAL REFLUX DISEASE (Patient indicates that his reflux increased) and THROAT IRRITATION (It was burning his throat). On an unknown date, the patient experienced VISION BLURRED (Blurred vision), OCULAR DISCOMFORT (He mentions that he thinks this triggered it after he had received the first and second vaccine for Covid-19, since he had eye discomfort and blurred vision , he was vaccinated for the first time his eye bothered him a little), ABDOMINAL DISCOMFORT (And that this was what "ended up affecting his stomach) and OFF LABEL USE (Patient consume Nexium 20 mg one dose in the morning and two doses as night (off-lable-use)). The patient was treated with ZINC for Herpes simplex, at an unspecified dose and frequency and VITAMIN C [ASCORBIC ACID] for Herpes simplex, at an unspecified dose and frequency. At the time of the report, HERPES OPHTHALMIC (Vaccines triggered the herpes because when he was vaccinated for the first time his eye bothered him a little/ Herpes in left eye), VISION BLURRED (Blurred vision), OCULAR DISCOMFORT (He mentions that he thinks this triggered it after he had received the first and second vaccine for Covid-19, since he had eye discomfort and blurred vision , he was vaccinated for the first time his eye bothered him a little), GASTROOESOPHAGEAL REFLUX DISEASE (Patient indicates that his reflux increased) and THROAT IRRITATION (It was burning his throat) had resolved and DEPRESSED MOOD (Felt sad / Felt depresssed), ABDOMINAL DISCOMFORT (And that this was what "ended up affecting his stomach) and OFF LABEL USE (Patient consume Nexium 20 mg one dose in the morning and two doses as night (off-lable-use)) outcome was unknown. mRNA-1273 (Spikevax) (Unknown Route) and mRNA-1273 (Spikevax) (Unknown) dosing remained unchanged. Co-suspect product included non-company product ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (NEXIUM [ESOMEPRAZOLE MAGNESIUM TRIHYDRATE]) for Reflux esophagitis. In 2010, the patient started ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (NEXIUM [ESOMEPRAZOLE MAGNESIUM TRIHYDRATE]) (Oral) 20 milligram once a day. The batch number was reported as 77762. The action taken with drug was dose increased.

Case ID	WW Identifier	Narrative (Complete)
		Since 2009 patient had Nexium 20 mg one dose per day. After patient had received the first and second vaccine for Covid-19, patient had eye discomfort and blurred vision, got herpes on one eye. Patient indicates that zinc and vitamin C were prescribed for his herpes and when he consumed them his reflux increased, he mentions that 20 or 25 days ago his reflux increased and it was burning his throat. Patient indicates that he has been taking the drug Nexium 20 mg for about 12 years. The patient is going to continue taking two doses of Nexium 20 mg a day for one more week and then going to return to a dose per day. Patient comments that he also took a medicine for the prostate and that this was what "ended up affecting his stomach." Patient stopped taking the medicine for the prostate but it was too late and it had already affected him, causing the reflux problem. No concomitant medication information was reported. Company comment: This spontaneous case concerns a male patient of an unknown age, with no relevant medical history, who experienced the serious unexpected event of HERPES OPHTHALMIC (among other non-serious events), approximately 6 months after the second dose of mRNA-1273 vaccine. As per narrative of the source document, he believes that the vaccine triggered the herpes, because with the first dose had mild eye symptoms without the need to apply any medication. That is why he is afraid to take the third dose. The benefit-risk relationship of the mRNA-1273 is not affected by this report. This case was linked to 4.1(b) (Patient Link).
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 17-May-2022. The most recent information was received on 30-May-2022 and was forwarded to Moderna on 30-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of VACCINATION FAILURE (This morning 06 May 2022 I performed an antigenic swab which tested positive), INTERCHANGE OF VACCINE PRODUCTS (BOOSTER dose Moderna on 02Dec2021), COVID-19 (This morning 06 May 2022 I performed an antigenic swab which tested positive) and OFF LABEL USE (BOOSTER dose Moderna on 02Dec2021) in a female patient of an unknown age who received mRNA-1273 (Spikevax) (batch no. 214019) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. The patient's past medical history included Metrorrhagia (for 12 years. Treated with Myrena for 8 years, Esmya dodecaptyl.), Uterine fibromatosis (for 12 years. Treated with Myrena for 8 years, Esmya dodecaptyl.), Post surgical hypothyroidism, Pregnancy (1 full term), Miscarriage (2 miscarriages) and Thyroidectomy total in February 2004. Concurrent medical conditions included Hashimoto's thyroiditis in 1994 and Hypertension (treated with 4.1(b)). Concomitant products included ATENOLOL (4.1(b)) for Hypertension, LEVOTHYROXINE SODIUM (EUTIROX) for an unknown indication. On 13-Apr-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) .3 milliliter. On 04-May-2021, received second dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to .3 milliliter. On 02-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Dec-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (BOOSTER dose Moderna on 02Dec2021) (seriousness criterion medically significant) and OFF LABEL USE (BOOSTER dose Moderna on 02Dec2021) (seriousness criterion medically significant). On 06-May-2022, the patient experienced VACCINATION FAILURE (This morning 06 May 2022 I performed an antigenic swab which tested positive) (seriousness criterion medically significant). On an unknown date, the patient experienced COVID-19 (This morning 06 May 2022 I performed an antigenic swab which tested positive) (seriousness

Case ID	WW Identifier	Narrative (Complete)
		criterion medically significant) and URTICARIA (yesterday afternoon, on 07May2022, onset of urticaria began). At the time of the report, VACCINATION FAILURE (This morning 06 May 2022 I performed an antigenic swab which tested positive), INTERCHANGE OF VACCINE PRODUCTS (BOOSTER dose Moderna on 02Dec2021) and OFF LABEL USE (BOOSTER dose Moderna on 02Dec2021) outcome was unknown and COVID-19 (This morning 06 May 2022 I performed an antigenic swab which tested positive) and URTICARIA (yesterday afternoon, on 07May2022, onset of urticaria began) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-May-2022, Body temperature: 37.5 37.5 degree Celsius and 38 38. On 06-May-2022, SARS-CoV-2 test: positive (Positive) Positive. On 17-May-2022, SARS-CoV-2 test: negative (Negative) Negative. No treatment information was provided. Company Comment: This regulatory case from EMA concerns a female patient of unknown age, with no relevant medical history reported, who experienced an unexpected, medically significant AESI COVID-19 in association with a 3rd dose of mRNA-1273 vaccine. The events of vaccination failure, interchange of vaccine products, and off label use were reported as medically significant by the regulatory authority. A 2-dose primary series of Pfizer's COVID-19 vaccine was given at an interval of 3 weeks, and the last dose from that series was given almost 7 months before her vaccination with a dose of mRNA-1273 vaccine. Approximately 5 months post-vaccination with mRNA-1273 vaccine, patient's body temperature increased from 37.5 degrees Celsius to 38 degrees Celsius, and patient tested positive with the COVID-19 antigen swab. Repeat swab showed a negative result 11 days later. Event COVID-19 has resolved. Vaccination failure cannot be established in this case as interchange of vaccine products occurred. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 20-May-2022: Follow-up received: Contains No New Information On 30-May-2022: Significant follow up received- Lab test, Event out come updated for Covid-19, urticaria updated
4.1(b)	4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 18-May-2022. The most recent information was received on 16-Jun-2022 and was forwarded to Moderna on 16-Jun-2022. This regulatory authority case was reported by an attorney and describes the occurrence of ISCHAEMIA (LACUNAR THALAMIC ISCHAEMIA), CEREBROVASCULAR ACCIDENT (STROKE), THALAMIC INFARCTION (LEFT THALAMIC INFARCTION), PARALYSIS (A FEW DAYS LATER THE RIGHT SIDE OF THE BODY SHOWED SIGNS OF PARALYSIS) and EMBOLISM (SMALL EMBOLISMS CANNOT BE RULED OUT WITH CERTAINTY) in a 40-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3002542) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for an unknown indication. Concurrent medical conditions included Hernia, Chronic gastritis and Coronary artery disease since 03-Sep-2021. Concomitant products included ROSUVASTATIN, AMFETAMINE SULFATE, PHENOBARBITAL, PHENYTOIN SODIUM (EPICRISINE), ACETYLSALICYLIC ACID and ESOMEPRAZOLE for an unknown indication.

Case ID	WW Identifier	Narrative (Complete)
		On 15-Mar-2021, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (Intramuscular) 1 dosage form. On 31-May-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 21-Mar-2021, the patient experienced OFF LABEL USE (SECOND DOSE WITH MODERNAL VACCINE (OFF-LABEL)). On 31-May-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (SECOND DOSE WITH MODERNA VACCINE (INTERCHANGE OF VACCINE)). On 03-Sep-2021, the patient experienced ISCHAEMIA (LACUNAR THALAMIC ISCHAEMIA) (seriousness criteria hospitalization and medically significant). On an unknown date, the patient experienced DYSPNOEA (DYSPNOEA), FEELING ABNORMAL (DOES NOT FEEL SUFFICIENTLY RESILIENT BOTH MENTALLY AND PHYSICALLY), HYPERSENSITIVITY (SENSITIVITY DISORDER OF THE LEFT LEG OF UNKNOWN ORIGIN), ASTHENIA (LESS ENERGY), SELF ESTEEM DECREASED (SELF-ESTEEM HAS REACHED A LOW POINT), HOT FLUSH (HOT FLASHES OCCURRED THE SAME NIGHT), HYPOAESTHESIA (LACK OF STRENGTH IN THE RIGHT ARM), INFERIORITY COMPLEX (THEY SEE THEMSELVES AS INFERIOR, NO LONGER PERFORMING OR EVEN ADORABLE), OTOLITHIASIS (DISPLACED OTOLITHS), MOVEMENT DISORDER (THE RIGHT INDEX FINGER WAS OUT OF CONTROL), ANXIETY DISORDER (ANXIETY DISORDER), DISTURBANCE IN ATTENTION (LIMITATIONS IN CONCENTRATION), SINUS TACHYCARDIA (UNDER EXERTION SINUS TACHYCARDIA SINUS RHYTHM WITH FREQUENT EPISODES OF SINUS TACHYCARDIA), DEPRESSION (DEPRESSION), FEELINGS OF WORTHLESSNESS (COMPARED TO OTHERS FEEL WORTHLESS), DISCOURAGEMENT (FEELINGS OF DISCOURAGEMENT), GLIAL SCAR (LEFT FRONT SUBCORTICAL FEW MILLIMETERS GLIOTIC SCAR WITH A MAXIMUM SIZE OF 0.3 CM DEFINED IN THE FLAIR SEQUENC), CHILLS (CHILLS APPEARED ON THE SAME NIGHT), HEADACHE (SEVERE CEPHALGIA), FALL (FEEL AS THOUGH YOU ARE FAILING), VERTIGO POSITIONAL (BENIGN PAROXYSMAL VERTIGO), INTERVERTEBRAL DISC PROTRUSION (FLAT BROAD BASE DISC PROTRUSION IN SEGMENT HWK-6/7 WITH NARROWING OF THE VENTRAL SUBARACHNOID SPACE), DYSPNOEA EXERTIONAL (EXERTIONAL DYSPNEA), MOTOR DYSFUNCTION (MOTOR IMPAIRMENTS), LACUNAR STROKE (SMALL, DEFINED LIKELY POST-ISCHEMIC LACUNAR DEFECT ON THE LEFT SIDE OF THALAMUS(A WELL-DEFINED 0.6 X 0.3 CM), CEREBROVASCULAR ACCIDENT (STROKE) (seriousness criterion medically significant), PALPITATIONS (INTERMITTENT PALPITATIONS), BURNING SENSATION (BURNING SENSATION ON THE CHEST BURNING IN THE CHEST), HYPOAESTHESIA (NUMBNESS IN THE AREA OF THE RIGHT HALF OF THE BODY), CORONARY ARTERY DISEASE (NON-INVASIVE NO INDICATION OF CORONARY HEART DISEASE), THALAMIC INFARCTION (LEFT THALAMIC INFARCTION) (seriousness criteria hospitalization and medically significant), PARALYSIS (A FEW DAYS LATER THE RIGHT SIDE OF THE BODY SHOWED SIGNS OF PARALYSIS) (seriousness criterion medically significant), EMBOLISM (SMALL EMBOLISMS CANNOT BE RULED OUT WITH CERTAINTY) (seriousness criteria hospitalization and medically significant), SLEEP DISORDER (A FEW DAYS LATER SLEEP DISTURBANCES OCCURRED FOR ABOUT 2.5 WEEKS), SOMNOLENCE (GROGGINESS), FATIGUE (FASTER EXHAUSTED), DEPRESSED MOOD (FEELINGS OF SADNESS), FATIGUE (FATIGUE), DIZZINESS (DIZZINESS OCCURRED THE SAME NIGHT ATTACKS OF DIZZINESS DIZZINESS), VERTEBRAL END PLATE IMPRESSION (MILD ABNORMAL STRAIGHTENING OTHERWISE A REGULAR NUMBER, FORM AND POSITION OF VERTEBRAE), FEELING GUILTY (FEEL GUILTY), PERIPHERAL COLDNESS (COLD FEELING FELT ON THE LEFT FEET), SENSORY DISTURBANCE (SENSORY DISTURBANCE OF THE LEFT ABDOMEN OF UNCLEAR GENESIS), MENTAL DISORDER (THERE WAS AN IMMENSE FEELING OF OVERLOAD BOTH PHYSICALLY AND PSYCHOLOGICALLY) and HEADACHE (HEADACHE OCCURRED IN THE SAME NIGHT). At the time of the report, DYSPNOEA (DYSPNOEA), FEELING ABNORMAL (DOES NOT FEEL SUFFICIENTLY RESILIENT BOTH MENTALLY AND PHYSICALLY), HYPERSENSITIVITY (SENSITIVITY DISORDER OF THE LEFT LEG OF UNKNOWN ORIGIN), ASTHENIA (LESS ENERGY), SELF ESTEEM DECREASED (SELF-ESTEEM HAS REACHED A LOW POINT), HOT FLUSH (HOT

Case ID	WW Identifier	Narrative (Complete)
		FLASHES OCCURRED THE SAME NIGHT), ISCHAEMIA (LACUNAR THALAMIC ISCHAEMIA), HYPOAESTHESIA (LACK OF STRENGTH IN THE RIGHT ARM), INFERIORITY COMPLEX (THEY SEE THEMSELVES AS INFERIOR, NO LONGER PERFORMING OR EVEN ADORABLE), OTOLITHIASIS (DISPLACED OTOLITHS), MOVEMENT DISORDER (THE RIGHT INDEX FINGER WAS OUT OF CONTROL), ANXIETY DISORDER (ANXIETY DISORDER), DISTURBANCE IN ATTENTION (LIMITATIONS IN CONCENTRATION), SINUS TACHYCARDIA (UNDER EXERTION SINUS TACHYCARDIA SINUS RHYTHM WITH FREQUENT EPISODES OF SINUS TACHYCARDIA), DEPRESSION (DEPRESSION), FEELINGS OF WORTHLESSNESS (COMPARED TO OTHERS FEEL WORTHLESS), DISCOURAGEMENT (FEELINGS OF DISCOURAGEMENT), GLIAL SCAR (LEFT FRONT SUBCORTICAL FEW MILLIMETERS GLIOTIC SCAR WITH A MAXIMUM SIZE OF 0.3 CM DEFINED IN THE FLAIR SEQUENC), CHILLS (CHILLS APPEARED ON THE SAME NIGHT), HEADACHE (SEVERE CEPHALGIA), FALL (FEEL AS THOUGH YOU ARE FAILING), VERTIGO POSITIONAL (BENIGN PAROXYSMAL VERTIGO), INTERVERTEBRAL DISC PROTRUSION (FLAT BROAD BASE DISC PROTRUSION IN SEGMENT HWK-6/7 WITH NARROWING OF THE VENTRAL SUBARACHNOID SPACE), DYSPNOEA EXERTIONAL (EXERTIONAL DYSPNEA), MOTOR DYSFUNCTION (MOTOR IMPAIRMENTS), LACUNAR STROKE (SMALL, DEFINED LIKELY POST-ISCHEMIC LACUNAR DEFECT ON THE LEFT SIDE OF THALAMUS(A WELL-DEFINED 0.6 X 0.3 CM), CEREBROVASCULAR ACCIDENT (STROKE), PALPITATIONS (INTERMITTENT PALPITATIONS), BURNING SENSATION (BURNING SENSATION ON THE CHEST BURNING IN THE CHEST), OFF LABEL USE (SECOND DOSE WITH MODERNAL VACCINE (OFF-LABEL)), HYPOAESTHESIA (NUMBNESS IN THE AREA OF THE RIGHT HALF OF THE BODY), CORONARY ARTERY DISEASE (NON-INVASIVE NO INDICATION OF CORONARY HEART DISEASE), THALAMIC INFARCTION (LEFT THALAMIC INFARCTION), PARALYSIS (A FEW DAYS LATER THE RIGHT SIDE OF THE BODY SHOWED SIGNS OF PARALYSIS), EMBOLISM (SMALL EMBOLISMS CANNOT BE RULED OUT WITH CERTAINTY), INTERCHANGE OF VACCINE PRODUCTS (SECOND DOSE WITH MODERNA VACCINE (INTERCHANGE OF VACCINE)), SLEEP DISORDER (A FEW DAYS LATER SLEEP DISTURBANCES OCCURRED FOR ABOUT 2.5 WEEKS), SOMNOLENCE (GROGGINESS), FATIGUE (FASTER EXHAUSTED), DEPRESSED MOOD (FEELINGS OF SADNESS), FATIGUE (FATIGUE), DIZZINESS (DIZZINESS OCCURRED THE SAME NIGHT ATTACKS OF DIZZINESS DIZZINESS), VERTEBRAL END PLATE IMPRESSION (MILD ABNORMAL STRAIGHTENING OTHERWISE A REGULAR NUMBER, FORM AND POSITION OF VERTEBRAE), FEELING GUILTY (FEEL GUILTY), PERIPHERAL COLDNESS (COLD FEELING FELT ON THE LEFT FEET), SENSORY DISTURBANCE (SENSORY DISTURBANCE OF THE LEFT ABDOMEN OF UNCLEAR GENESIS), MENTAL DISORDER (THERE WAS AN IMMENSE FEELING OF OVERLOAD BOTH PHYSICALLY AND PSYCHOLOGICALLY) and HEADACHE (HEADACHE OCCURRED IN THE SAME NIGHT) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 29-Aug-2021, Blood potassium: 3.45 3.45. On 29-Aug-2021, Glomerular filtration rate: 108 108. On 29-Aug-2021, Haematocrit: 0.41 0.41. On 03-Sep-2021, Blood albumin: 47.8 g/dl 47.8 g/dL. On 03-Sep-2021, Blood calcium: 2.33 mmol/l 2.33 mmol/L. On 03-Sep-2021, Blood creatinine: 0.73 mg/dl 0.73 mg/dL. On 03-Sep-2021, Blood glucose: 13
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 19-May-2022 and was forwarded to Moderna on 19-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEAFNESS (DEAFNESS), DEPRESSION (DEPRESSION), PARAESTHESIA (TINGLING/ ANT RACE), DIARRHOEA (CHRONIC DIARRHEA), DEPRESSED LEVEL OF CONSCIOUSNESS (REDUCED CONSCIOUSNESS), CARPAL TUNNEL SYNDROME

Case ID	WW Identifier	Narrative (Complete)
		(CARPAL TUNNEL SYNDROME:), SYNCOPE (SYNCOPE), CHEST DISCOMFORT (TIGHTNESS IN THE CHEST), CEREBROVASCULAR ACCIDENT (STROKE), MENIERE'S DISEASE (MENIER'S DISEASE) and TASTE DISORDER (TASTE DISORDERS) in a male patient of an unknown age who received mRNA-1273 (Spikevax) (batch nos. 092F21A and 3002542) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for an unknown indication. The patient's past medical history included Asthma. Concomitant products included TILIDINE, AMOXICILLIN TRIHYDRATE (AMOXICILINA GI), TAMSULOSIN, ROSUVASTATIN, EDOXABAN, CANDESARTAN CILEXETIL, TRAMADOL HYDROCHLORIDE, FLUOXETINE HYDROCHLORIDE, OLANZAPINE (FOSTERA), DULOXETINE HYDROCHLORIDE (DULOXETINA TEVA), AMLODIPINE, SALBUTAMOL SULFATE ([redacted] and ATENOLOL, CHLORTALIDONE (ATENOLOL/CHLORTALIDONE EG) for an unknown indication. On 01-Mar-2021 at 8:00 AM, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (Intramuscular) dosage was changed to 1 dosage form. On 31-May-2021 at 8:00 AM, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Dec-2021 at 7:30 AM, received third dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (unknown route) at an unspecified dose. On 03-Mar-2021, the patient experienced CEREBROVASCULAR ACCIDENT (STROKE) (seriousness criteria hospitalization and medically significant). On 13-Oct-2021, the patient experienced SYNCOPE (SYNCOPE) (seriousness criterion hospitalization) and MENIERE'S DISEASE (MENIER'S DISEASE) (seriousness criterion hospitalization). In October 2021, the patient experienced CARPAL TUNNEL SYNDROME (CARPAL TUNNEL SYNDROME:) (seriousness criterion hospitalization). On an unknown date, the patient experienced DEAFNESS (DEAFNESS) (seriousness criterion hospitalization), DEPRESSION (DEPRESSION) (seriousness criterion hospitalization), INTERCHANGE OF VACCINE PRODUCTS (FIRST DOSE COVID-19 VACCINE ASTRAZENECA, 2ND DOSE OF VACCINE FROM OTHER MAH (INTERCHANGE OF VACCINES)), PARAESTHESIA (TINGLING/ ANT RACE) (seriousness criterion hospitalization), DIARRHOEA (CHRONIC DIARRHEA) (seriousness criterion hospitalization), DEPRESSED LEVEL OF CONSCIOUSNESS (REDUCED CONSCIOUSNESS) (seriousness criterion hospitalization), CHEST DISCOMFORT (TIGHTNESS IN THE CHEST) (seriousness criterion hospitalization), OFF LABEL USE (FIRST DOSE COVID-19 VACCINE ASTRAZENECA, 2ND DOSE OF VACCINE FROM OTHER MAH) and TASTE DISORDER (TASTE DISORDERS) (seriousness criterion hospitalization). At the time of the report, DEAFNESS (DEAFNESS), DEPRESSION (DEPRESSION), INTERCHANGE OF VACCINE PRODUCTS (FIRST DOSE COVID-19 VACCINE ASTRAZENECA, 2ND DOSE OF VACCINE FROM OTHER MAH (INTERCHANGE OF VACCINES)), PARAESTHESIA (TINGLING/ ANT RACE), DIARRHOEA (CHRONIC DIARRHEA), DEPRESSED LEVEL OF CONSCIOUSNESS (REDUCED CONSCIOUSNESS), CARPAL TUNNEL SYNDROME (CARPAL TUNNEL SYNDROME:), SYNCOPE (SYNCOPE), CHEST DISCOMFORT (TIGHTNESS IN THE CHEST), CEREBROVASCULAR ACCIDENT (STROKE), MENIERE'S DISEASE (MENIER'S DISEASE), OFF LABEL USE (FIRST DOSE COVID-19 VACCINE ASTRAZENECA, 2ND DOSE OF VACCINE FROM OTHER MAH) and TASTE DISORDER (TASTE DISORDERS) outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown.

Case ID	WW Identifier	Narrative (Complete)
		It was reported that relevant history of asthma could be a possible risk factor for the event of chest discomfort. No treatment information was provided. Company Comment: This regulatory authority case concerns a male patient of unknown age with no relevant medical history reported who experienced the unexpected, serious (hospitalization, medically significant) adverse event of special interest of Stroke and unexpected, serious (hospitalization) events of Deafness, Depression, Paraesthesia, Diarrhoea, Depressed level of consciousness, Carpal tunnel syndrome, Syncope, Chest discomfort, Menieres disease and Taste disorder. Interchange of vaccine products and Off label use were reported as additional events as patient received Vaxzevria as first dose of COVID-19 vaccination. The event stroke occurred two months and nine months prior to second and third dose of mRNA-1273 vaccination respectively. The events Carpal tunnel syndrome, Syncope and Meniere's disease occurred approximately five months after the second dose of mRNA-1273 vaccination. The events Deafness, Depression, Paraesthesia, Diarrhoea, Depressed level of consciousness, Chest discomfort and Taste disorder occurred on unknown interval in reference to mRNA-1273 vaccination. The clinical course, diagnostic evaluation and treatment details were not reported in the case. Concomitant treatment with Rosuvastatin, Edoxaban, Candesartan, Amlodipine and Atenolol may signify an underlying cardiovascular condition which could be a risk factor for the event Stroke. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per regulatory authority's report.
4.1(b)	4.1(b) 4.1(b)	This literature-non-study case was reported in a literature article and describes the occurrence of ANAPHYLACTIC REACTION (Anaphylaxis) in a 31-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Van Meerbeke SW, Fajt ML, Marini RV, Domsic RT, Petrov AA. Antibody response to graded dosing of COVID-19 mRNA vaccines after allergic reaction to first dose. Ann Allergy Asthma Immunol. 2022 No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to .5 milliliter. On an unknown date, the patient experienced ANAPHYLACTIC REACTION (Anaphylaxis) (seriousness criterion medically significant) and OFF LABEL USE (patients received 0.05 mL, 0.1mL, 0.15 mL and 0.2 mL intramuscularly every 15 minutes). At the time of the report, ANAPHYLACTIC REACTION (Anaphylaxis) and OFF LABEL USE (patients received 0.05 mL, 0.1mL, 0.15 mL and 0.2 mL intramuscularly every 15 minutes) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 antibody test: >20 >20; Reactive; SARS-CoV-2 AB (IGG), Spike, Semi-quantitative (after 183 days of second vaccination). On an unknown date, Skin test: negative (Negative) Negative (for polysorbate 20 and 80).

Case ID	WW Identifier	Narrative (Complete)
		For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter considered ANAPHYLACTIC REACTION (Anaphylaxis) and OFF LABEL USE (patients received 0.05 mL, 0.1mL, 0.15 mL and 0.2 mL intramuscularly every 15 minutes) to be related. No concomitant and treatment medication provided. Patient consented to undergo a second dose graded vaccine administration. Patient was observed for 60 minutes after the last graded dose. Patient tolerated the graded dosing without evidence of allergic reaction. Patient met diagnostic criteria for anaphylaxis based on the Brighton Collaboration case definition and NIAID Criteria for Anaphylaxis. Time in between 1st and 2nd Vaccination was 33 days. Company Comment: This literature-non-study case concerns a 31-year-old female patient with no medical history reported, who experienced the expected serious (medically significant) event of Anaphylactic reaction, that occurred on an unknown date after receiving the first dose of mRNA-1273 vaccine. Additionally, Off label use (patient received 0.05 mL, 0.1mL, 0.15 mL and 0.2 mL intramuscularly every 15 minutes) was also noted for the second dose administration of mRNA-1273 vaccine. SARS-CoV-2 antibody test, SARS-CoV-2 AB (IgG), Spike Semi-quantitative were reactive after 183 days of second vaccination. Patient presented with negative COVID-19 vaccine component skin testing to polyethylene glycol and polysorbate 20 and 80. Interval between the first and second dose of mRNA-1273 vaccines was 33 days. Study results showed that graded dosing administration with COVID-19 mRNA vaccines is safe for people who experienced anaphylactic reaction to previous dose and provides reactive SARS-COV2 spike protein antibody response at least 6 months after completion of the initial COVID-19 vaccination series. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine is not affected by this report. This case was linked to 4.1(b) [redacted] (E2B Linked Report). Most recent FOLLOW-UP information incorporated above includes: On 25-May-2022: Significant Follow up received by safety on 26-May-2022 has Email with full text article received contains significant information: Author information, lab test, product details, event details updated.
4.1(b) [redacted]	4.1(b) [redacted] 4.1(b)	This literature-non-study case was reported in a literature article and describes the occurrence of ANAPHYLACTIC REACTION (met diagnostic criteria for anaphylaxis) in a 57-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Meerbeke SWV, Fajt ML, Marini RV, Domsic RT, Petrov AA. Antibody response to graded dosing of COVID-19 mRNA vaccines after allergic reaction to first dose. Ann Allergy Asthma Immunol. 2022 No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form.

Case ID	WW Identifier	Narrative (Complete)
		On an unknown date, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced ANAPHYLACTIC REACTION (met diagnostic criteria for anaphylaxis) (seriousness criterion medically significant), OFF LABEL USE (patients received 0.05 mL, 0.1mL, 0.15 mL and 0.2 mL intramuscularly every 15 minutes) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Time in Between 1st and 2nd Vaccination, days is 50 days). At the time of the report, ANAPHYLACTIC REACTION (met diagnostic criteria for anaphylaxis), OFF LABEL USE (patients received 0.05 mL, 0.1mL, 0.15 mL and 0.2 mL intramuscularly every 15 minutes) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Time in Between 1st and 2nd Vaccination, days is 50 days) outcome was unknown. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 antibody test: 18.12 18.12; Reactive; SARSCOV2 AB (IGG), SPIKE, SEMIQUANTITATIVE (after 218 days of second vaccination). On an unknown date, Skin test: negative (Negative) Patient had negative COVID-19 vaccine component skin testing to polyethylene glycol and polysorbate 20 and 80. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered ANAPHYLACTIC REACTION (met diagnostic criteria for anaphylaxis), OFF LABEL USE (patients received 0.05 mL, 0.1mL, 0.15 mL and 0.2 mL intramuscularly every 15 minutes) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Time in Between 1st and 2nd Vaccination, days is 50 days) to be related. Symptoms after first vaccination included diffuse hives, throat swelling (within 60 minutes) + Patient consented to undergo a second dose graded vaccine administration, which occurred 30 to 52 days after initial vaccination. Patient received 0.05 mL, 0.1mL, 0.15 mL and 0.2 mL intramuscularly every 15 minutes. Patient was observed for 60 minutes after the last dose. Patient tolerated the graded dosing without evidence of allergic reaction. No concomitant and treatment medications were reported Patient met diagnostic criteria for anaphylaxis based on the Brighton Collaboration case definition. Company Comment: This is a Literature non-study case, concerning a 57-year-old female patient, with no medical history reported, who experienced the expected and serious (due to medically significant) event of Anaphylactic reaction, on an unknown date after the second dose of mRNA-1273 vaccine. Inappropriate schedule of vaccine administered is also reported, as first and second dose were administered with an interval of 50 days. Off label use was also reported, as patient received 0.05 mL, 0.1mL, 0.15 mL and 0.2 mL intramuscularly every 15 minutes. SARS-CoV-2 antibody test: 18.12 18.12; Reactive; SARSCOV2 AB (IGG), SPIKE, SEMIQUANTITATIVE (after 218 days of second vaccination). Patient had negative COVID-19 vaccine component skin testing to polyethylene glycol and polysorbate 20 and 80. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes:

Case ID	WW Identifier	Narrative (Complete)
		On 25-May-2022: Live significant follow up received by safety on 26-May-2022 has email with full text article and contains significant information. Reporter details, patient demographics, events, onset latency to reaction and laboratory test added.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 26-May-2022 and was forwarded to Moderna on 26-May-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of OFF LABEL USE (Off label use), COVID-19 (COVID Infection), DRUG INEFFECTIVE (positive Corona-case despite vaccination (3 times vaccinated with Comirnaty, positive on 25-Apr-2022)) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) in a 27-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214007 and 3002614) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. The patient's past medical history included Addison's disease and SARS-CoV-2 test positive. Concomitant products included DIENOGEST, ESTRADIOL VALERATE (QLAIRA), HYDROCORTISON [HYDROCORTISONE], FLUDROCORTISONE (ASTONIN-H) and 4.1(b) for an unknown indication. On 06-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 14-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 20-Dec-2021, the patient received third dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 20-Dec-2021, the patient experienced OFF LABEL USE (Off label use) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criterion medically significant). On 22-Mar-2022, the patient experienced COVID-19 (COVID Infection) (seriousness criterion medically significant) and DRUG INEFFECTIVE (positive Corona-case despite vaccination (3 times vaccinated with Comirnaty, positive on 25-Apr-2022)) (seriousness criterion medically significant). At the time of the report, OFF LABEL USE (Off label use), DRUG INEFFECTIVE (positive Corona-case despite vaccination (3 times vaccinated with Comirnaty, positive on 25-Apr-2022)) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) outcome was unknown and COVID-19 (COVID Infection) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Mar-2022, SARS-CoV-2 test: 19.25 (Positive) Test Result:19.25. On 25-Apr-2022, SARS-CoV-2 test positive: positive (Positive) Positive(found out on 26-Apr-2022). For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. It was reported as there was limited information in the case provided, the causal association between the reported events: drug ineffective, COVID-19 and the suspect drug BNT162B2 cannot be excluded. The case would be reassessed once new information was available. The impact of this report on the benefit/risk profile of the Pfizer drug was evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, would be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. No treatment information was provided. Company comment: This is a regulatory case concerning a 27-year-old male patient with no relevant medical history reported, who experienced the unexpected serious (medically significant) adverse event of special interest COVID-19 supported by

Case ID	WW Identifier	Narrative (Complete)
		positive SARS-CoV-2 tests, which occurred approximately 8 months after receiving a 2-dose primary series of mRNA-1273 vaccine at an interval of 38 days which did not fall within the recommended vaccine dosing schedule (Inappropriate schedule of vaccine administered). Patient had given Comirnaty COVID-19 vaccine as booster dose approximately 5 months after the primary mRNA-1273 vaccination. Additionally, Off label use, Drug ineffective, and Interchange of vaccine products was also reported. No further details about the clinical course and treatments were provided. Patient reported that the event COVID-19 had resolved. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority reporting.
4.1(b)	4.1(b) 4.1(b)	This case was received via 4.1(b) (Reference number: 4.1(b) on 30-May-2022 and was forwarded to Moderna on 30-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of ALOPECIA (Alopecia), IMMUNISATION REACTION (Immunisation reaction), OFF LABEL USE (Off label use) and THROMBOCYTOPENIA (Thrombocytopenia) in a 61-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. Co-suspect products included non-company products VEDOLIZUMAB (ENTYVIO) powder for solution for infusion for Crohn's disease, VEDOLIZUMAB (ENTYVIO) powder for solution for infusion for Crohn's disease and VEDOLIZUMAB (ENTYVIO) powder for solution for infusion for Crohn's disease. Concurrent medical conditions included Crohn's disease. On an unknown date, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form, VEDOLIZUMAB (ENTYVIO) (Intravenous) 300 milligram, VEDOLIZUMAB (ENTYVIO) (Intravenous) 300 milligram and VEDOLIZUMAB (ENTYVIO) (Intravenous) 300 milligram. On an unknown date, the patient experienced ALOPECIA (Alopecia) (seriousness criterion medically significant), IMMUNISATION REACTION (Immunisation reaction) (seriousness criterion medically significant), OFF LABEL USE (Off label use) (seriousness criterion medically significant) and THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criterion medically significant). At the time of the report, ALOPECIA (Alopecia), IMMUNISATION REACTION (Immunisation reaction), OFF LABEL USE (Off label use) and THROMBOCYTOPENIA (Thrombocytopenia) had resolved. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. No concomitant and treatment medication was reported by patient. Company comment This regulatory authority case concerning a 61-year-old female patient with concomitant medication Vedolizumab indicated for Crohn's disease, who experienced the serious, medically significant, unexpected events of Alopecia, Immunisation reaction and Thrombocytopenia on an unknown date. The patient received a dose of mRNA-1273 on an unknown date, thus latency between vaccination and the event cannot be assessed. At the time of the last observation, the events had resolved. Off label use was considered an additional event. No further information regarding lab tests and treatment of the events was provided. The underlying Crohn's disease could be a contributory factor for Thrombocytopenia. Vedolizumab, although very rare reported in a case report, could contribute to Thrombocytopenia through Evan's syndrome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	WW Identifier	Narrative (Complete)
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 03-Jun-2022 and was forwarded to Moderna on 03-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of OFF LABEL USE (09-Apr-2021 Vaxzevria and 02-Jul-2021 Comirnaty), COVID-19 (Positive Corona), DRUG INEFFECTIVE (Positive Corona) and INTERCHANGE OF VACCINE PRODUCTS (09-Apr-2021 Vaxzevria and 02-Jul-2021 Comirnaty) in a 61-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for COVID-19 immunisation and TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. The patient's past medical history included Psoriatic arthritis. Concomitant products included CERTOLIZUMAB for Psoriatic arthritis. On 09-Apr-2021, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (unknown route) DOSE 1, SINGLE. On 02-Jul-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 11-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Jul-2021, the patient experienced OFF LABEL USE (09-Apr-2021 Vaxzevria and 02-Jul-2021 Comirnaty) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (09-Apr-2021 Vaxzevria and 02-Jul-2021 Comirnaty) (seriousness criterion medically significant). On 18-May-2022, the patient experienced COVID-19 (Positive Corona) (seriousness criterion medically significant) and DRUG INEFFECTIVE (Positive Corona) (seriousness criterion medically significant). At the time of the report, OFF LABEL USE (09-Apr-2021 Vaxzevria and 02-Jul-2021 Comirnaty), DRUG INEFFECTIVE (Positive Corona) and INTERCHANGE OF VACCINE PRODUCTS (09-Apr-2021 Vaxzevria and 02-Jul-2021 Comirnaty) outcome was unknown and COVID-19 (Positive Corona) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-May-2022, SARS-CoV-2 test: positive (Positive) Positive. No treatment was reported Company Comment: This is a regulatory case concerning a 61-year-old female patient with no relevant medical history, who experienced the unexpected, serious (medically significant) adverse event of special interest of COVID-19, approximately 5 months after receiving a dose of mRNA-1273 vaccine (third COVID-19 vaccine). Drug ineffective was also reported as an additional event. Off label use and Interchange of vaccine products were also reported as the patient received Vaxzevria and Comirnaty as first and second dose of COVID-19 vaccine, with the Comirnaty administered approximately 5 months prior to the mRNA-1273. Clinical course and treatment details were not provided in the case. The event had not resolved at the time of the report. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event retained as serious as per Regulatory Authority.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 03-Jun-2022 and was forwarded to Moderna on 03-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of INTERCHANGE OF VACCINE PRODUCTS (1st and 2nd: Moderna, 3rd: Comirnaty), OFF LABEL USE (1st and 2nd: Moderna, 3rd: Comirnaty),

Case ID	WW Identifier	Narrative (Complete)
		SUSPECTED COVID-19 (COVID-19 after 3 time vaccination) and DRUG INEFFECTIVE (COVID-19 after 3 time vaccination) in a female patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form On an unknown date, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. and third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (1st and 2nd: Moderna, 3rd: Comirnaty) (seriousness criterion medically significant), OFF LABEL USE (1st and 2nd: Moderna, 3rd: Comirnaty) (seriousness criterion medically significant), SUSPECTED COVID-19 (COVID-19 after 3 time vaccination) (seriousness criterion medically significant) and DRUG INEFFECTIVE (COVID-19 after 3 time vaccination) (seriousness criterion medically significant). At the time of the report, INTERCHANGE OF VACCINE PRODUCTS (1st and 2nd: Moderna, 3rd: Comirnaty), OFF LABEL USE (1st and 2nd: Moderna, 3rd: Comirnaty), SUSPECTED COVID-19 (COVID-19 after 3 time vaccination) and DRUG INEFFECTIVE (COVID-19 after 3 time vaccination) outcome was unknown. No concomitant product use was provided by the reporter. No treatment medication was provided. Company Comment: This is a regulatory case of Interchange of vaccine products concerning a female patient of unknown age with no reported medical history, who experienced the unexpected serious (medically significant) AESI of Suspected COVID-19. The event occurred unknown number of days after doses 1 and 2 of mRNA-1273 vaccine (dates of administration and dosing interval not provided) and unknown number of days after a booster dose (dose 3) of non-company product COVID-19 vaccine Comirnaty, administered unknown number of days after dose 2 of mRNA-1273 vaccine. There was no information about the clinical course, diagnostic tests, and treatment medication. Additional events of Drug ineffective and Off-label use were also reported. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 03-Jun-2022: Upon internal review on 07-Jun-2022, non-significant correction was performed. Event Receipt Date for the events were added as 03-Jun-2022.
4.1(b) [redacted]	4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 06-Jun-2022 and was forwarded to Moderna on 06-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of INTERCHANGE OF VACCINE PRODUCTS (1st and 2nd: Moderna, 3rd: Comirnaty), DRUG INEFFECTIVE (COVID-19 after 3 time vaccination), OFF LABEL USE (1st and 2nd: Moderna, 3rd: Comirnaty) and SUSPECTED COVID-19 (COVID-19 after 3 time vaccination) in a female patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization.

Case ID	WW Identifier	Narrative (Complete)
		No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form On an unknown date, received first dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. and third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (1st and 2nd: Moderna, 3rd: Comirnaty) (seriousness criterion medically significant), DRUG INEFFECTIVE (COVID-19 after 3 time vaccination) (seriousness criterion medically significant), OFF LABEL USE (1st and 2nd: Moderna, 3rd: Comirnaty) (seriousness criterion medically significant) and SUSPECTED COVID-19 (COVID-19 after 3 time vaccination) (seriousness criterion medically significant). At the time of the report, INTERCHANGE OF VACCINE PRODUCTS (1st and 2nd: Moderna, 3rd: Comirnaty), DRUG INEFFECTIVE (COVID-19 after 3 time vaccination), OFF LABEL USE (1st and 2nd: Moderna, 3rd: Comirnaty) and SUSPECTED COVID-19 (COVID-19 after 3 time vaccination) outcome was unknown. No concomitant product use was provided. No treatment medication was provided. Additional information on co-suspect drug includes Off label use. Company comment: This regulatory authority case concerns a female patient of unknown age with no reported medical history, who experienced the unexpected serious (medically significant) AESI of Suspected COVID-19 which occurred unknown days after administration of second dose of mRNA-1273 vaccine in COVID 19 vaccination series. Off-label use, Interchange of vaccine products and Drug ineffective have been also reported as serious events by regulatory authority. Patient received 1 dose of mRNA-1273 vaccine and 1 dose of Tozinameran unknown days prior to last dose. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness was assessed as per regulatory authority's report
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 09-Jun-2022 and was forwarded to Moderna on 09-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of INTERCHANGE OF VACCINE PRODUCTS (first vaccination AstraZeneca, second Moderna, third Biontech, forth Astrazeneca), SUSPECTED COVID-19 (2x corona despite three fold vaccination and I was feeling very unwell), OFF LABEL USE (first vaccination AstraZeneca, second Moderna, third Biontech, forth Astrazeneca) and DRUG INEFFECTIVE (2x corona despite three fold vaccination and I was feeling very unwell) in a 54-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for COVID-19 immunization and TOZINAMERAN (COMIRNATY) for COVID-19 immunization. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form, first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (unknown route) 1 dosage form and third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On an unknown date, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (first vaccination AstraZeneca, second Moderna, third Biontech, forth Astrazeneca) (seriousness criterion medically significant), SUSPECTED COVID-19 (2x corona despite three fold vaccination

Case ID	WW Identifier	Narrative (Complete)
		and I was feeling very unwell) (seriousness criterion medically significant), OFF LABEL USE (first vaccination AstraZeneca, second Moderna, third Biontech, forth Astrazeneca) (seriousness criterion medically significant) and DRUG INEFFECTIVE (2x corona despite three fold vaccination and I was feeling very unwell) (seriousness criterion medically significant). At the time of the report, INTERCHANGE OF VACCINE PRODUCTS (first vaccination AstraZeneca, second Moderna, third Biontech, forth Astrazeneca), SUSPECTED COVID-19 (2x corona despite three fold vaccination and I was feeling very unwell), OFF LABEL USE (first vaccination AstraZeneca, second Moderna, third Biontech, forth Astrazeneca) and DRUG INEFFECTIVE (2x corona despite three fold vaccination and I was feeling very unwell) outcome was unknown. No Concomitant medications were reported. No treatment information was provided. Company Comment: This regulatory authority case of Interchange of vaccine products, Off label use and Drug ineffective, concerns a 54-year-old female patient, with previous vaccinations of VAXZEVRIA and COMIRNATY, who experienced the unexpected serious (medically significant) AESI of Suspected COVID-19. The event occurred on an unknown date after receiving the second dose of mRNA-1273 Vaccine (First dose - Vaxzevria). The outcome of the event was reported as unknown. The patient's medical history of previous vaccination of VAXZEVRIA and COMIRNATY, remain as confounders for the occurrence of Drug ineffective. Event seriousness assessed as per Regulatory Authority report. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 10-Jun-2022 and was forwarded to Moderna on 10-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of OFF LABEL USE (4th vaccination), SUSPECTED COVID-19 (2x corona despite three fold vaccination and I was feeling very unwell."), DRUG INEFFECTIVE (2x corona despite three fold vaccination and I was feeling very unwell.) and INTERCHANGE OF VACCINE PRODUCTS (first vaccination, second Biontech, third, forth Moderna) in a 36-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunization. No Medical History information was reported. On an unknown date, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form On an unknown date, received fourth dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form and second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. and first dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced OFF LABEL USE (4th vaccination) (seriousness criterion medically significant), SUSPECTED COVID-19 (2x corona despite three fold vaccination and I was feeling very unwell.") (seriousness criterion medically significant), DRUG INEFFECTIVE (2x corona despite three fold vaccination and I was feeling very unwell.) (seriousness criterion medically significant) and INTERCHANGE OF VACCINE PRODUCTS (first vaccination, second Biontech, third, forth Moderna) (seriousness criterion medically significant). At the time of the report, OFF LABEL USE (4th vaccination), SUSPECTED COVID-19 (2x corona despite three fold vaccination and I was feeling very unwell."), DRUG INEFFECTIVE (2x corona despite three fold vaccination

Case ID	WW Identifier	Narrative (Complete)
		and I was feeling very unwell.) and INTERCHANGE OF VACCINE PRODUCTS (first vaccination, second Biontech, third, forth Moderna) outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Concomitant medications was not provided by the reporter. Treatment information was not provided. Company comment: This is a regulatory authority case concerning a 36-year-old, female patient with no reported medical history and with vaccine history of receiving first and second dose of Covid-19 Comirnaty, who experienced the unexpected serious (medically significant according to regulatory authority) AESI event of Suspected Covid-19. Drug ineffective, interchange of vaccine products and off label use (4th vaccination) were also reported. The event Suspected Covid-19 occurrence unknown with respect to the third and fourth dose of mRNA-1273 vaccine administration, in Covid-19 vaccination on series. No other information surrounding the event was reported. The outcome of the event was reported as unknown. The current Covid-19 pandemic remain confounder for the event Suspected Covid-19. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 09-Jun-2022 and was forwarded to Moderna on 09-Jun-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of COVID-19 (COVID-19 INFECTION) in a 47-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect products included non-company products RITUXIMAB solution for infusion for B-cell lymphoma and TOCILIZUMAB for COVID-19. The patient's past medical history included Dilated cardiomyopathy. Previously administered products included for B-cell lymphoma: PREDNISOLONE from April 2020 to August 2020, VINCRISTINE from April 2020 to August 2020, CYCLOPHOSPHAMIDE from April 2020 to August 2020 and DOXORUBICIN from April 2020 to August 2020. Past adverse reactions to the above products included No adverse event with CYCLOPHOSPHAMIDE, DOXORUBICIN, PREDNISOLONE and VINCRISTINE. In April 2020, the patient started RITUXIMAB (Intravenous) 375 milligram/sq. meter. In October 2020, RITUXIMAB (Intravenous) dosage was changed to 375 milligram/sq. meter. On 05-May-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-May-2021, RITUXIMAB (Intravenous) dosage was changed to 375 milligram/sq. meter. On 01-Jun-2021, received dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 29-Jul-2021, the patient started TOCILIZUMAB (unknown route) UNK, two doses of tocilizumab were administered. On 01-Oct-2021, RITUXIMAB (Intravenous) dosage was changed to 375 milligram/sq. meter. On 23-Nov-2021, received dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. In July 2021, the patient experienced COVID-19 (COVID-19 INFECTION) (seriousness criterion hospitalization). On an unknown

Case ID	WW Identifier	Narrative (Complete)
		date, the patient experienced OFF LABEL USE (OFF LABEL USE OF TOCILIZUMAB), DRUG INTERACTION (DRUG VACCINE INTERACTION), HYPOGAMMAGLOBULINAEMIA (HYPOGAMMAGLOBULINEMIA) and VACCINATION FAILURE (NO ANTIBODY RESPONSE TO SARS-COV-2 MRNA VACCINE (VACCINE RESPONSE IMPAIRED)). At the time of the report, OFF LABEL USE (OFF LABEL USE OF TOCILIZUMAB), DRUG INTERACTION (DRUG VACCINE INTERACTION), HYPOGAMMAGLOBULINAEMIA (HYPOGAMMAGLOBULINEMIA) and VACCINATION FAILURE (NO ANTIBODY RESPONSE TO SARS-COV-2 MRNA VACCINE (VACCINE RESPONSE IMPAIRED)) outcome was unknown and COVID-19 (COVID-19 INFECTION) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In July 2021, SARS-CoV-2 test: positive (Positive) Positive. In October 2021, SARS-CoV-2 test: positive (Positive) Positive. In December 2021, SARS-CoV-2 test: negative (Negative) Negative. On an unknown date, Blood lactate dehydrogenase: elevation elevation (613 U/L; cutoff <250 U/L). On an unknown date, Blood test: moderate neutropenia moderate neutropenia 710 and thrombocytopenia 84.000/L, mild IgM hypogammaglobulinemia (37 mg/dl; normal value, 5-300). On an unknown date, C-reactive protein: 89 (89 mg/L; cutoff less than 5 mg/L). On an unknown date, Interleukin level: 79 (79 pg/ml; cutoff less than 7 pg/mg). On an unknown date, SARS-CoV-2 test: positive (Positive) Positive. On an unknown date, Serum ferritin: 539 (539 ng/mg; cutoff less than 290 ng/mg). For mRNA-1273 (Spikevax) (Unknown), the reporter considered DRUG INTERACTION (DRUG VACCINE INTERACTION) and VACCINATION FAILURE (NO ANTIBODY RESPONSE TO SARS-COV-2 MRNA VACCINE (VACCINE RESPONSE IMPAIRED)) to be related and HYPOGAMMAGLOBULINAEMIA (HYPOGAMMAGLOBULINEMIA) to have a relationship that was not reported, OFF LABEL USE (OFF LABEL USE OF TOCILIZUMAB) and COVID-19 (COVID-19 INFECTION) to be not applicable. No concomitant medication details were provided. No treatment medication details were provided. Company comment: This is a regulatory authority case concerning a 47-year-old, male patient with no relevant medical history and with relevant concomitant and co-suspect medications of Rituximab for B cell lymphoma (1 October 2021) and Tocilizumab (29 July 2021) for Covid-19. Patient has vaccine history of receiving 3 doses of unknown dose number of mRNA-1273 vaccine with dosage interval of 27 days for the first 2 doses,(mRNA-1273 vaccine administration date: 5 May 2021, 1 June 2021 and 23 November 2021). Patient experienced the unexpected serious (hospitalization according to regulatory authority) AESI event of Covid-19 and the unexpected non-serious events of hypogammaglobulinemia, vaccination failure, off label use of Tocilizumab and drug vaccine interaction. The event Covid-19 occurred the month after (July 2021), the second administration of unknown dose number of mRNA-1273 vaccine. The event off-label use of Tocilizumab occurred approximately 58 days, (29 July 2021) after the second administration of unknown dose number of mRNA-1273 vaccine. The events hypogammaglobulinemia, vaccination failure and drug vaccine interaction exact occurrence were not reported. Diagnostics were done as follows, July 2021: SARS-CoV-2 RT-PCR test: positive, October 2021: SARS-CoV-2 RT-PCR test: positive, unknown date: SARS-CoV-2 RT-PCR test: positive, December 2021: SARS-CoV-2 RT-PCR test: negative, unknown date: Ferritin: 539 ng/mg-elevated (normal values: <290 ng/mg), unknown date: Lactate dehydrogenase: 613 U/L - elevated (normal values: <250 U/L), unknown date: C-reactive protein: 89 mg/L - elevated (normal values: <5 mg/L), unknown date: Interleukin-6: 79 pg/ml - elevated, unknown date: blood test: moderate neutropenia 710 and thrombocytopenia 84.000/L, mild IgM hypogammaglobulinemia: 37 mg/dL. The outcome of the event Covid-19 was reported as resolved. The outcome of the events

Case ID	WW Identifier	Narrative (Complete)
		hypogammaglobulinemia, vaccination failure, off label use of Tocilizumab and drug vaccine interaction was reported as unknown. The current Covid-19 pandemic remain confounder for the event Covid-19. The patient's immunocompromise state and the event hypogammaglobulinemia remain confounder for the events Covid-19 and vaccination failure. The concomitant use of Rituximab for B cell lymphoma remain confounder for the event drug vaccine interaction. The off-label use of Tocilizumab remain confounder for the event off-label use of Tocilizumab. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) (E2B Linked Report).
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 15-Jun-2022 and was forwarded to Moderna on 15-Jun-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products), COVID-19 (SARS-CoV-2 infection), DRUG INEFFECTIVE (Drug ineffective) and OFF LABEL USE (Off label use) in a female patient of an unknown age who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. No Medical History information was reported. On 11-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 22-Jun-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 11-Dec-2021, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 11-Dec-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) (seriousness criterion medically significant) and OFF LABEL USE (Off label use) (seriousness criterion medically significant). On 02-Jun-2022, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criterion medically significant) and DRUG INEFFECTIVE (Drug ineffective) (seriousness criterion medically significant). At the time of the report, INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) and OFF LABEL USE (Off label use) outcome was unknown and COVID-19 (SARS-CoV-2 infection) and DRUG INEFFECTIVE (Drug ineffective) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Jun-2022, SARS-CoV-2 test: positive (Positive) POSITIVE. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant were reported. It was reported that based on available information, a possible contributory role of the subject product BNT162b2 COMIRNATY, cannot be excluded for suspected LOE and other events. There was limited information provided in this report. This case had to be reassessed once additional information made available. The impact of this report on the benefit and risk profile of the Pfizer product was evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, have to be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate. No treatment were reported.

Case ID	WW Identifier	Narrative (Complete)
		Company comment. This regulatory authority case concerns a female patient (unknown age), with no medical history reported, who experienced the serious (medically significant) unexpected AESI of COVID-19 that occurred 11 months, 11 days after receiving the second dose of mRNA-1273. Off label use and drug ineffective were also reported; however, doses 1 and 2 were administered in an inappropriate schedule of vaccination (42-day interval). Interchange of vaccine products was reported; the patient received a dose of Comirnaty COVID – 19 vaccine (third dose) approximately 6 months after mRNA – 1273 vaccine. Co-suspect product included Comirnaty COVID – 19 vaccine. No further clinical information was provided for medical reviewing. The benefit risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 15-Jun-2022 and was forwarded to Moderna on 15-Jun-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (ACUTE MYOCARDITIS) in a 3-decade-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for COVID-19 prophylaxis. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form and first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced OFF LABEL USE (OFF LABEL USE), MYOCARDITIS (ACUTE MYOCARDITIS) (seriousness criteria hospitalization and medically significant) and INTERCHANGE OF VACCINE PRODUCTS (INTERCHANGE OF VACCINE PRODUCTS). At the time of the report, OFF LABEL USE (OFF LABEL USE) and INTERCHANGE OF VACCINE PRODUCTS (INTERCHANGE OF VACCINE PRODUCTS) outcome was unknown and MYOCARDITIS (ACUTE MYOCARDITIS) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Biopsy: myocarditis Subsiding Myocarditis. On an unknown date, Echocardiogram: negative (Negative) NEGATIVE. On an unknown date, Electrocardiogram: st-elevation ST-elevation. On an unknown date, Magnetic resonance imaging heart: global elevated t2 global elevated T2, LVEF 42 percent, RVEF 33 percent Subepicardial LGE and edema basal and medial lateral wall. On an unknown date, Troponin I: elevated ELEVATED. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered OFF LABEL USE (OFF LABEL USE), MYOCARDITIS (ACUTE MYOCARDITIS) and INTERCHANGE OF VACCINE PRODUCTS (INTERCHANGE OF VACCINE PRODUCTS) to be related. No concomitant details were provided. No treatment details were provided. Company comment: This is a regulatory case concerning an adult male patient of approximately 30 years of age, with no reported medical history, who experienced the serious (due to medically important condition and hospitalization) expected,

Case ID	WW Identifier	Narrative (Complete)
		AESI of Myocarditis. The event on an unknown date related to the mRNA-1273 vaccine, received as the second dose of COVID-19 vaccination schedule. Temporal association cannot be assessed since vaccination date and onset date of the event was not provided. Additionally, Interchange of vaccine products (vaccination with first dose of COVID-19 vaccine NRVV AD (CHADOX1 NCOV-19), reported as suspect drug) and off label use was also reported in the case. A biopsy showed Subsiding Myocarditis, Troponin I was elevated and ECG showed ST elevation. A cardiac MRI revealed: global elevated T2, LVEF 42%, RVEF 33% Subepicardial LGE and edema basal and medial lateral wall. Echocardiogram was reported as negative. The outcome was reported as recovered. The COVID-19 vaccine NRVV AD (CHADOX1 NCOV-19) was reported as suspect drug in the case by regulatory authority. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	4.1(b) 4.1(b)	This case was received via another Manufacturer (Reference number: 4.1(b)) on 14-Jun-2022 and was forwarded to Moderna on 14-Jun-2022. This spontaneous case was reported by a consumer and describes the occurrence of AUTOIMMUNE DISORDER (Autoimmune reaction) in an adult male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product ADALIMUMAB (HUMIRA) for Rheumatoid arthritis. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form and ADALIMUMAB (HUMIRA) (Subcutaneous) at an unspecified dose. On an unknown date, the patient experienced AUTOIMMUNE DISORDER (Autoimmune reaction) (seriousness criterion medically significant) and OFF LABEL USE (Off label use). At the time of the report, AUTOIMMUNE DISORDER (Autoimmune reaction) and OFF LABEL USE (Off label use) outcome was unknown. Not Provided The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. No concomitant medications were reported. The daily dose of SPIKEVAX was reported as 1 in 1 once. The reporter’s causality for the event of Autoimmune reaction was not provided. The reporter’s causality for the event of Off label use with Humira was no reasonable possibility. No treatment medications were reported. Company comment: This is a spontaneous case concerning unspecified age male patient with no medical history reported, who experienced the unexpected serious (medically significant) events of autoimmune disorder, which occurred unspecified days after first dose of mRNA-1273 vaccine. Additionally non serious event off label use is also reported. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness is assessed as per regulatory authority’s report.

Case ID	WW Identifier	Narrative (Complete)
4.1(b)	4.1(b) 4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of BRONCHIECTASIS (Bronchiectasis/Damaged right lung) in an adult female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product ADALIMUMAB (HUMIRA) solution for injection for Spondylosis and Radiculopathy. Previously administered products included for Product used for unknown indication: MELOXICAM, IODINE, ASPIRIN [ACETYLSALICYLIC ACID], HYDROCODONE BITARTRATE and EPINEPHRINE. Past adverse reactions to the above products included No adverse event with ASPIRIN [ACETYLSALICYLIC ACID], EPINEPHRINE, HYDROCODONE BITARTRATE, IODINE and MELOXICAM. Concurrent medical conditions included Diabetes, Food allergy, Latex allergy, Peanut allergy, Allergy to animal (Standardized cat hair allergy) and Shellfish allergy (Shrimp allergy). Concomitant products included SALBUTAMOL SULFATE (4.1(b)) and PRAVASTATIN SODIUM for an unknown indication. In 2020, the patient started ADALIMUMAB (HUMIRA) (Subcutaneous) 40 milligram. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced BRONCHIECTASIS (Bronchiectasis/Damaged right lung) (seriousness criterion medically significant), TRAUMATIC LUNG INJURY (Damaged right lung), HEPATIC PAIN (Pain in liver), HYPERSENSITIVITY (Allergy with Humira) and OFF LABEL USE (Off label use). At the time of the report, BRONCHIECTASIS (Bronchiectasis/Damaged right lung), TRAUMATIC LUNG INJURY (Damaged right lung), HEPATIC PAIN (Pain in liver), HYPERSENSITIVITY (Allergy with Humira) and OFF LABEL USE (Off label use) outcome was unknown. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. It was unknown if patient was enrolled in COVID-19 vaccine trial. On an unknown date, the patient experienced Damaged right lung, Off label use, pain in liver, bronchiectasis and allergy. On an unknown date, the patient also experienced Pain in liver. Treatment medications were not reported. Company comment: This is a spontaneous case concerning a adult female patient of unknown age with relevant concurrent medical condition of diabetes and with concomitant medication of Pravastatin sodium for unspecified indication. Patient had co-suspect medication of Adalimumab (Humira) for spondylosis without myelopathy/radiculopathy unspecified. Patient experienced the unexpected serious (medically significant) event of bronchiectasis, the unexpected non-serious events of hepatic pain and hypersensitivity (allergy with Humira). Off label use was also reported. The events occurrence was unknown with respect to the unknown dose number of mRNA-1273 vaccine administration. No other information surrounding the events was reported. The outcome of the events was reported as unknown. The co-suspect medication of Adalimumab (Humira) remain confounder for the events hypersensitivity (allergy with Humira) and hepatic pain. The concurrent medical condition of diabetes and concomitant

Case ID	WW Identifier	Narrative (Complete)
		medication of Pravastatin sodium remain confounders for the event hepatic pain. The unspecified indication for the concomitant medication of Pravastatin sodium may remain confounder for the event hepatic pain. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Reporter did not allow further contact Most recent FOLLOW-UP information incorporated above includes: On 15-Jun-2022: Significant live follow-up received on 15-Jun-2022, New Event was added as Liver pain, reporter opinion of causality and narrative description. Action taken of co suspect was added.

Appendix 11.26c Off-label use: Literature Search Methodology

(((((((off-label prescribing) or (off-label use)) or (Off-Label Uses)) or (Off-Label Prescribing)) OR (Prescribing, Off-Label)) OR (Unlabeled Indication)) OR (Indication, Unlabeled)) OR (Unlabeled Indications)) AND (AND (("2019-nCoV Vaccine mRNA-1273"[21] OR "COVID-19 Vaccines/adverse effects"[21] OR "COVID-19 Vaccines"[21] OR "SARS-CoV-2"[21] OR "COVID-19"[21] OR "COVID-19 Vaccines"[21] OR "mRNA Vaccines"[21] OR mRNA COVID vaccination [tw] OR mRNA-1273 [tw] OR "mRNA 1273" [tw] OR mRNA1273 [tw] OR "modernatx 1273" [tw] OR "Moderna Covid19 Vaccine" [tw] OR "Moderna Covid-19 Vaccine" [tw] OR SPIKEVAX [tw] OR "2019 nCoV Vaccine mRNA 1273" [tw] OR "mRNA-1273, 2019-nCoV Vaccine" [tw] OR "Moderna COVID-19 Vaccine" [tw] OR "COVID-19 Vaccine, Moderna" [tw] OR "Moderna COVID 19 Vaccine" [tw] OR "Moderna COVID 19 Vaccine" [tw] OR "Vaccine, Moderna COVID-19" [tw] OR Elasomeran [tw] OR "Moderna COVID-19 Vaccine RNA" [tw] OR "Moderna COVID 19 Vaccine RNA" [tw] OR "COVID-19 Vaccine Moderna" [tw] OR "COVID 19 Vaccine Moderna" [tw] OR "Moderna, COVID-19 Vaccine" [tw] OR "mRNA-1273" [tw] OR "mRNA 1273" [tw] OR TAK-919 [tw] OR "TAK 919" [tw] OR TAK919 [tw] OR M-1273 [tw] OR "M 1273" [tw] OR M1273 [tw] OR mRNA-1273.211 [tw] OR "mRNA 1273.211" [tw] OR COVID-19[tw] OR SARS-CoV-2[tw] OR "COVID-19 vaccines"[tw] OR "mRNA Vaccines"[tw] or vaccin*[tw])) AND ("2022/01/01"[Date - Publication] : "2022/06/18"[Date - Publication])))

Appendix 11.27a Interactions with Other Vaccines: Literature cases

PMID	Title	Link	Moderna Vaccine	Class of vaccine	Relevant	Authors	Citation	First Author	Journal/Book	Publication Year	Create Date	PMCID	NIHMS ID	DOI
35131444	Exercise after influenza or COVID-19 vaccination increases serum antibody without an increase in side effects	https://pubmed.ncbi.nlm.nih.gov/35131444/	No	m-RNA	No	Hallam J, Jones T, Alley J, Kohut ML.	Brain Behav Immun. 2022 May;102:1-10. doi: 10.1016/j.bbi.2022.02.005. Epub 2022 Feb 5.	Hallam J	Brain Behav Immun	2022	2/8/2022	PMC8816799		10.1016/j.bbi.2022.02.005
35486404	Association of Influenza Vaccination With Cardiovascular Risk: A Meta-analysis	https://pubmed.ncbi.nlm.nih.gov/35486404/	No	Non-COVID Vaccine	No	Behrouzi B, Bhatt DL, Cannon CP, Vardeny O, Lee DS, Solomon SD, Udell JA.	JAMA Netw Open. 2022 Apr 1;5(4):e228873. doi: 10.1001/jamanetworkopen.2022.8873.	Behrouzi B	JAMA Netw Open	2022	4/29/2022	PMC9055450		10.1001/jamanetworkopen.2022.8873
34739573	COVID-19 vaccine safety and nocebo-prone associated hesitancy in patients with systemic rheumatic diseases: a cross-sectional study	https://pubmed.ncbi.nlm.nih.gov/34739573/	Yes	m-RNA	No	Fragoulis GE, Bournia VK, Mavrea E, Evangelatos G, Fragiadaki K, Karamanakos A, Kravariti E, Laskari K, Panopoulos S, Pappa M, Mitsikostas DD, Tektonidou MG, Vassilopoulos D, Sfikakis PP.	Rheumatol Int. 2022 Jan;42(1):31-39. doi: 10.1007/s00296-021-05039-3. Epub 2021 Nov 5.	Fragoulis GE	Rheumatol Int	2022	11/5/2021	PMC8569844		10.1007/s00296-021-05039-3
35490689	How repeated influenza vaccination effects might apply to COVID-19 vaccines	https://pubmed.ncbi.nlm.nih.gov/35490689/	Yes	m-RNA	No	Thompson MG, Cowling BJ.	Lancet Respir Med. 2022 Jul;10(7):636-638. doi: 10.1016/S2213-2600(22)00162-X. Epub 2022 Apr 28.	Thompson MG	Lancet Respir Med	2022	5/1/2022	PMC9049845		10.1016/S2213-2600(22)00162-X
35174524	Association study between herpes zoster reporting and mRNA COVID-19 vaccines (BNT162b2 and mRNA-1273)	https://pubmed.ncbi.nlm.nih.gov/35174524/	Yes	m-RNA	Yes	Préta LH, Contejean A, Salvo F, Treluyer JM, Charlier C, Chouchana L.	Br J Clin Pharmacol. 2022 Jul;88(7):3529-3534. doi: 10.1111/bcp.15280. Epub 2022 Feb 28.	Préta LH	Br J Clin Pharmacol	2022	2/17/2022	PMC9111438		10.1111/bcp.15280
34998730	Immunization schedule of the Pediatric Spanish Association: 2022 recommendations	https://pubmed.ncbi.nlm.nih.gov/34998730/	Yes	m-RNA	No	Álvarez García FJ, Cilleruelo Ortega MJ, Álvarez Aldeán J, Garcés-Sánchez M, Garrote Llanos E, Iofrio de Arce A, Montesdeoca Melián A, Navarro Gómez ML, Pineda Solas V, Rivero Calle I, Ruiz-Contreras J, Serrano Marchuet P; en representación del Comité Asesor de Vacunas de la Asociación Española de Pediatría (CAV-AEP).	An Pediatr (Engl Ed). 2022 Jan;96(1):59.e1-59.e10. doi: 10.1016/j.anpede.2021.11.002. Epub 2022 Jan 5.	Álvarez García FJ	An Pediatr (Engl Ed)	2022	1/9/2022			10.1016/j.anpede.2021.11.002
35634013	Attitudes toward coronavirus disease 2019 vaccination in people with multiple sclerosis	https://pubmed.ncbi.nlm.nih.gov/35634013/	Yes	No	No	Marrie RA, Dolovich C, Cutter GR, Fox RJ, Salter A.	Mult Scler J Exp Transl Clin. 2022 May 22;8(2):20552173221102067. doi: 10.1177/20552173221102067. eCollection 2022 Apr-Jun.	Marrie RA	Mult Scler J Exp Transl Clin	2022	5/31/2022	PMC9131385		10.1177/20552173221102067
35296643	Antibody decay, T cell immunity and breakthrough infections following two SARS-CoV-2 vaccine doses in inflammatory bowel disease patients treated with infliximab and vedolizumab	https://pubmed.ncbi.nlm.nih.gov/35296643/	No	No	No	Lin S, Kennedy NA, Saifuddin A, Sandoval DM, Reynolds CJ, Seoane RC, Kottoor SH, Pieper FP, Lin KM, Butler DK, Chanchlani N, Nice R, Chee D, Bewshea C, Janjua M, McDonald TJ, Sebastian S, Alexander JL, Constable L, Lee JC, Murray CD, Hart AL, Irving PM, Jones GR, Kok KB, Lamb CA, Lees CW, Altmann DM, Boyton RJ, Goodhand JR, Powell N, Ahmad T; CLARITY IBD study.	Nat Commun. 2022 Mar 16;13(1):1379. doi: 10.1038/s41467-022-28517-z.	Lin S	Nat Commun	2022	3/17/2022	PMC8927425		10.1038/s41467-022-28517-z
35114141	Safety and immunogenicity of a high-dose quadrivalent influenza vaccine administered concomitantly with a third dose of the mRNA-1273 SARS-CoV-2 vaccine in adults aged ≥65 years: a phase 2, randomised, open-label study	https://pubmed.ncbi.nlm.nih.gov/35114141/	Yes	m-RNA	Yes	Izikson R, Brune D, Bolduc JS, Bourron P, Fournier M, Moore TM, Pandey A, Perez L, Sater N, Shrestha A, Wague S, Samson SI.	Lancet Respir Med. 2022 Apr;10(4):392-402. doi: 10.1016/S2213-2600(21)00557-9. Epub 2022 Feb 1.	Izikson R	Lancet Respir Med	2022	2/3/2022	PMC8803382		10.1016/S2213-2600(21)00557-9

Appendix 11.27b Interactions with Other Vaccines: Literature Search Methodology

("combination vaccines"[All Fields] OR "vaccine co-administration"[All Fields] OR "Influenza Vaccination"[All Fields]) AND ("mrna vaccines"[MeSH Terms] OR "2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "mRNA 1273"[All Fields] OR "mRNA 1273"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "mrna1273"[All Fields]) OR ("modernatx"[All Fields] AND "1273"[All Fields]) OR "1273"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "m 1273"[All Fields]) OR "m 1273"[All Fields] OR ("moderna"[All Fields] AND ("covid 19 vaccines"[MeSH Terms] OR ("covid 19"[All Fields] AND "vaccines"[All Fields]) OR "covid 19 vaccines"[All Fields] OR ("covid19"[All Fields] AND "vaccine"[All Fields]) OR "covid19 vaccine"[All Fields])) OR "moderna covid 19 vaccine"[All Fields] OR "moderna covid 19 vaccine"[All Fields] OR "moderna covid 19 vaccine"[All Fields] OR "SPIKEVAX"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "elasomeran"[All Fields]) OR "CX-024414"[All Fields] OR "tak 919"[All Fields] OR "tak 919"[All Fields] OR (("2019 ncov vaccine mrna 1273"[MeSH Terms] OR "2019 ncov"[All Fields] OR (("sars cov 2"[MeSH Terms] OR "sars cov 2"[All Fields] OR "sars cov 2"[All Fields]) AND ("vaccin"[Supplementary Concept] OR "vaccin"[All Fields] OR "vaccination"[MeSH Terms] OR "vaccination"[All Fields] OR "vaccinable"[All Fields] OR "vaccinal"[All Fields] OR "vaccinate"[All Fields] OR "vaccinated"[All Fields] OR "vaccinates"[All Fields] OR "vaccinating"[All Fields] OR "vaccinations"[All Fields] OR "vaccination s"[All Fields] OR "vaccinator"[All Fields] OR "vaccinators"[All Fields] OR "vaccine s"[All Fields] OR "vaccined"[All Fields] OR "vaccines"[MeSH Terms] OR "vaccines"[All Fields] OR "vaccine"[All Fields] OR "vaccins"[All Fields]))) AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields])) AND 2022/01/01:2022/06/18[Date - Publication]

Appendix 11.28a Lack of Efficacy/Vaccine failure: Variant cases

Case_ID	Flags	Narrative
4.1(b) [redacted]	Alpha	This literature-non-study case was reported in a literature article and describes the occurrence of AUTOIMMUNE THYROIDITIS (Hashimoto's Thyroiditis) in a 21-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. ..LITERATURE REFERENCE:.Cluff E, Bellusci L, Golding H, Khurana S. Immune response to SARS-CoV-2 Vaccine and following breakthrough Omicron infection in an autoimmune patient with Hashimoto's thyroiditis, pernicious anemia, and chronic atrophic autoimmune gastritis: A case report. Vaccines (Basel). 2022;10(3):450 . .The patient's past medical history included SARS-CoV-2 infection (first infected with SARS-CoV-2 in November 2020 when the Alpha variant was predominant. Patient had severe symptoms for 6 days but was not hospitalized.) in November 2020.. .On 06-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form..On 06-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 10-Aug-2021, the patient experienced AUTOIMMUNE THYROIDITIS (Hashimoto's Thyroiditis) (seriousness criterion medically significant). On 29-Sep-2021, the patient experienced PERNICIOUS ANAEMIA (Pernicious Anemia) and CHRONIC GASTRITIS (Chronic Atrophic Autoimmune Gastritis). On 28-Dec-2021, the patient experienced COVID-19 (Breakthrough infection with the Omicron variant). On an unknown date, the patient experienced DRUG INEFFECTIVE (Lack of drug effect) and VACCINATION COMPLICATION (Moderate reaction). The patient was treated with LEVOTHYROXINE at a dose of 25 microgram and DULOXETINE at a dose of 20 milligram. At the time of the report, AUTOIMMUNE THYROIDITIS (Hashimoto's Thyroiditis), PERNICIOUS ANAEMIA (Pernicious Anemia), COVID-19 (Breakthrough infection with the Omicron variant), VACCINATION COMPLICATION (Moderate reaction) and CHRONIC GASTRITIS (Chronic Atrophic Autoimmune Gastritis) outcome was unknown and DRUG INEFFECTIVE (Lack of drug effect) had resolved. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 01-Jan-2022, Polymerase chain reaction: positive (Positive) tested PCR-positive for SARS-CoV-2 Omicron..On an unknown date, Polymerase chain reaction: negative (Negative) A second blood sample was obtained two weeks post Omicron infection PCR-negative.. .For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered AUTOIMMUNE THYROIDITIS (Hashimoto's Thyroiditis), PERNICIOUS ANAEMIA (Pernicious Anemia), COVID-19 (Breakthrough infection with the Omicron variant), DRUG INEFFECTIVE (Lack of drug effect), VACCINATION COMPLICATION (Moderate reaction) and CHRONIC GASTRITIS (Chronic Atrophic Autoimmune Gastritis) to be related. . .Company comment:This Literature non-study case concerns a 21-year-old, female patient with reported medical history of prior COVID-19, who experienced the unexpected, serious (medically significant) AESI of Autoimmune thyroiditis, unexpected, serious (medically significant) event of hypothyroidism, unexpected non-serious AESI of COVID-19 (SARS-CoV-2 Omicron variant infection). The events Autoimmune Thyroiditis and Hypothyroidism occurred approximately 5 months and 4 days after the receiving the second dose of mRNA 1273. the event COVID-19 (SARS-CoV-2 Omicron variant infection) occurred approximately 9 months and 26 days after the second dose of mRNA 1273. Drug ineffective was also reported in this case. It should be noted that the patient had pernicious anaemia and chronic atrophic autoimmune gastritis after completing the primary series of mRNA 1273. The patient is not on any immunosuppressant medication at the time of vaccination and COVID-19 infection. The patient was tested for neutralizing antibodies post-infection which showed enhanced titers for multiple COVID-19 variants, compared to pre-infection status, including presence of neutralization of omicron. Treatment details were not reported in the case. The Omicron surge during the COVID-19 pandemic remains a confounder for the event COVID-19. The benefit-risk relationship of mRNA-1273 is not affected by this report. .Most recent FOLLOW-UP information incorporated above includes:.On 07-Apr-2022: Follow up received by safety on 08-Apr-2022 has Email with full text article received from SARA team and contains significant information. Reporter details, Page number, Laboratory data, Product information and Event details updated.
4.1(b) [redacted]	Alpha	This spontaneous case was reported by a consumer and describes the occurrence of SYNCOPE (Fainting spell) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 013H21B) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .Concurrent medical conditions included Anemia, Alpha thalassaemia and Drug allergy (Drug was not specified)..Concomitant products included FAMOTIDINE from 13-May-2022 to an unknown date for an unknown indication.. ..On 30-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-May-2022, the patient experienced SYNCOPE (Fainting spell) (seriousness criterion medically significant), COVID-19 (Strongly positive antigen test), ASTHENIA (Weakness after going to toilet), DIZZINESS (Extreme dizziness) and PYREXIA (Return of fever (99.5-99.9F)). The patient was treated with NIRMATRELVIR, RITONAVIR (PAXLOVID) from 18-May-2022 to 22-May-2022 for COVID-19 treatment, at a dose of 1 dosage form. At the time of the report, SYNCOPE (Fainting spell), COVID-19 (Strongly positive antigen test), ASTHENIA (Weakness after going to toilet), DIZZINESS (Extreme dizziness) and PYREXIA (Return of fever (99.5-99.9F)) was resolving. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 26-May-2022, Body temperature: 99.5 - 99.9 f (High) 99.5 - 99.9 F..On 26-May-2022, SARS-CoV-2 test: strongly positive antigen test. (Positive) Strongly positive antigen test... . . . .The patient took other medications/products within 2 weeks of receiving COVID-19 treatment...Patient stated return of fever (99.5--99.9F) on 26-May-2022 (d4 after

Case_ID	Flags	Narrative
		stopping paxlovid, d10 post start of symptoms)...Patient went to ER for hydration. Patient received IV fluids as treatment for the adverse event...CC: This spontaneous case concerns a patient of unknown age and gender, with a relevant history of anemia and alpha thalassemia, who experienced the unexpected non-serious adverse event of special interest COVID-19 and the serious (medically significant) event of Syncope, that occurred 147 days after receiving mRNA-1273 vaccine as third dose in the COVID-19 vaccination series. Patient stated return of fever (99.5--99.9F) on the 4th day after stopping Paxlovid and on the 10th day after initial occurrence of symptoms, and experienced extreme weakness, fainting spell and dizziness. Patient was brought to ER for hydration with IV fluids. Outcome of the event was reported as resolving. Patient completed 5 days of treatment with Paxlovid. Underlying history of anemia and alpha thalassemia and the ongoing COVID-19 could be confounders for the events Syncope and COVID-19. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b) [redacted]	Delta	This spontaneous case was reported by an other health care professional and describes the occurrence of COVID-19 (Rebound COVID-19 and symptoms/s positive both times) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002MZ1A/00ZMZIA) for COVID-19 vaccination. . .Previously administered products included for COVID-19 vaccination: Pfizer COVID-19 Vaccine (COVID-19 Vaccine: Dose 1, Manufacturer: Pfizer, LOT: EL9261) on 08-Feb-2021, Pfizer COVID-19 Vaccine (COVID-19 Vaccine: Dose 2, Manufacturer: Pfizer, LOT: EN6202) on 01-Mar-2021, Pfizer COVID-19 Vaccine (COVID-19 Vaccine: Dose 3, Manufacturer: Pfizer and LOT: FC3182) on 26-Sep-2021..Past adverse reactions to the above products included No adverse event with Pfizer COVID-19 Vaccine, Pfizer COVID-19 Vaccine and Pfizer COVID-19 Vaccine.. ..On 06-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 18-May-2022, the patient experienced COVID-19 (Rebound COVID-19 and symptoms/s positive both times) (seriousness criterion medically significant). The patient was treated with NIRMATRELVIR, RITONAVIR (PAXLOVID) from 19-May-2022 to 23-May-2022 for COVID-19, at an unspecified dose and frequency. At the time of the report, COVID-19 (Rebound COVID-19 and symptoms/s positive both times) was resolving. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 27-May-2022, SARS-CoV-2 test: positive (Positive) Result: Positive; Unit: Not Provided..On 31-May-2022, SARS-CoV-2 test: positive (Positive) Result: Positive; Unit: Not Provided.. . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .On 06-Apr-2022 she took Moderna COVID-19 Vaccine Dose 4, LOT: 00ZMZIA or 002MZIA, but thought 00ZMZIA or 00ZMZ1A. All vaccination information was provided from patient's record card. .She was not admitted on 18-May-2022 - positive COVID-19 at home. On 19-May-2022 started Paxlovid She took 5 days course of Paxlovid Symptoms quickly abated Then it wasn't even a couple days after stopped taking Paxlovid, she felt symptoms were coming back definitely was on day 5 of symptoms Still positive for COVID-19 and back in isolation had no scary symptoms ,had stuffy/runny nose, headache, and off-on sore throat. better than 4-5 days ago. It was nothing more than an upper respiratory head cold. She read in the last few days that Pfizer continued to say it was very low and they were calling it rebound COVID-19. Knew when the Paxlovid studies were done it was the delta variant, which was different. She had Pfizer vaccines two doses and been boosted twice. She was upset. Disappointed because she already did isolation. She should have gone and stayed the course of COVID-19 without medicine. She should not have taken Paxlovid. Emergency Room visit on 19-May-2022, but not admitted to hospital Physician Office. There were no predisposing factors. No culture was performed. Rebound COVID-19 and symptoms improved a little, but not a lot COVID-19 test remained positive entire time, tested twice, 27-May-2022 and 31-May-2022. a pain in the neck Clarified symptoms as stuffy/runny nose, headache, off-on sore throat, sinuses did not feel quite as bad. At first, had pressure and pain in the sinuses. Treatment was none, Paxlovid discarded the product Dose, standard, normal dose, it was 500/something else but she was not sure. Took it twelve hours apart If she wouldn't have taken Paxlovid, she would have been over it at this time and not experienced it twice. .PSCC Communication: PC filed. There was a product complaint to report...Company Comment:.This spontaneous case concerns a 71-year-old female patient with history of interchange of vaccine products, who experienced the unexpected serious (medically significant) AESI of Covid-19, 42 days after receiving mRNA-1273 vaccine as 4th dose. She was tested positive for SARS-CoV-2 test and was treated with Paxlovid (Nirmatrelvir + Ritonavir) for five days. Two days later she had rebound symptoms and tested positive again and was diagnosed as rebound Covid-19. The outcome was reported as resolving. Details of symptoms, start date, clinical course, investigation reports and further treatment details were not provided. Six months prior to the Moderna vaccine, the patient had taken three doses of Pfizer COVID-19 Vaccine. Elderly age of the patient could be a risk factor. The current pandemic situation of Covid-19 could be a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	Omicron	This literature-non-study case was reported in a literature article and describes the occurrence of COVID-19 (Breakthrough SARS-CoV-2 infection caused by the Omicron variant) in an adult male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. ..LITERATURE REFERENCE:.Maruki T, Iwamoto N, Kanda K, Okumura N, Yamada G, Ishikane M, et al.. Two cases of breakthrough SARS-CoV-2 infections caused by the Omicron variant (B. 1.1. 529 lineage) in international travelers to 4.1(b) [redacted] Clin Infect Dis. 2022 . .No Medical History information was reported.. .On 01-Jul-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna)

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		(unknown route) 1 dosage form..On 30-Jul-2021, received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 28-Nov-2021, the patient experienced COVID-19 (Breakthrough SARS-CoV-2 infection caused by the Omicron variant) (seriousness criterion hospitalization) and DRUG INEFFECTIVE (Lack of drug effect). On 28-Nov-2021, DRUG INEFFECTIVE (Lack of drug effect) had resolved. At the time of the report, COVID-19 (Breakthrough SARS-CoV-2 infection caused by the Omicron variant) had resolved. Related . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 27-Nov-2021, SARS-CoV-2 test: negative (Negative) tested for SARS-CoV-2 via real-time reverse transcriptase PCR (rRT-PCR) with a negative result..On 28-Nov-2021, SARS-CoV-2 test: positive (Positive) tested positive 23 for SARS-CoV-2 via quantitative antigen test..On 30-Nov-2021, Alanine aminotransferase: 19 u/l 19 U/L..On 30-Nov-2021, Aspartate aminotransferase: 21 u/l 21 U/L..On 30-Nov-2021, Blood bilirubin: 0.9 mg/dl 0.9 mg/dL..On 30-Nov-2021, Blood creatinine: 0.91 (mg/dl) 0.91 (mg/dL)..On 30-Nov-2021, Blood lactate dehydrogenase: 137 u/l 137 U/L..On 30-Nov-2021, Blood urea: 13.4 13.4..On 30-Nov-2021, Body mass index: 22.2 22.2..On 30-Nov-2021, Body temperature: 38.8 degrees celsius 38.8 degrees celsius..On 30-Nov-2021, C-reactive protein: 1.5 mg/dl 1.5 mg/dL..On 30-Nov-2021, Chest X-ray: unremarkable Unremarkable..On 30-Nov-2021, Fibrin D dimer: <0.5 <0.5..On 30-Nov-2021, Haematocrit: 42.7 percent 42.7 percent..On 30-Nov-2021, Haemoglobin: 14.4 g/dl 14.4 g/dl..On 30-Nov-2021, Lymphocyte count: 20.9 percent 20.9 percent..On 30-Nov-2021, Neutrophil count: 52.6 percent 52.6 percent..On 30-Nov-2021, Oxygen saturation: 98 percent 98 percent..On 30-Nov-2021, Platelet count decreased: 18.5x10*4/µl 18.5x10*4/µL..On 30-Nov-2021, White blood cell count: 3,580 µ/l 3,580 µ/L.. . .For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered COVID-19 (Breakthrough SARS-CoV-2 infection caused by the Omicron variant) and DRUG INEFFECTIVE (Lack of drug effect) to be related. . .Patient was a healthy male in his 30s...he presented with a fever on 22 the airplane, and arrived at an international airport in 4.1(b) on the same day..Patient tested positive for SARS-CoV-2 via quantitative antigen test at the airport quarantine procedure and was isolated in an isolation facility...On November 29, patient was transferred to the hospital. He presented with a mild fever, a cough, and a sore throat..On day 3, the results of viral genome sequencing confirmed infection with Omicron variant (GISAID Accession ID: EPI_ISL_6913953). He had fever for four days and became afebrile on day 5 and improved without medication..Cq value / date / number of days since onset: 36.2/29-Nov-2021/day 2. 22.2/01-Dec-2021/day 4. 24.2/05-Dec-2021/day 8. 33.9/07-Dec-2021/day 10..No concomitant and treatment were not reported..Company comment: This case concerns an adult male patient with unknown medical history who experienced breakthrough SARS-CoV-2 infection caused by the Omicron variant and was hospitalized approximately four months after the second dose of mRNA-1273. Lack of drug effect is also reported. At the time of the report, breakthrough SARS-CoV-2 infection caused by the Omicron variant had resolved. The reporter assessed the event as related to the mRNA-1273 vaccine. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.. .Most recent FOLLOW-UP information incorporated above includes:.On 13-Jan-2022: Follow up received by safety on 13-Jan-2022 included an Email with FTA received from SARA team and contains significant information.
4.1(b)	Omicron	This spontaneous case was reported by a consumer and describes the occurrence of ARRHYTHMIA (Arrhythmia) in an 81-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. RA4945 and RA4945) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .Concurrent medical conditions included Diabetes since 08-Oct-2012, Hypertension, Depression and Hypercholesteremia..Concomitant products included ROSUVASTATIN from 14-Nov-2015 to an unknown date for Cholesterol, ESCITALOPRAM from 05-Mar-2013 to an unknown date for Depression, METFORMIN HYDROCHLORIDE, SITAGLIPTIN PHOSPHATE MONOHYDRATE (JANUMET) from 10-Aug-2012 to an unknown date for Diabetes, METOPROLOL SUCCINATE (METOPROLOL [METOPROLOL SUCCINATE]) from 08-Apr-2011 to an unknown date for Hypertension.. .On 18-Feb-2021 at 2:00 PM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form..On 18-Mar-2021 at 1:00 PM, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 28-Dec-2021, the patient experienced ARRHYTHMIA (Arrhythmia) (seriousness criterion medically significant), COVID-19 (diagnosed with COVID-19) and DRUG INEFFECTIVE (Drug ineffective). The patient was treated with IBUPROFEN from 29-Dec-2021 to 02-Jan-2022 for COVID-19, at a dose of 600 milligram every eight hours. On 21-Jan-2022, COVID-19 (diagnosed with COVID-19) had resolved. On 01-Feb-2022, ARRHYTHMIA (Arrhythmia) and DRUG INEFFECTIVE (Drug ineffective) had resolved. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 28-Dec-2021, SARS-CoV-2 test: positive (Positive) Positive anterior swab..On 21-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative anterior nasal swab..On an unknown date, Blood test: high volume antibodies (High) high volume antibodies were found.. . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered ARRHYTHMIA (Arrhythmia) and COVID-19 (diagnosed with COVID-19) to be not related. No further causality assessment was provided for DRUG INEFFECTIVE (Drug ineffective). . .Patient didn't experienced cardiovascular disease, chronic respiratory conditions, HIV/AIDS, immunodeficiency conditions, liver related problems, obesity.On 26-Nov-2021, the patient received shingles I vaccine on shoulder (batch- 58160-0823-11)..The concomitant medication also includes olmesa medox 20 mg for

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		hypertension since 10-08-2012. .The vaccine was administered in the shoulder of the patent...The patient reported having Omicron for 5 days..The patient had symptoms of COVID-19 which were chills for 2 days, muscle aches for 3 days, diarrhea for 2 days and nasal congestion for 4 days..On 28-Jan-2022, the patient received shingles II vaccine on shoulder..The patient took the booster dose on 16-Feb-2022, batch- 80777-0273-10..Company comment: This spontaneous case concerns an 81-year-old female with no relevant medical history, who experienced unlisted, serious (medically significant) AESI of Arrhythmia and unlisted, non-serious AESI of Covid-19 approximately 10 months after her second dose of mRNA1273. The first 2 doses of mRNA1273 were given approximately 11 months prior to the event, thus drug ineffective was also noted in the case. At the time of reporting, the events have resolved. No further information on the clinical course and the medications given for the said events. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report.. .This case was linked to 4.1(b) , 4.1(b) (Patient Link).. .Most recent FOLLOW-UP information incorporated above includes:.On 22-Feb-2022: No new information was updated..On 22-Feb-2022: Follow up received contains No New Information..On 22-Feb-2022: Follow up received contains No New Information..On 03-Mar-2022: Significant Follow Up Appended _ Added Reporter details, Medical history, Lab data, Suspect batch number and anatomical location. Concomitant medications and Treatment medications were added. New events Arrhythmia was added, Updated onset date and stop date for Drug ineffective, Case was upgraded to serious.
4.1(b)	Omicron	This spontaneous case was reported by an other health care professional and describes the occurrence of ILLNESS ('Felt really sick; was sick/down for 5 days), FEELING ABNORMAL (She has also had a brain fog), DRUG INEFFECTIVE (Lack of drug effect), SINUSITIS (felt like having sinus infection) and VOMITING (throwing up) in a 50-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 008C21A, 046A21A and 011M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .Concurrent medical conditions included COPD, Blood pressure high, Diabetes and Obesity.. .On 22-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form..On 25-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form..On 03-Sep-2021, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 03-Sep-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced VOMITING (throwing up). On 18-Jan-2022, the patient experienced DRUG INEFFECTIVE (Lack of drug effect). 18-Jan-2022, the patient experienced COVID-19 (she had COVID-19). On an unknown date, the patient experienced ILLNESS ('Felt really sick; was sick/down for 5 days), FEELING ABNORMAL (She has also had a brain fog), SINUSITIS (felt like having sinus infection), FATIGUE (Fatigued/She felt exhausted at that time) and NAUSEA (Really nauseated). On 07-Sep-2021, VOMITING (throwing up) outcome was unknown. At the time of the report, ILLNESS ('Felt really sick; was sick/down for 5 days) and COVID-19 (she had COVID-19) had resolved, FEELING ABNORMAL (She has also had a brain fog) had not resolved and DRUG INEFFECTIVE (Lack of drug effect), SINUSITIS (felt like having sinus infection), FATIGUE (Fatigued/She felt exhausted at that time) and NAUSEA (Really nauseated) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 28-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative.. . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medication was provided...Patient received three doses of Moderna vaccine: first dose, 22Feb2021; second dose, 25Mar2021; and booster dose, 03Sep2021...Within 15 minutes after the booster dose, patient had thrown up and was down for 5 days. She was fatigued, felt really sick and nauseated. Patient also mentioned that she had COVID-19 on 18Jan2022 and was administered with monoclonal antibodies on 20Jan2022. She felt exhausted at that time, like she went out to work and felt like having sinus infection on steroids. She thought she had Omicron at that time. Her repeat COVID-19 test on 28Jan2022 was negative...Patient also had brain fog after receiving the booster dose which had not resolved until the time of the report. Patient tried to talk to her doctor about the second booster dose of the vaccine but claimed that her doctor is 'completely anti-vax'...Company Comment: This spontaneous case concerns a 50-year-old, female patient with relevant medical history of Chronic Obstructive Pulmonary Disease (COPD), Hypertension, Diabetes Mellitus (DM) and Obesity, who experienced the unexpected, non-serious AESI of COVID-19 and drug ineffective (lack of drug effect) was considered as an additional event. The patient also experienced other unexpected and expected, non-serious events beginning 15 minutes after administration of the booster dose of the Moderna mRNA-1273 vaccine. The events COVID-19 and drug ineffective occurred approximately 9 months after administration of the second dose of the Moderna mRNA-1273 vaccine, and 4 months after administration of the booster dose of the Moderna mRNA-1273 vaccine. On 20Jan2022, the patient was administered with monoclonal antibodies. On 28Jan2022, the repeat COVID-19 test was negative. The medical history of COPD, Hypertension, DM and Obesity, which are known risk factors for COVID-19, remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.. .This case was linked to 4.1(b) (Patient Link).. .Most recent FOLLOW-UP information incorporated above includes:.On 04-Apr-2022: Follow-up received and updated reporter type from consumer to Other Health care professional and added event.

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4.1(b)	Omicron	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 25-Feb-2022. The most recent information was received on 24-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. .This regulatory authority prospective pregnancy case was reported by a consumer and describes the occurrence of VACCINATION FAILURE (vaccination failure) and COVID-19 (covid-19) in a 33-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. . .Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation.. .Concurrent medical conditions included Polycystic ovary (treatment: letrozole for 1 month + injection to induce ovulation, pregnant in the 1st month) and Non-smoker.. .On 05-May-2021 at 7:15 PM, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form..On 26-May-2021 at 7:00 PM, received second dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form..On 02-Dec-2021 at 3:00 PM, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On 05-May-2021 at 7:15 PM, after starting mRNA-1273 (Spikevax), the patient experienced MATERNAL EXPOSURE TIMING UNSPECIFIED (Exposure during pregnancy). On 21-Jan-2022, the patient experienced VACCINATION FAILURE (vaccination failure) (seriousness criterion medically significant) and COVID-19 (covid-19) (seriousness criterion medically significant). At the time of the report, VACCINATION FAILURE (vaccination failure) and COVID-19 (covid-19) had resolved and MATERNAL EXPOSURE TIMING UNSPECIFIED (Exposure during pregnancy) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 24-Dec-2021, SARS-CoV-2 test: negative (Negative) Performed by pharmacist..On 21-Jan-2022, SARS-CoV-2 test: positive (Positive) Ct Covid = 35.5203 RT-PCR COVID 19 LogixSmart..On 23-Jan-2022, SARS-CoV-2 test: positve (Positive) ORF1AB = 22.9 N = 21.2 S = 0.0, 21K clade , B.1.1.529 (BA.1) lineage, This is the Omicron variant..On an unknown date, Cytomegalovirus test: igm quantitative 0.12 index < 0.85 Test Result:Negative IgM, negative igg Test Result:IgM quantitative 0.12 index < 0.85, igg quantitative 0.30 u/ml < 6.00 Test Result:IgG quantitative 0.30 U/mL < 6.00 and negative igm Test Result:Negative IgG..On an unknown date, HIV test: negative (Negative) Complete [V]..On an unknown date, Hepatitis B virus test: surface antibody 59 u/l Test Result:surface antigen Negative, surface ag quantitative 0.33 index Test Result:surface ag quantitative 0.33 index and surface antigen negative Test Result:surface antibody 59 u/l..On an unknown date, Hepatitis C virus test: antibody quantitative 0.09 index Test Result:antibody quantitative 0.09 index..On an unknown date, Rubella antibody test: igg quantitative 37.50 + iu/ml <7.00 (Negative) Test Result:IgG quantitative 37.50 + IU/mL <7.00 Complete [V] < 7 IU/mL : negative 7 - 9 IU/mL : gray zone >= 10 IU/mL : positive and negative (Negative) Test Result:IgG quantitative 37.50 + IU/mL <7.00..On an unknown date, Serology test: abnormal Test Result:In the comment..On an unknown date, Treponema test: negative (Negative) Complete [V] Syphilis decision: k. No arguments for active or experienced syphilis. If there is a suspicion of recent infection (within 2 weeks after the development of the chancre), the test may still be negative and should be repeated after 2 weeks...On an unknown date, Varicella virus test negative: igg quantitative 568.2 + miu/ml <135.0 Test Result:IgG quantitative 568.2 + mIU/mL <135.0 and igg pos negative Test Result:IgG pos negative.. . . . .No treatment medication was reported...Company comment: .This regulatory authority case concerns a 33-year-old, female patient with no relevant medical history reported, who experienced the unexpected serious AESI event of COVID-19 (seriousness criteria medically significant) which occurred 1 month 20 days after the third dose of mRNA 1273 Vaccine. Vaccination failure is also reported in the case. The event Maternal exposure timing unspecified is noted in the case. The patient received previous 2 doses with Pfizer COVID-19 Vaccine (Interchange of vaccine products). At the time of reporting events had resolved. Current pandemic situation of COVID 19 could be risk factor for COVID-19. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority's report.. .Most recent FOLLOW-UP information incorporated above includes:.On 24-Mar-2022: Significant follow-up received on 24-MAR-2022, event outcome for vaccination failure, COVID-19, and lab dates were updated
4.1(b)	Omicron	This regulatory authority case was reported by an other health care professional and describes the occurrence of COVID-19 PNEUMONIA (COVID-19 pneumonitis) and VACCINATION FAILURE (Vaccination failure) in a 54-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 057621A and 3002335) for COVID-19 vaccination. . .Co-suspect product included non-company product COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for COVID-19 vaccination.. .The patient's past medical history included Colonic polyp, Renal colic and Ex-tobacco user..Concurrent medical conditions included Thymoma.. .On 06-Mar-2021, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (Intramuscular) 1 dosage form..On 28-May-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form..On 08-Dec-2021, received dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 21-Dec-2021, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonitis) (seriousness criterion hospitalization) and VACCINATION FAILURE (Vaccination failure) (seriousness criterion hospitalization). At the time of the report, COVID-19 PNEUMONIA (COVID-19 pneumonitis) and VACCINATION FAILURE (Vaccination failure) was resolving. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 24-Dec-2021, SARS-CoV-2 test: positive (Positive) Positive..On 05-Jan-2022, Computerised tomogram: no pulmonary embolism. no pulmonary embolism.

Case_ID	Flags	Narrative
		Ground glass areas with crazy paving typical of COVID 19 type pneumonia with severe damage to approximately 70% of the lung parenchyma..On 06-Jan-2022, SARS-CoV-2 test: omicron variant with presence of 417n mutation omicron variant with presence of 417N mutation and absence of 484K and 452R mutations..On 07-Jan-2022, SARS-CoV-2 antibody test: negative (Negative) Negative..On 12-Jan-2022, Bone marrow myelogram: bone marrow of normal richness Bone marrow of normal richness, seat of granular hyperplasia, without excess blasts or significant dysplasia. Medullary lymphocytosis evaluated at 4.5% of cells. Presence of numerous macrophages, with frequent images of hemophagocytosis. Cytological table in favor of SAM...On 12-Jan-2022, SARS-CoV-2 antibody test: negative (Negative) Negative..On 15-Jan-2022, X-ray: improvement of interstitial opacities improvement of interstitial opacities..On 18-Jan-2022, Positron emission tomogram: ground glass areas and hypermetabolic bilateral Ground glass areas and hypermetabolic bilateral pulmonary parenchymal condensations in connection with known SARS-CoV2-pneumopathy. Moderately hypermetabolic supra and sub-diaphragmatic adenopathies. Splenomegaly with a subcapsular hypermetabolic focus of the splenic tip. Diffuse reaction-like osteo-medullary hypermetabolism..On 20-Jan-2022, Computerised tomogram: regression of ground glass ranges regression of ground glass ranges in relation to COVID attack. Appearance of condensation of the upper lobes, evoking a secondary infection...On 20-Jan-2022, SARS-CoV-2 antibody test: 157 157 [iU]/mL (international unit per millilitre) Negative IgM..On 26-Jan-2022, SARS-CoV-2 antibody test: 161 161 [iU]/mL (international unit per millilitre)..On 26-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive..On 01-Feb-2022, SARS-CoV-2 test: positive (Positive) Positive..On 02-Feb-2022, SARS-CoV-2 antibody test: 1520 1520 [iU]/mL (international unit per millilitre)..On 05-Feb-2022, SARS-CoV-2 antibody test: 1420 1420 [iU]/mL (international unit per millilitre)..On 06-Feb-2022, SARS-CoV-2 test: positive (Positive) Positive..On 08-Feb-2022, Computerised tomogram: decrease in pulmonary parenchymal involvement decrease in pulmonary parenchymal involvement, except at the right base. Increase in hepatosplenomegaly and mediastinal, coelio-mesenteric and inguinal adenomegaly. No abdomino-pelvic infectious focus visible. Reduction of peritoneal effusion. Minimal increase in sinusopathy...On 10-Feb-2022, Biopsy: high-grade t-cell lymphoma high-grade T-cell lymphoma..On 21-Feb-2022, SARS-CoV-2 test: positive (Positive) Positive.. . .For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.. .No concomitant medications were provided...Dosage text was reported as D2+R1...It was reported that, patient was presented with severe SARS-Cov2 pneumonia with 70% parenchymal involvement (variant Omicron), two weeks after the SPIKEVAX booster (heterologous initial scheme VAXZEVRIA + SPIKEVAX) with negative serology. Favorable evolution of the COVID-19 pneumonia but complications such as SAM and DIC revealing high-grade T-cell lymphoma. At the time of the declaration of persistence of a positive COVID PCR at omicron variant 2 months from the onset of symptoms...No treatment medications were provided...This regulatory case concerns a 54-year-old, male patient with past medical history of Colonic polyp, Renal colic and Ex-tobacco user and concurrent medical conditions of Thymoma, who experienced the unexpected, serious (Seriousness criterion Hospitalization), AESI of COVID-19 pneumonia. Additional serious event of Vaccination failure was also reported. The events occurred 13 days after the third dose of mRNA-1273 COVID 19 Vaccine. COVID-19 PCR test done on 24-Dec-21 was positive and Computerised tomogram noted significant findings. Outcome of the events was Resolving. The past medical history of Colonic polyp, Renal colic and Ex-tobacco user and concurrent medical conditions of Thymoma remains a confounder for the event Covd-19 pneumonia. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. . .Most recent FOLLOW-UP information incorporated above includes:.On 14-Mar-2022: Translation received on 16-MAR-2022. Updated lab tests name..On 14-Mar-2022: Upon internal review on 21-Mar-2022, significant correction was performed. The seriousness of event COVID-19 pneumonia was updated from hospitalization and medically significant to hospitalization.
4.1(b) [redacted]	Omicron	This spontaneous case was reported by a physician and describes the occurrence of COVID-19 (Tested positive for Omicron/tested positive for COVID-19) and DRUG INEFFECTIVE (Tested positive for COVID-19 after completing more than 14 days of second dose) in a 44-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 031BZ1A and 036AZ1A) for COVID-19 vaccination. . .No Medical History information was reported.. .On 06-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form..On 03-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 31-Jan-2022, the patient experienced COVID-19 (Tested positive for Omicron/tested positive for COVID-19) and DRUG INEFFECTIVE (Tested positive for COVID-19 after completing more than 14 days of second dose). The patient was treated with MOLNUPIRAVIR (oral) for COVID-19, at a dose of 400 milligram twice a day. At the time of the report, COVID-19 (Tested positive for Omicron/tested positive for COVID-19) had resolved and DRUG INEFFECTIVE (Tested positive for COVID-19 after completing more than 14 days of second dose) outcome was unknown. . .DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):.On 31-Jan-2022, SARS-CoV-2 test positive: positive (Positive) Positive..On an unknown date, SARS-CoV-2 test negative: negative (Negative) tested negative for COVID-19... . .For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.. .No concomitant medications was reported...Patient heard that booster shots should be held for 90 days after antiviral treatments. Patient was recovered and does not have any symptoms, and was tested negative for COVID-19...Company comment: This is a spontaneous case concerning a 44-year-old male patient with no reported medical history, who experienced the non-serious unexpected event of COVID-19 (AESI), more

Case_ID	Flags	Narrative
		than 9 months after the administration of second dose of mRNA-1273 vaccine. SARS-CoV-2 test was performed with positive result. According to the genomic test, he had the Omicron variant. The patient was treated with Molpunavir (oral) 400 mg twice a day for 5 days. At the time of the report COVID-19 had resolved. Drug ineffective was also captured as an event. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Appendix 11.28b Lack of Efficacy/Vaccine failure: Fatal case listings-RP

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	SWITZERLAND	COVID-19, Diarrhoea, Dyspnoea, Oxygen saturation decreased, Vaccination failure	86	Female	Asthma(C); Myocardial ischaemia(C); Hypertension(C); Hypothyroidism(C); Small cell lung cancer(C)	CLOPIDOGREL; ESOMEPRAZOLE; EUTHYROX; LISINOPRIL; NEBILET; ZOLPIDEM; SERETIDE; LAXOBERON; PURSANA; ATOZET; KALCIPOS D3; LERCANIDIPINE; FLUIMUCIL; DOMPERIDONE; CO-DAFALGAN; TRAMADOL	4.1(b)	
	AUSTRIA	COVID-19, Vaccination failure	67	Male				3001177; 3000493
	AUSTRIA	COVID-19, Vaccination failure	69	Female				3001939; 3001531
	AUSTRIA	COVID-19, Vaccination failure	79	Male				3002188; 3000493
	AUSTRIA	COVID-19, Vaccination failure	73	Male				3002545; 3001938
	AUSTRIA	COVID-19, Vaccination failure	90	Male				
	FRANCE	Vaccination failure	71	Female	Hypertension(C); Dyslipidaemia(H); Diffuse large B-cell lymphoma(H)			3002616; 214004
	FRANCE	COVID-19, Vaccination failure	80	Male	Alcohol use(H); Arterial disorder(H)			214011
	FRANCE	Vaccination failure	85	Female	Chronic obstructive pulmonary disease(C); Hypertension(C); Type 2 diabetes mellitus(C); Cardiac failure(H); Cerebrovascular accident(H); Anaemia(H); Chronic kidney disease(C)			3004234; 3005834
	SPAIN	Atrial fibrillation, COVID-19 pneumonia, Pneumothorax, Vaccination failure, Vaccine associated enhanced respiratory disease	64	Male	Peripheral venous disease(H); Mixed anxiety and depressive disorder(H)			3001532; 3001177

Appendix 11.28c Lack of Efficacy/Vaccine failure: Fatal case narratives-RP

Case ID	Narrative (Complete)
4.1(b) [redacted]	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Infection despite vaccination), DIARRHOEA (Watery diarrhoea), DYSPNOEA (Dyspnea), OXYGEN SATURATION DECREASED (Desaturation) and COVID-19 (SARS-CoV-2 infection) in an 86-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Asthma, Ischemic heart disease, Hypertension arterial, Hypothyroidism (substituted) and Small cell carcinoma of the lung. Concomitant products included CLOPIDOGREL, ESOMEPRAZOLE, LEVOTHYROXINE SODIUM (EUTHYROX), LISINOPRIL, NEBIVOLOL HYDROCHLORIDE (NEBILET), ZOLPIDEM, FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE (SERETIDE), SODIUM PICOSULFATE (LAXOBERON), FICUS CARICA EXTRACT, SORBITOL (PURSANA), ATORVASTATIN CALCIUM, EZETIMIBE (ATOZET), CALCIUM CARBONATE, COLECALCIFEROL (KALCIPOS D3), LERCANIDIPINE, ACETYLCYSTEINE (FLUIMUCIL), DOMPERIDONE, CODEINE PHOSPHATE HEMIHYDRATE, PARACETAMOL (CO-DAFALGAN) and TRAMADOL for an unknown indication. On 12-Feb-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 18-Mar-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 19-Nov-2021, the patient experienced VACCINATION FAILURE (Infection despite vaccination) (seriousness criteria death, hospitalization and medically significant), DIARRHOEA (Watery diarrhoea) (seriousness criteria death, hospitalization and medically significant), DYSPNOEA (Dyspnea) (seriousness criteria death, hospitalization and medically significant), OXYGEN SATURATION DECREASED (Desaturation) (seriousness criteria death, hospitalization and medically significant) and COVID-19 (SARS-CoV-2 infection) (seriousness criteria death, hospitalization and medically significant). The patient died on 28-Nov-2021. The reported cause of death was infection despite vaccination, SARS-CoV-2 infection, Watery diarrhoea, Dyspnea and desaturation. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Nov-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered VACCINATION FAILURE (Infection despite vaccination), DIARRHOEA (Watery diarrhoea), DYSPNOEA (Dyspnea), OXYGEN SATURATION DECREASED (Desaturation) and COVID-19 (SARS-CoV-2 infection) to be possibly related. It was verbally reported that, dyspnea with desaturation as of 22 November. She was hospitalized on 26.11.2021. In continuous care, treatment of dexamethasone and tocilizumab was introduced. The evolution was unfavorable. This patient experienced SARS-CoV-2 infection approximately 8 months after the second injection of Spikevax Moderna vaccine. The Phase 3 study that allowed the registration of the COVID-19 Vaccine Moderna® vaccine included approximately 30,000 people and showed 94% efficacy of the vaccine, based on the number of symptomatic COVID-19 infections reported in each group; 11 out of 14'134 vaccine cases versus 185 cases out of 14,073 placebo (1). The final analysis of this study demonstrated an overall effectiveness in the prevention of COVID-19 disease of 93.2%. The effectiveness in the prevention of severe disease was 98.2%, and the effectiveness in the prevention of asymptomatic infection starting 14 days after the second injection was 63%. In addition, vaccine effectiveness was consistent across all ethnic and racial groups, age groups and participants with co-morbidities such as chronic lung disease, heart disease, obesity, diabetes, liver failure, or HIV (2). In studies conducted in “real life”, high efficacy of more than 90% was also observed after the second dose (3.4). Company Comment - This regulatory authority case concerns an 86 year old female patient with medical history of hypothyroidism and small cell carcinoma of the lung who experienced the serious unexpected events of vaccination failure, diarrhea, dyspnea, oxygen saturation decreased and COVID-19. The events occurred approximately 8 months after the second dose of mRNA-1273 vaccine, and the outcome was fatal, with death occurring 9 days later. The reported causes of death were infection despite vaccination, SARS-CoV-2 infection, diarrhoea, dyspnea and desaturation. Patient's medical history of hypothyroidism and small cell carcinoma of the lung remains a confounder. The rechal
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 (SARS-CoV-2 infection) and VACCINATION FAILURE (Vaccination failure) in a 67-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3001177 and 3000493) for COVID-19 vaccination.

Case ID	Narrative (Complete)
	No Medical History information was reported. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 22-Apr-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 08-Oct-2021, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criterion death) and VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Oct-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company comment: This is a regulatory authority case concerning a 67-year-old male patient with no medical history reported, who experienced unexpected events of COVID-19 (AESI) and vaccination failure (seriousness criterion death assessed as per Regulatory Authority reporting). The events occurred approximately 5 months 16 days after the administration of second dose of mRNA-1273 vaccine. Clinical course and treatment details were not provided. The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. Very limited information has been provided at this time. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 5-Jan-2022.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and COVID-19 (SARS-CoV-2 infection) in a 69-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3001939 and 3001531) for COVID-19 vaccination. No Medical History information was reported. On 03-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 01-May-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 14-Oct-2021, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death) and COVID-19 (SARS-CoV-2 infection) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Oct-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Company Comment: This case concerns a 69-year-old female patient, with no medical history reported, who experienced the unexpected events of COVID-19 (AESI) and Vaccination failure. The events occurred 5 months and 13 days after the second dose of mRNA-1273 vaccine, and had a fatal outcome, with death occurring. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 05-Jan-2022.

Case ID	Narrative (Complete)
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 10-Jan-2022 and was forwarded to Moderna on 10-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 (SARS-CoV-2 infection) and VACCINATION FAILURE (Vaccination failure) in a 79-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3002188 and 3000493) for COVID-19 vaccination. No Medical History information was reported. On 10-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 18-May-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 09-Oct-2021, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criterion death) and VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Oct-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant products were not provided. Treatment medication were not reported. Company comment: This case concerns a 79-year-old male patient with unknown medical history who experienced fatal unexpected SARS-CoV-2 infection and Vaccination failure approximately five months after the second dose of mRNA-1273. No information regarding death details was disclosed, it is unknown if an autopsy was performed. The patient's advanced age remains major confounder. Based on the current available information, the mRNA-1273 vaccine does not contain a virus capable of causing COVID-19 infection after vaccination, therefore, the causality for COVID-19 is not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 13-Jan-2022 and was forwarded to Moderna on 13-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and COVID-19 (SARS-CoV-2 infection) in a 73-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3002545 and 3001938) for COVID-19 vaccination. No Medical History information was reported. On 23-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 04-Jun-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 05-Nov-2021, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death) and COVID-19 (SARS-CoV-2 infection) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Nov-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was provided. No treatment medication was provided. Company Comment: This regulatory case concerns a 73-year-old male patient with no relevant medical history reported, who experienced the unexpected serious adverse events of special interest of COVID-19 (sars cov2 test positive) and unexpected serious event of vaccination failure which resulted in a fatal outcome, with death occurring 6 months 14 days after the second dose of mRNA-1273 vaccine. Vaccination failure was coded as an additional event as per RA, and was retained as such, having in mind that the patient developed COVID-19 after vaccination with both doses of vaccine. Based on the current available information, the mRNA-1273 vaccine does not contain a virus capable of causing COVID-19 infection after vaccination, therefore, the causality for COVID-19 is not applicable, while the causality for the event of Vaccination failure is assessed as possible. Patients elderly age and infection with covid-19 remains as confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Case ID	Narrative (Complete)
	Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 12-Jan-2022.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 22-Jan-2022 and was forwarded to Moderna on 22-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 (SARS-CoV-2 infection) and VACCINATION FAILURE (Vaccination failure) in a 90-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 28-Feb-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-Mar-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 13-Oct-2021, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criterion death) and VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Oct-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was provided by reporter. No treatment drug was provided by reporter. The report was for a patient/patient. None mail was sent to reporters. Company comment: This case concerns a 90-year-old male patient with no relevant medical history, who experienced the unexpected fatal event of COVID-19 (SARS-COV-2 Infection), vaccination failure was considered as an additional event. The fatal events occurred approximately 6 months 15 days after the second dose of mRNA-1273 (Moderna covid-19 vaccine). The rechallenge was not applicable as events occurred after second dose with a fatal outcome. This patient's advanced age remains a contributory factor to the fatal outcomes. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 01-Mar-2022 and was forwarded to Moderna on 01-Mar-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of VACCINATION FAILURE (Vaccination failure) in a 71-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3002616 and 214004) for COVID-19 vaccination. The patient's past medical history included Dyslipidaemia and Diffuse large B-cell lymphoma. Concurrent medical conditions included Hypertension arterial. On 08-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 20-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On 03-Jan-2022, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). The patient died on 18-Jan-2022. The reported cause of death was sars-cov2 pneumonia. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.

Case ID	Narrative (Complete)
	Concomitant medication of the patient was not reported. No treatment information was provided by the reporter. Company Comment: This regulatory case concerns a 71-year-old, female patient with relevant medical history of Hypertension and Diffuse Large B-Cell Lymphoma, who experienced vaccination failure. The event occurred 5 months, 14 days after administration of the second dose of the Moderna mRNA-1273 vaccine. The patient tested positive for SARS-CoV-2 on 03Jan2022. No further details were provided. The report stated that the patient expired on 18Jan2022 which was 15 days after she tested positive for SARS-CoV-2. It is unknown if an autopsy was performed. However, the reported cause of death was SARS-CoV2 pneumonia. The patient's advanced age (high risk for infections) and medical history of Hypertension and Diffuse Large B-Cell Lymphoma, which are risk factors for COVID-19, remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 30-Mar-2022 and was forwarded to Moderna on 30-Mar-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and COVID-19 (covid-19) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214011) for COVID-19 vaccination. The patient's past medical history included Alcohol use (2-3 glasses/week) and Arteriopathic disease. On 11-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 22-Jan-2022, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death) and COVID-19 (covid-19) (seriousness criterion death). The patient died on 25-Jan-2022. The reported cause of death was pneumopathie covid-19. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No Concomitant Drug details were reported. No Treatment information was provided. Dosage text was reported as D2. Company comment. This fatal regulatory authority case concerns an 80 – year – old male patient with relevant medical history of arteriopathy disease, who experienced the unexpected AESI of COVID-19 approximately 5 months and 11 days after receiving a dose of mRNA-1273, reported as second dose of his COVID – 19 immunization schedules. Vaccination failure was also reported; however, no information regarding the first dose was provided. Death occurred three days after the onset of COVID – 19, and the cause of death was reported as pneumopathy COVID-19. It is unknown if an autopsy was performed. Patient´s age and medical history of arteriopathy disease could be a confounding factor for severe COVID-19 illness. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 05-May-2022 and was forwarded to Moderna on 05-May-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of VACCINATION FAILURE (Failure of vaccination) in an 85-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3004234 and 3005834) for COVID-19 vaccination. The patient's past medical history included Cardiac failure, Stroke and Anaemia. Concurrent medical conditions included Chronic obstructive airways disease, Hypertension arterial, Type 2 diabetes mellitus and Chronic renal failure. On 07-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 2 dosage form. On 07-Oct-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 2 dosage form. On 08-Feb-2022, the patient experienced VACCINATION FAILURE (Failure of vaccination) (seriousness criterion death). The patient died on 09-Apr-2022. The reported cause of death was epileptic seizure. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.

Case ID	Narrative (Complete)
	No concomitant medication were reported. No treatment information was provided by the reporter. Company Comment: This regulatory case concerns an 85-year-old female patient with medical history and concurrent conditions of Cardiac failure, Stroke, Anaemia, Chronic obstructive airways disease, Hypertension arterial, Type 2 diabetes mellitus and Chronic renal failure, who experienced the unexpected serious event of Vaccination failure approximately 4 months and 1 day after receiving second dose of mRNA-1273 vaccine that led to a fatal outcome. Patient died 6 months and 2 days after vaccination (2 months and 1 day from event onset) with cause of death reported as epileptic seizure. No autopsy was provided nor COVID-19 test reported. The interval between the first and second dose of mRNA-1273 vaccines was noted to be 30 days. The advanced age of the patient and the medical history and concurrent conditions of Cardiac failure, Stroke, Anaemia, Chronic obstructive airways disease, Hypertension arterial, Type 2 diabetes mellitus and Chronic renal failure could be considered as contributory factors to the event and fatal outcome. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report. This case was linked to 4.1(b) (E2B Linked Report).
4.1(b)	This case was received via European Medicines Agency (Reference number 4.1(b)) on 24-May-2022 and was forwarded to Moderna on 24-May-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of VACCINATION FAILURE (Vaccination failure), COVID-19 PNEUMONIA (Bilateral pneumonia), ATRIAL FIBRILLATION (Fibrillation), PNEUMOTHORAX (Pneumothorax) and VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (Vaccine associated enhanced respiratory disease) in a 64-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3001532 and 3001177) for COVID-19 vaccination. The patient's past medical history included Chronic venous insufficiency and Anxiodepressive syndrome. On 14-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 13-May-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 26-Dec-2021, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death), COVID-19 PNEUMONIA (Bilateral pneumonia) (seriousness criterion death), ATRIAL FIBRILLATION (Fibrillation) (seriousness criterion death) and VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE (Vaccine associated enhanced respiratory disease) (seriousness criterion death). On 01-Jan-2022, the patient experienced PNEUMOTHORAX (Pneumothorax) (seriousness criterion death). The patient died on 20-Jan-2022. The reported cause of death was covid-19 pneumonia (10084380). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Dec-2021, SARS-CoV-2 test positive: positive (Positive) Positive. On 26-Dec-2021, Blood test: abnormal Blood count at admission: Hb 14.2, hto 41. Leukocytes 6830.83% Gr. Lymphocytes 440 Platelets 171000. - Coagulation at admission: INR 1.19 - D-dimer: 962 - Biochemistry: Glu 127, urea 38, Cr 0.94, FG 85, albumin 4, LDH 276, GOT 24, GPT 17 - PCT at admission: 0.17 - PCR at admission 195 - Tp I 15.85 - ProBNP: 1900 - GAB: ph 7.48, pCO2 33, Po2 51, Sat 89%. On 26-Dec-2021, Chest X-ray: bilateral infiltrates patched in tarnished glass bilateral infiltrates patched in tarnished glass. On 26-Dec-2021, Electrocardiogram: fa at 120 bpm (after taking bisoprolol 2.5 and afe FA at 120 bpm (after taking bisoprolol 2.5 and afebryl, FA at 100 bpm). On 28-Dec-2021, Chest X-ray: worsening worsening with respect to previous RX with progression of alveolo-interstitial infiltrates in both HT.. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Company comment: This fatal regulatory authority case concerns 64-year-old male patient, with no relevant medical history, who experienced the unexpected, serious (due to death) events of VACCINATION FAILURE, PNEUMOTHORAX and VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE; and the unexpected, serious (due to death) AESIs of COVID-19 PNEUMONIA and ATRIAL FIBRILLATION. The events VACCINATION FAILURE, VACCINE ASSOCIATED ENHANCED RESPIRATORY DISEASE, COVID-19 PNEUMONIA and ATRIAL FIBRILLATION occurred 7 months after the second dose of mRNA-1273 vaccine; a week later PNEUMOTHORAX developed. He died twenty days later. The cause of death was covid-19 pneumonia. A positive SARS-CoV-2 test was performed and the chest X-ray showed initially bilateral infiltrates patched in tarnished glass, and two days later showed worsening with progression of alveolo-interstitial infiltrates. It is unknown if an autopsy was

Case ID	Narrative (Complete)
	performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event´s seriousness assessed as per Regulatory Authority's report.

Appendix 11.28d Lack of Efficacy/Vaccine failure: Fatal case listings after Booster

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	FRANCE	Vaccination failure	53.00	Male	Heart transplant	CICLOSPORINE; CELLSEPT	4.1(b)	214004; 3002543; 3001945
4.1(b)	UNITED KINGDOM	COVID-19, Ruptured cerebral aneurysm	76.00	Female			4.1(b)	000014A
4.1(b)	SPAIN	COVID-19 pneumonia, Dyspnoea, Vaccination failure	68.00	Male	Type 1 diabetes mellitus(C); Solid organ transplant; Chronic kidney disease(C); Angina pectoris(H); Myocardial ischaemia(H); COVID-19(H)		4.1(b)	3005790; 300042722; 3000494
4.1(b)	ESTONIA	COVID-19, Vaccination failure	84.00	Female	Osteoporosis(C); Glaucoma(C)	ATORVASTATIN; VITAMIN D 3; CALCIUM	4.1(b)	3005243

Appendix 11.28e Lack of Efficacy/Vaccine failure: Fatal case narratives after Booster

Appendix 11.28e Lack of Efficacy/Vaccine failure: literature Search Vaccine Inefficacy cases

Case ID	Narrative (Complete)
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 11-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) in a 53-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214004, 3002543 and 3001945) for COVID-19 vaccination. The patient's past medical history included Heart transplant. Concomitant products included CICLOSPORINE and MYCOPHENOLATE MOFETIL (CELLSEPT) for an unknown indication. On 12-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 21-Jun-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 20-Jul-2021, received third dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 10-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criteria death and hospitalization). The patient died on 16-Dec-2021. The reported cause of death was cardiopulmonary arrest on major hypovolemia and massive left pleural effusion. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment medications were reported. Company Comment: This is a regulatory case concerning a 53-year-old male patient with medical history of heart transplant and immunosuppressive therapy, who experienced the serious unexpected fatal event of vaccination failure. The event occurred 4 months 21 days after the third dose of mRNA-1273 vaccine administration. Causality was conservatively assessed as related to the product administration. The rechallenge was not applicable since the event occurred after the third dose. The vaccination dose 1 and dose 2 were administered 41 days apart and the diagnosis of COVID infection was not reported; therefore, the event of vaccination failure does not meet two LOE criteria. The medical history of heart transplant with Immunosuppressive therapy considered as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 10-Jan-2022.
4.1(b) [redacted]	This case was received via United Kingdom MHRA (Reference number: 4.1(b) [redacted]) on 23-Jan-2022 and was forwarded to Moderna on 23-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (SARS-CoV-2 infection) and RUPTURED CEREBRAL ANEURYSM (Intracranial hemorrhage ruptured aneurysm) in a 76-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000014A) for an unknown indication. No Medical History information was reported. On 08-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 23-Dec-2021, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criteria death and life threatening) and RUPTURED CEREBRAL ANEURYSM (Intracranial hemorrhage ruptured aneurysm) (seriousness criteria death and life threatening). The patient died on 25-Dec-2021. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Dec-2021, SARS-CoV-2 test: positive (Positive) Positive. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. No concomitant products were reported. No treatment information was reported by the reporter.

Case ID	Narrative (Complete)
	N/a no underlying illnesses Unsure if patient had symptoms associated with COVID-19. It was reported that her mother tested positive for COVID on the 23-Dec-2021, when she was tested in the hospital as she was brought in with a ruptured aneurysm. However, test results sent to her phone said she was negative. Patient was not enrolled in clinical trial. Patient report did not relate to possible inflammation of the heart (myocarditis or pericarditis). COMPANY COMMENT : This is a regulatory case concerning a 76 years old female patient with no medical history reported. who experienced the unexpected serious AESI event of Covid-19 and unexpected serious event of ruptured cerebral aneurysm. The events occurred 15 days after the third dose of mRNA-1273 vaccine. The outcome of the events are fatal. SARS -COV-2 test was positive. The patient died on 25-Dec-2021. It is unknown if an autopsy was performed. It was reported that her mother tested positive for COVID on the 23-Dec-2021, when she was tested in the hospital as she was brought in with a ruptured aneurysm. However, test results sent to her phone said she was negative. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authority´s report due to death and life threating.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 07-Apr-2022 and was forwarded to Moderna on 07-Apr-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of VACCINATION FAILURE (Vaccine failure), DYSPNOEA (Dyspnoea) and COVID-19 PNEUMONIA (COVID-19 pneumonia) in a 68-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005790, 300042722 and 3000494) for COVID-19 vaccination. The patient's past medical history included Effort angina, Ischaemic heart disease, COVID-19 (COVID-19 has passed) and Solid organ transplant (RENAL) in 2017. Concurrent medical conditions included Type I diabetes mellitus and Chronic renal failure (DIALYSIS DUE TO DIABETIC NEPHROPATHY). On 08-Mar-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Apr-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 17-Sep-2021, received third dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 14-Dec-2021, the patient experienced VACCINATION FAILURE (Vaccine failure) (seriousness criteria death and hospitalization) and DYSPNOEA (Dyspnoea) (seriousness criteria death and hospitalization). On 24-Dec-2021, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death and hospitalization). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Dec-2021, SARS-CoV-2 test positive: positive (Positive) Positive. On 24-Dec-2021, Chest X-ray: bilateral infiltrate (abnormal) bilateral infiltrate. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication details was reported. No treatment medication details was reported. Company Comment: This regulatory authority case concerns a 68-year-old male patient, with relevant medical history of Effort angina, Ischemic heart disease, COVID-19, Solid organ transplant (RENAL), Type I diabetes mellitus and Chronic renal failure, who experienced the unexpected serious events of Vaccination failure, Dyspnea and the AESI COVID-19 pneumonia. The events occurred approximately 3 months after receiving the third dose of mRNA-1273 Vaccine requiring hospitalization. Diagnostic test showed SARS-CoV-2 test positive and Chest X-ray with bilateral infiltrates. No treatment information was provided. The events led to a fatal outcome. It is unknown if an autopsy was performed. The patient's medical history of Effort angina, Ischemic heart disease, COVID-19, Solid organ transplant (RENAL), Type I diabetes mellitus and Chronic renal failure, remain as confounders for the occurrence of the events. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes:

Case ID	Narrative (Complete)
	On 07-Apr-2022: Translation document received on 10-Apr-2022 contains translated event verbatim with no new information.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 16-Jun-2022 and was forwarded to Moderna on 16-Jun-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 (COVID-19) and VACCINATION FAILURE (Vaccination failure) in an 84-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005243) for COVID-19 vaccination. Concurrent medical conditions included Osteoporosis and Glaucoma. Concomitant products included ATORVASTATIN, COLECALCIFEROL (VITAMIN D 3) and CALCIUM for an unknown indication. On 23-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 29-May-2022, the patient experienced COVID-19 (COVID-19) (seriousness criteria death and hospitalization) and VACCINATION FAILURE (Vaccination failure) (seriousness criteria death and hospitalization). The reported cause of death was extensive myocardial infarction associated with covid and Vaccination failure. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. It was reported that serious vaccine ineffectiveness report. However, the booster dose was done 6 months earlier, the effectiveness might have been reduced. No treatment medications were provided. Company comment. This fatal regulatory case concerns an 84 – year – old, female patient with no relevant medical history, who experienced the unexpected, serious (due to criteria of death and hospitalization) AESI of COVID – 19 that occurred approximately 6 months after receiving a booster dose of mRNA-1273. Vaccination failure was also reported, however, no information about previous vaccination schedule was provided. It was unspecified if an autopsy was performed. The report stated that the patient died by extensive myocardial infarction associated with COVID. Death date was not reported. No further clinical information was provided for medical reviewing. Patient´s age could be a confounding factor for serious illness from COVID-19 and for myocardial infarction. Patient´s concomitant medication atorvastatin could be suggestive of underlying hyperlipidemia, risk factor for myocardial infarction. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Appendix 11.28f Lack of Efficacy/Vaccine failure: Scientific abstracts

PMID	Title	Link	Type of vaccine	Class of Vaccine	Type of study (Case Report/Cohort or any other study type)	About Infection	Relevant	Comment (Only for Relevant ones)	Authors	Citation	First Author	Journal/Book	Publication Year	Create Date	PMCID	NIHMS ID	DOI
34800687	Real-world effectiveness of COVID-19 vaccines: a literature review and meta-analysis	https://pubmed.ncbi.nlm.nih.gov/34800687/	Pfizer-BioNTech vaccine,Moderna vaccine,CoronaVac vaccine	mRNA Vaccine	other study type	N/A	NO	N/A	Zheng C, Shao W, Chen X, Zhang B, Wang G, Zhang W.	Int J Infect Dis. 2022 Jan;114:252-260. doi: 10.1016/j.ijid.2021.11.009. Epub 2021 Nov 17.	Zheng C	Int J Infect Dis	2022	11/20/2021	PMC8595975		10.1016/j.ijid.2021.11.009
35297591	Efficacy of a Fourth Dose of Covid-19 mRNA Vaccine against Omicron	https://pubmed.ncbi.nlm.nih.gov/35297591/	Pfizer-BioNTech vaccine,Moderna vaccine	mRNA Vaccine	other study type	N/A	NO	N/A	Regev-Yochay G, Gonen T, Gilboa M, Mandelboim M, Indenbaum V, Amit S, Meltzer L, Asraf K, Cohen C, Fluss R, Biber A, Nemet I, Kliker L, Joseph G, Doolman R, Mendelson E, Freedman LS, Harats D, Kreiss Y, Lustig Y.	N Engl J Med. 2022 Apr 7;386(14):1377-1380. doi: 10.1056/NEJMc2202542. Epub 2022 Mar 16.	Regev-Yochay G	N Engl J Med	2022	3/17/2022	PMC9006792		10.1056/NEJMc2202542
34965337	Third BNT162b2 Vaccination Neutralization of SARS-CoV-2 Omicron Infection	https://pubmed.ncbi.nlm.nih.gov/34965337/	Pfizer–BioNTech	mRNA Vaccine	N/A	N/A	NO	N/A	Nemet I, Kliker L, Lustig Y, Zuckerman N, Erster O, Cohen C, Kreiss Y, Alroy-Preis S, Regev-Yochay G, Mendelson E, Mandelboim M.	N Engl J Med. 2022 Feb 3;386(5):492-494. doi: 10.1056/NEJMc2119358. Epub 2021 Dec 29.	Nemet I	N Engl J Med	2022	12/29/2021	PMC8823651		10.1056/NEJMc2119358
35249272	Covid-19 Vaccine Effectiveness against the Omicron (B.1.1.529) Variant	https://pubmed.ncbi.nlm.nih.gov/35249272/	Pfizer–BioNTech, AstraZeneca, or Moderna vaccine	ChAdOx1 nCoV-19,mRNA Vaccine,BNT162b2	other study type	N/A	NO	N/A	Andrews N, Stowe J, Kirsebom F, Toffa S, Rickeard T, Gallagher E, Gower C, Kall M, Groves N, O'Connell AM, Simons D, Blomquist PB, Zaidi A, Nash S, Iwani Binti Abdul Aziz N, Thelwall S, Dabrera G, Myers R, Amirthalingam G, Gharbia S, Barrett JC, Elson R, Ladhani SN, Ferguson N, Zambon M, Campbell CNJ, Brown K, Hopkins S, Chand M, Ramsay M, Lopez Bernal J.	N Engl J Med. 2022 Apr 21;386(16):1532-1546. doi: 10.1056/NEJMoa2119451. Epub 2022 Mar 2.	Andrews N	N Engl J Med	2022	3/6/2022	PMC8908811		10.1056/NEJMoa2119451
34598660	The COVID-19 pandemic: viral variants and vaccine efficacy	https://pubmed.ncbi.nlm.nih.gov/34598660/	Pfizer-BioNTech, Moderna, AstraZeneca and Janssen	mRNA Vaccine,viral vector vaccine,COVID-19 vaccines	N/A	N/A	NO	N/A	Ciotti M, Ciccozzi M, Pieri M, Bernardini S.	Crit Rev Clin Lab Sci. 2022 Jan;59(1):66-75. doi: 10.1080/10408363.2021.1979462. Epub 2021 Oct 1.	Ciotti M	Crit Rev Clin Lab Sci	2022	10/2/2021			10.1080/10408363.2021.1979462
35202601	Duration of effectiveness of vaccines against SARS-CoV-2 infection and COVID-19 disease: results of a systematic review and meta-regression	https://pubmed.ncbi.nlm.nih.gov/35202601/	Pfizer-BioNTech-Comirnaty,Moderna,Janssen COVID-19 vaccine,AstraZeneca-Vaxzevria	mRNA vaccine,26.COV2.S covid-19 vaccine,Viral vector	other study type	N/A	NO	N/A	Feikin DR, Higdon MM, Abu-Raddad LJ, Andrews N, Araos R, Goldberg Y, Groome MJ, Huppert A, O'Brien KL, Smith PG, Wilder-Smith A, Zeger S, Deloria Knoll M, Patel MK.	Lancet. 2022 Mar 5;399(10328):924-944. doi: 10.1016/S0140-6736(22)00152-0. Epub 2022 Feb 23.	Feikin DR	Lancet	2022	2/24/2022	PMC8863502		10.1016/S0140-6736(22)00152-0
34812653	Immune correlates analysis of the mRNA-1273 COVID-19 vaccine efficacy clinical trial	https://pubmed.ncbi.nlm.nih.gov/34812653/	Moderna COVID-19 vaccine), other COVID-19 vaccines	mRNA-1273 SARS-CoV-2 Vaccine	Clinical trails	N/A	NO	N/A	Gilbert PB, Montefiori DC, McDermott AB, Fong Y, Benkeser D, Deng W, Zhou H, Houchens CR, Martins K, Jayashankar L, Castellino F, Flach B, Lin BC, O'Connell S, McDanal C, Eaton A, Sarzotti-Kelsoe M, Lu Y, Yu C, Borate B, van der Laan LWP, Hejazi NS, Huynh C, Miller J, El Sahly HM, Baden LR, Baron M, De La Cruz L, Gay C, Kalams S, Kelley CF, Andrasik MP, Kublin JG, Corey L, Neuzil KM, Carpp LN, Pajon R, Follmann D, Donis RO, Koup RA; Immune Assays Team§; Moderna, Inc. Team§; Coronavirus Vaccine Prevention Network (CoVPN)/Coronavirus Efficacy (COVE) Team§; United States Government (USG)/CoVPN Biostatistics Team§.	Science. 2022 Jan 7;375(6576):43-50. doi: 10.1126/science.abm3425. Epub 2021 Nov 23.	Gilbert PB	Science	2022	11/23/2021	PMC9017870	NIHMS1800809	10.1126/science.abm3425
34726239	Effectiveness of a Third Dose of BNT162b2 mRNA Vaccine	https://pubmed.ncbi.nlm.nih.gov/34726239/	Pfizer-BioNTech vaccine	mRNA BNT162b2	other study type	N/A	NO	N/A	Saciuk Y, Kertes J, Shamir Stein N, Ekka Zohar A.	J Infect Dis. 2022 Jan 5;225(1):30-33. doi: 10.1093/infdis/jiab556.	Saciuk Y	J Infect Dis	2022	11/2/2021	PMC8689889		10.1093/infdis/jiab556
35060999	Association Between 3 Doses of mRNA COVID-19 Vaccine and Symptomatic Infection Caused by the SARS-CoV-2 Omicron and Delta Variants	https://pubmed.ncbi.nlm.nih.gov/35060999/	Pfizer-BioNTech or Moderna vaccine	BNT162b2 ,mRNA-1273	retrospective test-negative case-control analysis	N/A	NO	N/A	Accorsi EK, Britton A, Fleming-Dutra KE, Smith ZR, Shang N, Derado G, Miller J, Schrag SJ, Verani JR.	JAMA. 2022 Feb 15;327(7):639-651. doi: 10.1001/jama.2022.0470.	Accorsi EK	JAMA	2022	1/21/2022	PMC8848203		10.1001/jama.2022.0470
35320659	Safety and Efficacy of a Third Dose of BNT162b2 Covid-19 Vaccine	https://pubmed.ncbi.nlm.nih.gov/35320659/	Pfizer-BioNTech	BNT162b2 Covid-19 Vaccine	other study type	N/A	NO	N/A	Moreira ED Jr, Kitchin N, Xu X, Dychter SS, Lockhart S, Gurtman A, Perez JL, Zerbini C, Dever ME, Jennings TW, Brandon DM, Cannon KD, Koren MJ, Denham DS, Berhe M, Fitz-Patrick D, Hammitt LL, Klein NP, Nell H, Keep G, Wang X, Koury K, Swanson KA, Cooper D, Lu C, Türeci Ö, Lagkadinou E, Tresnan DB, Dormitzer PR, Şahin U, Gruber WC, Jansen KU; C4591031 Clinical Trial Group.	N Engl J Med. 2022 May 19;386(20):1910-1921. doi: 10.1056/NEJMoa2200674. Epub 2022 Mar 23.	Moreira ED Jr	N Engl J Med	2022	3/23/2022	PMC9006787		10.1056/NEJMoa2200674
34735261	SARS-CoV-2 vaccine protection and deaths among US veterans during 2021	https://pubmed.ncbi.nlm.nih.gov/34735261/	Pfizer-BioNTech and Moderna and the JNJ-78436735 (Janssen)	BNT162b2, mRNA-1273, viral vector vaccine	other study type	N/A	NO	N/A	Cohn BA, Cirillo PM, Murphy CC, Krigbaum NY, Wallace AW.	Science. 2022 Jan 21;375(6578):331-336. doi: 10.1126/science.abm0620. Epub 2021 Nov 4.	Cohn BA	Science	2022	11/4/2021			10.1126/science.abm0620
34965358	Effectiveness of BNT162b2 Vaccine against Omicron Variant in South Africa	https://pubmed.ncbi.nlm.nih.gov/34965358/	Pfizer–BioNTech	BNT162b2 MRNA Vaccine	other study type	N/A	NO	N/A	Collie S, Champion J, Moultrie H, Bekker LG, Gray G.	N Engl J Med. 2022 Feb 3;386(5):494-496. doi: 10.1056/NEJMc2119270. Epub 2021 Dec 29.	Collie S	N Engl J Med	2022	12/29/2021	PMC8757569		10.1056/NEJMc2119270
35021004	Effectiveness of BNT162b2 Vaccine against Critical Covid-19 in Adolescents	https://pubmed.ncbi.nlm.nih.gov/35021004/	Pfizer-Biontech COVID-19 Vaccine	BNT162b2 MRNA Vaccine	case–control study report	N/A	NO	N/A	Olson SM, Newhams MM, Halasa NB, Price AM, Boom JA, Sahni LC, Pannaraj PS, Irby K, Walker TC, Schwartz SP, Maddux AB, Mack EH, Bradford TT, Schuster JE, NoFziger RA, Cameron MA, Chiotos K, Cullimore ML, Gertz SJ, Levy ER, Kong M, Cvijanovich NZ, Staat MA, Kamidani S, Chatani BM, Bhumbra SS, Bline KE, Gaspers MG, Hobbs CV, Heidemann SM, Maamari M, Flori HR, Hume JR, Zinter MS, Michelson KN, Zambrano LD, Campbell AP, Patel MM, Randolph AG; Overcoming Covid-19 Investigators.	N Engl J Med. 2022 Feb 24;386(8):713-723. doi: 10.1056/NEJMoa2117995. Epub 2022 Jan 12.	Olson SM	N Engl J Med	2022	1/12/2022	PMC8781318		10.1056/NEJMoa2117995
35172051	Protection against SARS-CoV-2 after Covid-19 Vaccination and Previous Infection	https://pubmed.ncbi.nlm.nih.gov/35172051/	Pfizer-BioNTech,AstraZeneca	BNT162b2 vaccine, ChAdOx1 nCoV-19 vaccine	Cohort studies	Yes	NO	N/A	Hall V, Foulkes S, Insalata F, Kirwan P, Saei A, Atti A, Wellington E, Khawam J, Munro K, Cole M, Tranquillini C, Taylor-Kerr A, Hettiarachchi N, Calbraith D, Sajedi N, Milligan I, Themistocleous Y, Corrigan D, Cromey L, Price L, Stewart S, de Lacy E, Norman C, Linley E, Otter AD, Semper A, Hewson J, D'Arcangelo S, Chand M, Brown CS, Brooks T, Islam J, Charlett A, Hopkins S; SIREN Study Group.	N Engl J Med. 2022 Mar 31;386(13):1207-1220. doi: 10.1056/NEJMoa2118691. Epub 2022 Feb 16.	Hall V	N Engl J Med	2022	2/16/2022	PMC8908850		10.1056/NEJMoa2118691
35021002	Duration of Protection against Mild and Severe Disease by Covid-19 Vaccines	https://pubmed.ncbi.nlm.nih.gov/35021002/	Pfizer-BioNTech,AstraZeneca	ChAdOx1-S (ChAdOx1 nCoV-19) and BNT162b2 vaccines	other study type	Yes	NO	N/A	Andrews N, Tessier E, Stowe J, Gower C, Kirsebom F, Simmons R, Gallagher E, Thelwall S, Groves N, Dabrera G, Myers R, Campbell CNJ, Amirthalingam G, Edmunds M, Zambon M, Brown K, Hopkins S, Chand M, Ladhani SN, Ramsay M, Lopez Bernal J.	N Engl J Med. 2022 Jan 27;386(4):340-350. doi: 10.1056/NEJMoa2115481. Epub 2022 Jan 12.	Andrews N	N Engl J Med	2022	1/12/2022	PMC8781262		10.1056/NEJMoa2115481
34727554	Scientific Evidence Supporting Coronavirus Disease 2019 (COVID-19) Vaccine Efficacy and Safety in People Planning to Conceive or Who Are Pregnant or Lactating	https://pubmed.ncbi.nlm.nih.gov/34727554/	Pfizer-BioNTech, Moderna, and Johnson & Johnson-Janssen	MRNA Covid-19 vaccine	N/A	N/A	NO	N/A	Girardi G, Bremer AA.	Obstet Gynecol. 2022 Jan 1;139(1):3-8. doi: 10.1097/AOG.0000000000004636.	Girardi G	Obstet Gynecol	2022	11/2/2021	PMC8678336	NIHMS1750645	10.1097/AOG.0000000000004636
35020982	Effectiveness of Covid-19 Vaccines over a 9-Month Period in North Carolina	https://pubmed.ncbi.nlm.nih.gov/35020982/	Pfizer-BioNTech, Moderna, and Johnson & Johnson-Janssen	BNT162b2 , mRNA-1273 , and Ad26.COV2.S vaccines	Other study type(Observational studies)	N/A	NO	N/A	Lin DY, Gu Y, Wheeler B, Young H, Holloway S, Sunny SK, Moore Z, Zeng D.	N Engl J Med. 2022 Mar 10;386(10):933-941. doi: 10.1056/NEJMoa2117128. Epub 2022 Jan 12.	Lin DY	N Engl J Med	2022	1/12/2022	PMC8781317		10.1056/NEJMoa2117128

PMID	Title	Link	Type of vaccine	Class of Vaccine	Type of study (Case Report/Cohort or any other study type)	About Infection	Relevant	Comment (Only for Relevant ones)	Authors	Citation	First Author	Journal/Book	Publication Year	Create Date	PMCID	NIHMS ID	DOI
35085224	Effectiveness of a Third Dose of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance - VISION Network, 10 States, August 2021-January 2022	https://pubmed.ncbi.nlm.nih.gov/35085224/	Pfizer-BioNTech COVID-19 vaccine	MRNA vaccine, BNT162b2	N/A	N/A	NO	N/A	Thompson MG, Natarajan K, Irving SA, Rowley EA, Griggs EP, Gaglani M, Klein NP, Grannis SJ, DeSilva MB, Stenehjem E, Reese SE, Dickerson M, Naleway AL, Han J, Konatham D, McEvoy C, Rao S, Dixon BE, Dascomb K, Lewis N, Levy ME, Patel P, Liao IC, Kharbanda AB, Barron MA, Fadel WF, Grisel N, Goddard K, Yang DH, Wondimu MH, Murthy K, Valvi NR, Arndorfer J, Fireman B, Dunne MM, Embi P, Azziz-Baumgartner E, Zerbo O, Bozio CH, Reynolds S, Ferdinands J, Williams J, Link-Gelles R, Schrag SJ, Verani JR, Ball S, Ong TC.	MMWR Morb Mortal Wkly Rep. 2022 Jan 21;71(4):139-145. doi: 10.15585/mmwr.mm7104e3.	Thompson MG	MMWR Morb Mortal Wkly Rep	2022	1/27/2022			10.15585/mmwr.mm7104e3
35172072	Effectiveness of the BNT162b2 Vaccine after Recovery from Covid-19	https://pubmed.ncbi.nlm.nih.gov/35172072/	Pfizer–BioNTech COVID-19 vaccine	BNT162b2 Vaccine	Retrospective cohort study	N/A	NO	N/A	Hammerman A, Sergienko R, Friger M, Beckenstein T, Peretz A, Netzer D, Yaron S, Arbel R.	N Engl J Med. 2022 Mar 31;386(13):1221-1229. doi: 10.1056/NEJMoa2119497. Epub 2022 Feb 16.	Hammerman A	N Engl J Med	2022	2/16/2022	PMC8908846		10.1056/NEJMoa2119497
34942066	Comparative Effectiveness of BNT162b2 and mRNA-1273 Vaccines in U.S. Veterans	https://pubmed.ncbi.nlm.nih.gov/34942066/	Pfizer–BioNTech,Moderna vaccine	BNT162b2 and mRNA-1273 Vaccines	N/A	Yes	NO	N/A	Dickerman BA, Gerlovin H, Madenci AL, Kurgansky KE, Ferolito BR, Figueroa Muñiz MJ, Gagnon DR, Gaziano JM, Cho K, Casas JP, Hernán MA.	N Engl J Med. 2022 Jan 13;386(2):105-115. doi: 10.1056/NEJMoa2115463. Epub 2021 Dec 1.	Dickerman BA	N Engl J Med	2022	12/23/2021	PMC8693691		10.1056/NEJMoa2115463
35353976	BNT162b2 Protection against the Omicron Variant in Children and Adolescents	https://pubmed.ncbi.nlm.nih.gov/35353976/	Pfizer–BioNTech	BNT162b2 messenger RNA vaccine	N/A	N/A	NO	N/A	Price AM, Olson SM, Newhams MM, Halasa NB, Boom JA, Sahni LC, Pannaraj PS, Irby K, Bline KE, Maddux AB, Nofziger RA, Cameron MA, Walker TC, Schwartz SP, Mack EH, Smallcomb L, Schuster JE, Hobbs CV, Kamidani S, Tarquinio KM, Bradford TT, Levy ER, Chiotos K, Bhumbra SS, Cvijanovich NZ, Heidemann SM, Cullimore ML, Gertz SJ, Coates BM, Staat MA, Zinter MS, Kong M, Chatani BM, Hume JR, Typpo KV, Maamari M, Flori HR, Tenforde MW, Zambrano LD, Campbell AP, Patel MM, Randolph AG; Overcoming Covid-19 Investigators.	N Engl J Med. 2022 May 19;386(20):1899-1909. doi: 10.1056/NEJMoa2202826. Epub 2022 Mar 30.	Price AM	N Engl J Med	2022	3/30/2022	PMC9006785		10.1056/NEJMoa2202826
34986328	COVID-19 mRNA booster vaccines elicit strong protection against SARS-CoV-2 Omicron variant in patients with cancer	https://pubmed.ncbi.nlm.nih.gov/34986328/	Moderna or Pfizer	mRNA vaccine Or BNT162b2	N/A	N/A	No	N/A	Zeng C, Evans JP, Chakravarthy K, Qu P, Reisinger S, Song NJ, Rubinstein MP, Shields PG, Li Z, Liu SL.	Cancer Cell. 2022 Feb 14;40(2):117-119. doi: 10.1016/j.ccell.2021.12.014. Epub 2021 Dec 30.	Zeng C	Cancer Cell	2022	1/5/2022	PMC8716174		10.1016/j.ccell.2021.12.014
35025852	Effectiveness of BNT162b2 (Pfizer-BioNTech) mRNA Vaccination Against Multisystem Inflammatory Syndrome in Children Among Persons Aged 12-18 Years - United States, July-December 2021	https://pubmed.ncbi.nlm.nih.gov/35025852/	Pfizer-BioNTech	BNT162b2 mRNA	Other study type	N/A	No	N/A	Zambrano LD, Newhams MM, Olson SM, Halasa NB, Price AM, Boom JA, Sahni LC, Kamidani S, Tarquinio KM, Maddux AB, Heidemann SM, Bhumbra SS, Bline KE, Nofziger RA, Hobbs CV, Bradford TT, Cvijanovich NZ, Irby K, Mack EH, Cullimore ML, Pannaraj PS, Kong M, Walker TC, Gertz SJ, Michelson KN, Cameron MA, Chiotos K, Maamari M, Schuster JE, Orzel AO, Patel MM, Campbell AP, Randolph AG; Overcoming COVID-19 Investigators.	MMWR Morb Mortal Wkly Rep. 2022 Jan 14;71(2):52-58. doi: 10.15585/mmwr.mm7102e1.	Zambrano LD	MMWR Morb Mortal Wkly Rep	2022	1/13/2022	PMC8757620		10.15585/mmwr.mm7102e1
35263534	Effect of mRNA Vaccine Boosters against SARS-CoV-2 Omicron Infection in Qatar	https://pubmed.ncbi.nlm.nih.gov/35263534/	Pfizer-BioNTech and Moderna	mRNA Vaccine,BNT162b2	Retrospective cohort studies	Yes	No	N/A	Abu-Raddad LJ, Chemaitelly H, Ayoub HH, AlMukdad S, Yassine HM, Al-Khatib HA, Smatti MK, Tang P, Hasan MR, Coyle P, Al-Kanaani Z, Al-Kuwari E, Jeremijenko A, Kaleeckal AH, Latif AN, Shaik RM, Abdul-Rahim HF, Nasrallah GK, Al-Kuwari MG, Butt AA, Al-Romaihi HE, Al-Thani MH, Al-Khal A, Bertollini R.	N Engl J Med. 2022 May 12;386(19):1804-1816. doi: 10.1056/NEJMoa2200797. Epub 2022 Mar 9.	Abu-Raddad LJ	N Engl J Med	2022	3/9/2022	PMC8929389		10.1056/NEJMoa2200797
35544369	Evaluation of mRNA-1273 Covid-19 Vaccine in Children 6 to 11 Years of Age	https://pubmed.ncbi.nlm.nih.gov/35544369/	Moderna Vaccine	mRNA-1273	Other study type	N/A	No	N/A	Creech CB, Anderson E, Berthaud V, Yildirim I, Atz AM, Melendez Baez I, Finkelstein D, Pickrell P, Kirstein J, Yut C, Blair R, Clifford RA, Dunn M, Campbell JD, Montefiori DC, Tomassini JE, Zhao X, Deng W, Zhou H, Ramirez Schrempp D, Hautzinger K, Girard B, Slobod K, McPhee R, Pajon R, Das R, Miller JM, Schnyder Ghamloush S; KidCOVE Study Group.	N Engl J Med. 2022 May 26;386(21):2011-2023. doi: 10.1056/NEJMoa2203315. Epub 2022 May 11.	Creech CB	N Engl J Med	2022	5/11/2022	PMC9127699		10.1056/NEJMoa2203315
35239634	Effectiveness of COVID-19 Pfizer-BioNTech BNT162b2 mRNA Vaccination in Preventing COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Nonimmunocompromised Children and Adolescents Aged 5-17 Years - VISION Network, 10 States, April 2021-January 2022	https://pubmed.ncbi.nlm.nih.gov/35239634/	Pfizer-BioNTech	BNT162b2 mRNA Vaccine	N/A	Yes	No	N/A	Klein NP, Stockwell MS, Demarco M, Gaglani M, Kharbanda AB, Irving SA, Rao S, Grannis SJ, Dascomb K, Murthy K, Rowley EA, Dalton AF, DeSilva MB, Dixon BE, Natarajan K, Stenehjem E, Naleway AL, Lewis N, Ong TC, Patel P, Konatham D, Embi PJ, Reese SE, Han J, Grisel N, Goddard K, Barron MA, Dickerson M, Liao IC, Fadel WF, Yang DH, Arndorfer J, Fireman B, Griggs EP, Valvi NR, Hallowell C, Zerbo O, Reynolds S, Ferdinands J, Wondimu MH, Williams J, Bozio CH, Link-Gelles R, Azziz-Baumgartner E, Schrag SJ, Thompson MG, Verani JR.	MMWR Morb Mortal Wkly Rep. 2022 Mar 4;71(9):352-358. doi: 10.15585/mmwr.mm7109e3.	Klein NP	MMWR Morb Mortal Wkly Rep	2022	3/3/2022	PMC8893336		10.15585/mmwr.mm7109e3
35061702	Vaccines to prevent COVID-19: A living systematic review with Trial Sequential Analysis and network meta-analysis of randomized clinical trials	https://pubmed.ncbi.nlm.nih.gov/35061702/	Unknown	mRNA vaccines	Other study type	N/A	No	N/A	Korang SK, von Rohden E, Veroniki AA, Ong G, Ngalamika O, Siddiqui F, Juul S, Nielsen EE, Feinberg JB, Petersen JJ, Legart C, Kokogho A, Maagaard M, Klingenberg S, Thabane L, Bardach A, Ciapponi A, Thomsen AR, Jakobsen JC, Gluud C.	PLoS One. 2022 Jan 21;17(1):e0260733. doi: 10.1371/journal.pone.0260733. eCollection 2022.	Korang SK	PLoS One	2022	1/21/2022	PMC8782520		10.1371/journal.pone.0260733
35006256	Association of a Third Dose of BNT162b2 Vaccine With Incidence of SARS-CoV-2 Infection Among Health Care Workers in Israel	https://pubmed.ncbi.nlm.nih.gov/35006256/	Pfizer-BioNTech	BNT162b2	prospective cohort study	Yes	No	N/A	Spitzer A, Angel Y, Marudi O, Zeltser D, Saiag E, Goldshmidt H, Goldiner I, Stark M, Halutz O, Gamzu R, Slobodkin M, Amrami N, Feigin E, Elbaz M, Furman M, Bronstein Y, Chikly A, Eshkol A, Furer V, Mayer T, Meijer S, Melloul A, Mizrahi M, Yakubovsky M, Rosenberg D, Safir A, Spitzer L, Taleb E, Elkayam O, Silberman A, Eviatar T, Elalouf O, Levinson T, Pozyuchenko K, Itzhaki-Alfia A, Sprecher E, Ben-Ami R, Henig O.	JAMA. 2022 Jan 25;327(4):341-349. doi: 10.1001/jama.2021.23641.	Spitzer A	JAMA	2022	1/10/2022	PMC8749710		10.1001/jama.2021.23641
34921774	Protection from SARS-CoV-2 Delta one year after mRNA-1273 vaccination in rhesus macaques coincides with anamnestic antibody response in the lung	https://pubmed.ncbi.nlm.nih.gov/34921774/	Moderna COVID-19 vaccine)	mRNA-1273	N/A	N/A	No	N/A	Gagne M, Corbett KS, Flynn BJ, Foulds KE, Wagner DA, Andrew SF, Todd JM, Honeycutt CC, McCormick L, Nurmukhambetova ST, Davis-Gardner ME, Pessaint L, Bock KW, Nagata BM, Minai M, Werner AP, Moliva JI, Tucker C, Lorang CG, Zhao B, McCarthy E, Cook A, Dodson A, Teng IT, Mudvari P, Roberts-Torres J, Laboune F, Wang L, Goode A, Kar S, Boyoglu-Barnum S, Yang ES, Shi W, Ploquin A, Doria-Rose N, Carfi A, Mascola JR, Boritz EA, Edwards DK, Andersen H, Lewis MG, Suthar MS, Graham BS, Roederer M, Moore IN, Nason MC, Sullivan NJ, Douek DC, Seder RA.	Cell. 2022 Jan 6;185(1):113-130.e15. doi: 10.1016/j.cell.2021.12.002. Epub 2021 Dec 3.	Gagne M	Cell	2022	12/18/2021	PMC8639396		10.1016/j.cell.2021.12.002
34861036	Efficacy of a third BNT162b2 mRNA COVID-19 vaccine dose in patients with CLL who failed standard 2-dose vaccination	https://pubmed.ncbi.nlm.nih.gov/34861036/	Pfizer–BioNTech COVID-19 vaccine	BNT162b2 mRNA COVID-19 vaccine	prospective cohort study	Yes	No	N/A	Herishanu Y, Rahav G, Levi S, Braester A, Itchaki G, Bairey O, Dally N, Shvidel L, Ziv-Baran T, Polliack A, Tadmor T, Benjamini O; Israeli CLL Study Group.	Blood. 2022 Feb 3;139(5):678-685. doi: 10.1182/blood.2021014085.	Herishanu Y	Blood	2022	12/3/2021	PMC8648353		10.1182/blood.2021014085

PMID	Title	Link	Type of vaccine	Class of Vaccine	Type of study (Case Report/Cohort or any other study type)	About Infection	Relevant	Comment (Only for Relevant ones)	Authors	Citation	First Author	Journal/Book	Publication Year	Create Date	PMCID	NIHMS ID	DOI
34826381	Efficacy and safety of the CVnCoV SARS-CoV-2 mRNA vaccine candidate in ten countries in Europe and Latin America (HERALD): a randomised, observer-blinded, placebo-controlled, phase 2b/3 trial	https://pubmed.ncbi.nlm.nih.gov/34826381/	CureVac COVID-19 vaccine	CVnCoV SARS-CoV-2 mRNA vaccine	cohort study	Yes	No	N/A	Kremsner PG, Ahuad Guerrero RA, Arana-Arri E, Aroca Martinez GJ, Bonten M, Chandler R, Corral G, De Block EJL, Ecker L, Gabor JJ, Garcia Lopez CA, Gonzales L, Granados González MA, Gorini N, Grobusch MP, Hrabar AD, Junker H, Kimura A, Lanata CF, Lehmann C, Leroux-Roels I, Mann P, Martinez-Reséndez MF, Ochoa TJ, Poy CA, Reyes Fentanes MJ, Rivera Mejia LM, Ruiz Herrera VV, Sáez-Llorens X, Schönborn-Kellenberger O, Schunk M, Sierra Garcia A, Vergara I, Verstraeten T, Vico M, Oostvogels L; HERALD Study Group.	Lancet Infect Dis. 2022 Mar;22(3):329-340. doi: 10.1016/S1473-3099(21)00677-0. Epub 2021 Nov 23.	Kremsner PG	Lancet Infect Dis	2022	11/26/2021	PMC8610426		10.1016/S1473-3099(21)00677-0
35176007	Waning 2-Dose and 3-Dose Effectiveness of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance - VISION Network, 10 States, August 2021-January 2022	https://pubmed.ncbi.nlm.nih.gov/35176007/	Unknown	COVID-19 mRNA vaccine	N/A	N/A	No	N/A	Ferdinands JM, Rao S, Dixon BE, Mitchell PK, DeSilva MB, Irving SA, Lewis N, Natarajan K, Stenehjem E, Grannis SJ, Han J, McEvoy C, Ong TC, Naleway AL, Reese SE, Embi PJ, Dascomb K, Klein NP, Griggs EP, Konatham D, Kharbanda AB, Yang DH, Fadel WF, Grisel N, Goddard K, Patel P, Liao IC, Birch R, Valvi NR, Reynolds S, Arndorfer J, Zerbo O, Dickerson M, Murthy K, Williams J, Bozio CH, Blanton L, Verani JR, Schrag SJ, Dalton AF, Wondimu MH, Link-Gelles R, Azziz-Baumgartner E, Barron MA, Gaglani M, Thompson MG, Fireman B.	MMWR Morb Mortal Wkly Rep. 2022 Feb 18;71(7):255-263. doi: 10.15585/mmwr.mm7107e2.	Ferdinands JM	MMWR Morb Mortal Wkly Rep	2022	2/17/2022	PMC8853475		10.15585/mmwr.mm7107e2
34942067	Covid-19 Vaccine Effectiveness in New York State	https://pubmed.ncbi.nlm.nih.gov/34942067/	Pfizer–BioNTech COVID-19 vaccine,Moderna vaccine,Johnson & Johnson vaccine	BNT162b2, mRNA-1273, and Ad26.COV2.S vaccines	Cohorts Study	N/A	No	N/A	Rosenberg ES, Dorabawila V, Easton D, Bauer UE, Kumar J, Hoen R, Hoefer D, Wu M, Lutterloh E, Conroy MB, Greene D, Zucker HA.	N Engl J Med. 2022 Jan 13;386(2):116-127. doi: 10.1056/NEJMoa2116063. Epub 2021 Dec 1.	Rosenberg ES	N Engl J Med	2022	12/23/2021	PMC8693697		10.1056/NEJMoa2116063
35636910	COVID-19 Vaccines	https://pubmed.ncbi.nlm.nih.gov/35636910/	Janssen, Pfizer-BioNTech, and Moderna vaccine	Ad.26.CoV2, BNT162b2, and mRNA-1273 vaccines	N/A	N/A	No	N/A	Hahn WO, Wiley Z.	Infect Dis Clin North Am. 2022 Jun;36(2):481-494. doi: 10.1016/j.idc.2022.01.008. Epub 2022 Jan 31.	Hahn WO	Infect Dis Clin North Am	2022	5/31/2022	PMC8802612		10.1016/j.idc.2022.01.008
35348368	mRNA-1273 and BNT162b2 COVID-19 vaccines elicit antibodies with differences in Fc-mediated effector functions	https://pubmed.ncbi.nlm.nih.gov/35348368/	Pfizer/BioNTech and Moderna vaccine	mRNA-1273 and BNT162b2	Cohort Study	N/A	No	N/A	Kaplonek P, Cizmeci D, Fischinger S, Collier AR, Suscovich T, Linde C, Broge T, Mann C, Amanat F, Dayal D, Rhee J, de St Aubin M, Nilles EJ, Musk ER, Menon AS, Saphire EO, Krammer F, Lauffenburger DA, Barouch DH, Alter G.	Sci Transl Med. 2022 May 18;14(645):eabm2311. doi: 10.1126/scitranslmed.abm2311. Epub 2022 May 18.	Kaplonek P	Sci Transl Med	2022	3/29/2022	PMC8995030		10.1126/scitranslmed.abm2311
35081288	Audio Interview: Addressing the Omicron Variant of SARS-CoV-2	https://pubmed.ncbi.nlm.nih.gov/35081288/	N/A	N/A	N/A	N/A	No	N/A	Rubin EJ, Baden LR, Barocas JA, Morrissey S.	N Engl J Med. 2022 Jan 27;386(4):e16. doi: 10.1056/NEJMe2201214.	Rubin EJ	N Engl J Med	2022	1/26/2022			10.1056/NEJMe2201214
35660280	Efficacy of COVID-19 vaccines by race and ethnicity	https://pubmed.ncbi.nlm.nih.gov/35660280/	Moderna Vaccine	mRNA-1273	N/A	Yes	No	N/A	Salari N, Vepa A, Daneshkhah A, Darvishi N, Ghasemi H, Khunti K, Mohammadi M.	Public Health. 2022 May 5;208:14-17. doi: 10.1016/j.puhe.2022.04.009. Online ahead of print.	Salari N	Public Health	2022	6/6/2022	PMC9069229		10.1016/j.puhe.2022.04.009
34788497	mRNA vaccines against COVID-19: a showcase for the importance of microbial biotechnology	https://pubmed.ncbi.nlm.nih.gov/34788497/	Pfizer-BioNTech and Moderna	mRNA vaccines	observational studies	Yes	No	N/A	Brüssow H.	Microb Biotechnol. 2022 Jan;15(1):135-148. doi: 10.1111/1751-7915.13974. Epub 2021 Nov 17.	Brüssow H	Microb Biotechnol	2022	11/17/2021	PMC8652446		10.1111/1751-7915.13974
35045222	Effectiveness of mRNA-1273 and BNT162b2 Vaccines in Qatar	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8796790/	Pfizer-BioNTech and Moderna	mRNA-1273 and BNT162b2	N/A	Yes	No	N/A	Abu-Raddad LJ, Chemaitelly H, Bertollini R; National Study Group for COVID-19 Vaccination.	N Engl J Med. 2022 Feb 24;386(8):799-800. doi: 10.1056/NEJMc2117933. Epub 2022 Jan 19.	Abu-Raddad LJ	N Engl J Med	2022	1/19/2022	PMC8796790		10.1056/NEJMc2117933
35113151	Boosting BNT162b2 vaccine efficacy in CLL	https://pubmed.ncbi.nlm.nih.gov/35113151/	Pfizer-BioNTech	BNT162b2 mRNA vaccine	N/A	Yes	No	N/A	Bhat SA, Woyach JA.	Blood. 2022 Feb 3;139(5):639-640. doi: 10.1182/blood.2021014903.	Bhat SA	Blood	2022	2/3/2022	PMC8812057		10.1182/blood.2021014903
34931885	Post-vaccine COVID-19 in patients with multiple sclerosis or neuromyelitis optica	https://pubmed.ncbi.nlm.nih.gov/34931885/	Pfizer-BioNTech	BNT162b2-vaccination	Case Series	Yes	Yes	This article describes 18 cases of COVID-19 infection occurring despite double-dose of BNT162b2 vaccine among patients with MS or NMOSD in the COVISEP registry, and 13 of them were treated with anti-CD20 therapies. COVID-19 severity was mild. But these patients had taken Pfizer vaccine.	Januel E, De Seze J, Vermersch P, Maillart E, Bourre B, Pique J, Moisset X, Bensa C, Maarouf A, Pelletier J, Vukusic S, Audoin B, Louapre C; COVISEP Investigators.	Mult Scler. 2022 Jun;28(7):1155-1159. doi: 10.1177/13524585211049737. Epub 2021 Dec 21.	Januel E	Mult Scler	2022	12/21/2021			10.1177/13524585211049737
35151018	Real world SARS-COV-2 vaccine effectiveness in a Miami academic institution	https://pubmed.ncbi.nlm.nih.gov/35151018/	Moderna, Pfizer	mRNA	Retrospective Cohort study	Yes	NO	N/A	Mallow C, Ferreira T, Shukla B, Warde P, Sosa MA, Parekh DJ, Gershengorn HB.	Am J Emerg Med. 2022 Apr;54:97-101. doi: 10.1016/j.ajem.2022.01.066. Epub 2022 Feb 3.	Mallow C	Am J Emerg Med	2022	2/12/2022	PMC8810434		10.1016/j.ajem.2022.01.066
35012777	Safety and effectiveness of BNT162b2 mRNA Covid-19 vaccine in adolescents	https://pubmed.ncbi.nlm.nih.gov/35012777/	Pfizer–BioNTech COVID-19 vaccine	BNT162b2 mRNA	Retrospective cohort study	N/A	NO	N/A	June Choe Y, Yi S, Hwang I, Kim J, Park YJ, Cho E, Jo M, Lee H, Hwa Choi E.	Vaccine. 2022 Jan 31;40(5):691-694. doi: 10.1016/j.vaccine.2021.12.044. Epub 2021 Dec 24.	June Choe Y	Vaccine	2022	1/11/2022	PMC8702409		10.1016/j.vaccine.2021.12.044
35081294	Waning mRNA-1273 Vaccine Effectiveness against SARS-CoV-2 Infection in Qatar	https://pubmed.ncbi.nlm.nih.gov/35081294/	Moderna Vaccine	mRNA-1273	N/A	Yes	NO	N/A	Abu-Raddad LJ, Chemaitelly H, Bertollini R; National Study Group for COVID-19 Vaccination.	N Engl J Med. 2022 Mar 17;386(11):1091-1093. doi: 10.1056/NEJMc2119432. Epub 2022 Jan 26.	Abu-Raddad LJ	N Engl J Med	2022	1/26/2022	PMC8809505		10.1056/NEJMc2119432
35126377	mRNA Vaccine: How to Meet the Challenge of SARS-CoV-2	https://pubmed.ncbi.nlm.nih.gov/35126377/	Moderna Vaccine	mRNA vaccine	Other Study type	Yes	NO	N/A	Jin Y, Hou C, Li Y, Zheng K, Wang C.	Front Immunol. 2022 Jan 21;12:821538. doi: 10.3389/fimmu.2021.821538. eCollection 2021.	Jin Y	Front Immunol	2022	2/7/2022	PMC8813741		10.3389/fimmu.2021.821538
35143256	Broad anti-SARS-CoV-2 antibody immunity induced by heterologous ChAdOx1/mRNA-1273 vaccination	https://pubmed.ncbi.nlm.nih.gov/35143256/	Moderna Vaccine,Astrazeneca vaccine	ChAdOx1/mRNA-1273	Other Study type	Yes	NO	N/A	Kaku CI, Champney ER, Normark J, Garcia M, Johnson CE, Ahlm C, Christ W, Sakharkar M, Ackerman ME, Klingström J, Forsell MNE, Walker LM.	Science. 2022 Mar 4;375(6584):1041-1047. doi: 10.1126/science.abn2688. Epub 2022 Feb 10.	Kaku CI	Science	2022	2/10/2022	PMC8939765		10.1126/science.abn2688
35238933	Assessment of Clinical Effectiveness of BNT162b2 COVID-19 Vaccine in US Adolescents	https://pubmed.ncbi.nlm.nih.gov/35238933/	Pfizer–BioNTech COVID-19 vaccine	BNT162b2	Retrospective case-control study	Yes	NO	N/A	Oliveira CR, Niccolai LM, Sheikha H, Elmansy L, Kalinich CC, Grubaugh ND, Shapiro ED; Yale SARS-CoV-2 Genomic Surveillance Initiative.	JAMA Netw Open. 2022 Mar 1;5(3):e220935. doi: 10.1001/jamanetworkopen.2022.0935.	Oliveira CR	JAMA Netw Open	2022	3/3/2022	PMC8895259		10.1001/jamanetworkopen.2022.0935
35421378	Efficacy of vaccination and previous infection against the Omicron BA.1 variant in Syrian hamsters	https://pubmed.ncbi.nlm.nih.gov/35421378/	Moderna mRNA	mRNA	Animal study report	Yes	NO	N/A	Halfmann PJ, Kuroda M, Maemura T, Chiba S, Armbrust T, Wright R, Balaram A, Florek KR, Bateman AC, Kawaoka Y.	Cell Rep. 2022 Apr 19;39(3):110688. doi: 10.1016/j.celrep.2022.110688. Epub 2022 Mar 28.	Halfmann PJ	Cell Rep	2022	4/14/2022	PMC8958134		10.1016/j.celrep.2022.110688

PMID	Title	Link	Type of vaccine	Class of Vaccine	Type of study (Case Report/Cohort or any other study type)	About Infection	Relevant	Comment (Only for Relevant ones)	Authors	Citation	First Author	Journal/Book	Publication Year	Create Date	PMCID	NIHMS ID	DOI
35144972	Seroresponse to SARS-CoV-2 Vaccines among Maintenance Dialysis Patients over 6 Months	https://pubmed.ncbi.nlm.nih.gov/35144972/	Moderna, Pfizer, Janssen	mRNA-1273, BNT162b2 and Ad26.COV2.S	Retrospective cohort study	yes	NO	N/A	Hsu CM, Weiner DE, Manley HJ, Aweh GN, Ladik V, Frament J, Miskulin D, Argyropoulos C, Abreo K, Chin A, Gladish R, Salman L, Johnson D, Lacson EK Jr.	Clin J Am Soc Nephrol. 2022 Mar;17(3):403-413. doi: 10.2215/CJN.12250921. Epub 2022 Feb 10.	Hsu CM	Clin J Am Soc Nephrol	2022	2/11/2022	PMC8975038		10.2215/CJN.12250921
35113351	Implication of the emergence of the delta (B.1.617.2) variants on vaccine effectiveness	https://pubmed.ncbi.nlm.nih.gov/35113351/	Pfizer-BioNTech, Oxford-AstraZeneca and Moderna vaccin	mRNA-1273, BNT162b2 and Ad26.COV2.S	N/A	yes	NO	N/A	Al-Tawfiq JA, Koritala T, Alhumaid S, Barry M, Alshukairi AN, Temsah MH, Al Mutair A, Rabaan A, Tirupathi R, Gautret P.	Infection. 2022 Jun;50(3):583-596. doi: 10.1007/s15010-022-01759-1. Epub 2022 Feb 3.	Al-Tawfiq JA	Infection	2022	2/3/2022	PMC8811010		10.1007/s15010-022-01759-1
35084937	Vaccination with BNT162b2 reduces transmission of SARS-CoV-2 to household contacts in Israel	https://pubmed.ncbi.nlm.nih.gov/35084937/	Pfizer-BioNTech	BNT162b2 messenger RNA	N/A	Yes	NO	N/A	Prunas O, Warren JL, Crawford FW, Gazit S, Patalon T, Weinberger DM, Pitzer VE.	Science. 2022 Mar 11;375(6585):1151-1154. doi: 10.1126/science.abl4292. Epub 2022 Jan 27.	Prunas O	Science	2022	1/27/2022			10.1126/science.abl4292
35032813	Impaired seroconversion after SARS-CoV-2 mRNA vaccines in patients with solid tumours receiving anticancer treatment	https://pubmed.ncbi.nlm.nih.gov/35032813/	Moderna, Pfizer	BNT162b2, mRNA-1273,	prospective, single-centre cohort study	N/A	NO	N/A	Amatu A, Pani A, Patelli G, Gagliardi OM, Loparco M, Piscazzi D, Cassingena A, Tosi F, Ghezzi S, Campisi D, Grifantini R, Abrignani S, Siena S, Scaglione F, Sartore-Bianchi A.	Eur J Cancer. 2022 Mar;163:16-25. doi: 10.1016/j.ejca.2021.12.006. Epub 2021 Dec 22.	Amatu A	Eur J Cancer	2022	1/15/2022	PMC8692068		10.1016/j.ejca.2021.12.006
35234883	Effectiveness of Ad26.COV2.S Vaccine vs BNT162b2 Vaccine for COVID-19 Hospitalizations	https://pubmed.ncbi.nlm.nih.gov/35234883/	Johnson & Johnson vaccine, Pfizer	Ad26.COV2.S, BNT162b2	Cohort study	Yes	NO	N/A	Botton J, Semenzato L, Jabagi MJ, Baricault B, Weill A, Dray-Spira R, Zureik M.	JAMA Netw Open. 2022 Mar 1;5(3):e220868. doi: 10.1001/jamanetworkopen.2022.0868.	Botton J	JAMA Netw Open	2022	3/2/2022	PMC8892225		10.1001/jamanetworkopen.2022.0868
35235734	Audio Interview: Using Our Covid-19 Experience to Develop Vaccines More Quickly	https://pubmed.ncbi.nlm.nih.gov/35235734/	N/A	N/A	N/A	N/A	NO	N/A	Rubin EJ, Baden LR, Morrissey S.	N Engl J Med. 2022 Mar 3:386(9):e29. doi: 10.1056/NEJMe2203035.	Rubin EJ	N Engl J Med	2022	3/2/2022			10.1056/NEJMe2203035
35430229	Preserved recognition of Omicron spike following COVID-19 messenger RNA vaccination in pregnancy	https://pubmed.ncbi.nlm.nih.gov/35430229/	Pfizer/BioNTech or Moderna	BNT62b2, mRNA-1273	other study type	N/A	NO	N/A	Bartsch YC, Atyeo C, Kang J, Cai Y, Chen B, Gray KJ, Edlow AG, Alter G.	Am J Obstet Gynecol. 2022 Apr 14:S0002-9378(22)00281-2. doi: 10.1016/j.ajog.2022.04.009. Online ahead of print.	Bartsch YC	Am J Obstet Gynecol	2022	4/17/2022	PMC9008975		10.1016/j.ajog.2022.04.009
34747190	The mRNA COVID-19 vaccine in patients with cancer receiving checkpoint inhibitor therapy: what we know and what we don't	https://pubmed.ncbi.nlm.nih.gov/34747190/	Unknown	mRNA COVID-19 vaccine	Cohort study	N/A	NO	N/A	Malek AE, Cornejo PP, Daoud N, Alam M.	Immunotherapy. 2022 Feb;14(2):91-94. doi: 10.2217/imt-2021-0235. Epub 2021 Nov 8.	Malek AE	Immunotherapy	2022	11/8/2021	PMC8582594		10.2217/imt-2021-0235
34974072	Pfizer-BioNTech vaccine effectiveness against Sars-Cov-2 infection: Findings from a large observational study in Israel	https://pubmed.ncbi.nlm.nih.gov/34974072/	Pfizer-BioNTech	mRNA BNT162b2	retrospective cohort study	yes	NO	N/A	Saciuk Y, Kertes J, Mandel M, Hemo B, Shamir Stein N, Ekka Zohar A.	Prev Med. 2022 Feb;155:106947. doi: 10.1016/j.ypmed.2021.106947. Epub 2021 Dec 30.	Saciuk Y	Prev Med	2022	1/2/2022	PMC8717697		10.1016/j.ypmed.2021.106947
35331933	Waning COVID-19 Vaccine Effectiveness for BNT162b2 and CoronaVac in Malaysia: An Observational Study	https://pubmed.ncbi.nlm.nih.gov/35331933/	Pfizer-BioNTech	BNT162b2	observational study	Yes	NO	N/A	Suah JL, Husin M, Tok PSK, Tng BH, Thevananthan T, Low EV, Appannan MR, Muhamad Zin F, Mohd Zin S, Yahaya H, Peariasamy KM, Sivasampu S.	Int J Infect Dis. 2022 Jun;119:69-76. doi: 10.1016/j.ijid.2022.03.028. Epub 2022 Mar 22.	Suah JL	Int J Infect Dis	2022	3/25/2022	PMC8938298		10.1016/j.ijid.2022.03.028
34906898	Outcome of SARS-CoV-2 variant breakthrough infection in fully immunized solid organ transplant recipients	https://pubmed.ncbi.nlm.nih.gov/34906898/	Pfizer-BioNTech, AstraZeneca	BNT162b2 mRNA, ChAdOx1 AZD12220 COVID-19 vaccines	case series	yes	NO	This case series is not related to Moderna vaccine. Here in this article, four fully vaccinated solid organ transplant recipients who developed SARS-CoV-2 variants of concern breakthrough infections. Three patients received BNT162b2 mRNA (Pfizer-BioNTech) and one patient received ChAdOx1 (AZD12220) COVID-19 vaccines. The patients were infected with SARS-CoV-2 variants circulating in Saudi Arabia. Two patients were infected	Almaghrabi RS, Alhamlan FS, Dada A, Al-Tawfiq JA, Al Hroub MK, Saeedi MF, Alamri M, Alhothaly B, Alqasabi A, Al-Qahtani AA, Al-Omari A, Alshukairi AN.	J Infect Public Health. 2022 Jan;15(1):51-55. doi: 10.1016/j.jiph.2021.11.021. Epub 2021 Dec 4.	Almaghrabi RS	J Infect Public Health	2022	12/15/2021	PMC8642837		10.1016/j.jiph.2021.11.021
35568588	Covid-19 vaccine immunogenicity in people living with HIV-1	https://pubmed.ncbi.nlm.nih.gov/35568588/	Covid-19 Vaccine	mRNA vaccine	N/A	N/A	No	N/A	Nault L, Marchitto L, Goyette G, Tremblay-Sher D, Fortin C, Martel-Laferrière V, Trottier B, Richard J, Durand M, Kaufmann D, Finzi A, Tremblay C.	Vaccine. 2022 Jun 9;40(26):3633-3637. doi: 10.1016/j.vaccine.2022.04.090. Epub 2022 May 5.	Nault L	Vaccine	2022	5/14/2022	PMC9069249		10.1016/j.vaccine.2022.04.090
35584653	mRNA-1273 and Ad26.COV2.S vaccines protect against the B.1.621 variant of SARS-CoV-2	https://pubmed.ncbi.nlm.nih.gov/35584653/	Moderna mRNA vaccine,Johnson & Johnson recombinant adenoviral-vectored vaccine	mRNA-1273 and Ad26.COV2.S	Animal study report	N/A	No	N/A	Darling TL, Ying B, Whitener B, VanBlargan LA, Bricker TL, Liang CY, Joshi A, Bamunuarachchi G, Sechra K, Schmitz AJ, Halfmann PJ, Kawaoka Y, Elbashir SM, Edwards DK, Thackray LB, Diamond MS, Boon ACM.	Med (N Y). 2022 May 13;3(5):309-324.e6. doi: 10.1016/j.medj.2022.03.009. Epub 2022 Apr 15.	Darling TL	Med (N Y)	2022	5/18/2022	PMC9011903	NIHMS1800026	10.1016/j.medj.2022.03.009
35370016	Benefit-risk assessment of COVID-19 vaccine, mRNA (Comirnaty) for age 16-29 years	https://pubmed.ncbi.nlm.nih.gov/35370016/	Pfizer-BioNTech	COVID-19 Vaccine, mRNA	N/A	N/A	No	N/A	Funk PR, Yogurtcu ON, Forshee RA, Anderson SA, Marks PW, Yang H.	Vaccine. 2022 Apr 26;40(19):2781-2789. doi: 10.1016/j.vaccine.2022.03.030. Epub 2022 Mar 28.	Funk PR	Vaccine	2022	4/4/2022	PMC8958165		10.1016/j.vaccine.2022.03.030
34971714	How many lives do COVID vaccines save? Evidence from Israel	https://pubmed.ncbi.nlm.nih.gov/34971714/	Pfizer-BioNTech	COVID-19 BNT162b2 vaccine	N/A	N/A	No	N/A	Arbel R, Moore CM, Sergienko R, Pliskin J.	Am J Infect Control. 2022 Mar;50(3):258-261. doi: 10.1016/j.ajic.2021.12.019. Epub 2021 Dec 29.	Arbel R	Am J Infect Control	2022	12/31/2021	PMC8714257		10.1016/j.ajic.2021.12.019
35133533	Factors associated with SARS-CoV-2 antibody titers and prognosis of breakthrough infection in hemodialysis patients	https://pubmed.ncbi.nlm.nih.gov/35133533/	Unknown	COVID-19 vaccine	N/A	yes	No	N/A	Toda M, Yoshifuji A, Kikuchi K, Koinuma M, Komatsu M, Fujii K, Kato A, Kikuchi T, Nakazawa A, Ryuzaki M.	Clin Exp Nephrol. 2022 Jun;26(6):571-580. doi: 10.1007/s10157-022-02188-y. Epub 2022 Feb 8.	Toda M	Clin Exp Nephrol	2022	2/8/2022	PMC8824537		10.1007/s10157-022-02188-y
34848871	BNT162b2 vaccine induces divergent B cell responses to SARS-CoV-2 S1 and S2	https://pubmed.ncbi.nlm.nih.gov/34848871/	Pfizer-BioNTech	BNT162b2 vaccine	N/A	N/A	NO	N/A	Brewer RC, Ramadoss NS, Lahey LJ, Jahanbani S, Robinson WH, Lanz TV.	Nat Immunol. 2022 Jan;23(1):33-39. doi: 10.1038/s41590-021-01088-9. Epub 2021 Nov 30.	Brewer RC	Nat Immunol	2022	12/1/2021	PMC8776031	NIHMS1761016	10.1038/s41590-021-01088-9
35150884	Vaccine effectiveness of ChAdOx1 nCoV-19 against COVID-19 in a socially vulnerable community in Rio de Janeiro, Brazil: a test-negative design study	https://pubmed.ncbi.nlm.nih.gov/35150884/	Astrazeneca vaccine	ChAdOx1 nCoV-19	Other Study type	N/A	NO	N/A	Ranzani OT, Silva AAB, Peres IT, Antunes BBP, Gonzaga-da-Silva TW, Soranz DR, Cerbino-Neto J, Hamacher S, Bozza FA.	Clin Microbiol Infect. 2022 May;28(5):736.e1-736.e4. doi: 10.1016/j.cmi.2022.01.032. Epub 2022 Feb 9.	Ranzani OT	Clin Microbiol Infect	2022	2/12/2022	PMC8828302		10.1016/j.cmi.2022.01.032
35383307	SARS-CoV-2 antigen exposure history shapes phenotypes and specificity of memory CD8(+) T cells	https://pubmed.ncbi.nlm.nih.gov/35383307/	Unknown	mRNA vaccine	N/A	N/A	NO	N/A	Minervina AA, Pogorelyy MV, Kirk AM, Crawford JC, Allen EK, Chou CH, Mettelman RC, Allison KJ, Lin CY, Brice DC, Zhu X, Vegesana K, Wu G, Trivedi S, Kottapalli P, Darnell D, McNeely S, Olsen SR, Schultz-Cherry S, Estepp JH; SJTRC Study Team, McGargill MA, Wolf J, Thomas PG.	Nat Immunol. 2022 May;23(5):781-790. doi: 10.1038/s41590-022-01184-4. Epub 2022 Apr 5.	Minervina AA	Nat Immunol	2022	4/6/2022	PMC9106845	NIHMS1788551	10.1038/s41590-022-01184-4
34715314	BNT162b2 vaccine effectiveness was marginally affected by the SARS-CoV-2 beta variant in fully vaccinated individuals	https://pubmed.ncbi.nlm.nih.gov/34715314/	Pfizer	BNT162b2 vaccine	Other Study type	yes	NO	N/A	Mor O, Zuckerman NS, Hazan I, Fluss R, Ash N, Ginish N, Mendelson E, Alroy-Preis S, Freedman L, Huppert A.	J Clin Epidemiol. 2022 Feb;142:38-44. doi: 10.1016/j.jclinepi.2021.10.011. Epub 2021 Oct 29.	Mor O	J Clin Epidemiol	2022	10/29/2021	PMC8553421		10.1016/j.jclinepi.2021.10.011

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35120605	SARS-CoV-2 prolonged infection during advanced HIV disease evolves extensive immune escape	https://pubmed.ncbi.nlm.nih.gov/35120605/	Pfizer	BNT162b2	N/A	yes	NO	N/A	Cele S, Karim F, Lustig G, San JE, Hermanus T, Tegally H, Snyman J, Moyo-Gwete T, Wilkinson E, Bernstein M, Khan K, Hwa SH, Tilles SW, Singh L, Giandhari J, Mthabela N, Mazibuko M, Ganga Y, Gosnell BI, Karim SSA, Hanekom W, Van Voorhis WC, Ndung'u T; COMMIT-KZN Team, Lessells RJ, Moore PL, Moosa MS, de Oliveira T, Sigal A.	Cell Host Microbe. 2022 Feb 9;30(2):154-162.e5. doi: 10.1016/j.chom.2022.01.005. Epub 2022 Jan 14.	Cele S	Cell Host Microbe	2022	2/5/2022	PMC8758318		10.1016/j.chom.2022.01.005
35131444	Exercise after influenza or COVID-19 vaccination increases serum antibody without an increase in side effects	https://pubmed.ncbi.nlm.nih.gov/35131444/	PfizerBioNTech	COVID-19 vaccine	Other Study type	N/A	No	N/A	Hallam J, Jones T, Alley J, Kohut ML.	Brain Behav Immun. 2022 May;102:1-10. doi: 10.1016/j.bbi.2022.02.005. Epub 2022 Feb 5.	Hallam J	Brain Behav Immun	2022	2/8/2022	PMC8816799		10.1016/j.bbi.2022.02.005
35264455	Vaccine Effectiveness Against SARS-CoV-2 Infection and Severe Outcomes in the Maintenance Dialysis Population in Ontario, Canada	https://pubmed.ncbi.nlm.nih.gov/35264455/	Pfizer and Moderna	BNT162b2and mRNA	Retrospective cohort studies	Yes	No	N/A	Oliver MJ, Thomas D, Balamchi S, Ip J, Naylor K, Dixon SN, McArthur E, Kwong J, Perl J, Atiquzzaman M, Singer J, Yeung A, Hladunewich M, Yau K, Garg AX, Leis JA, Levin A, Krajden M, Blake PG.	J Am Soc Nephrol. 2022 Apr;33(4):839-849. doi: 10.1681/ASN.2021091262. Epub 2022 Mar 9.	Oliver MJ	J Am Soc Nephrol	2022	3/10/2022	PMC8970446		10.1681/ASN.2021091262
35226399	Sex-associated differences between BMI and SARS-CoV-2 antibody titers following the BNT162b2 vaccine	https://pubmed.ncbi.nlm.nih.gov/35226399/	PfizerBioNTech	COVID-19 vaccine	Other Study type	N/A	No	N/A	Yamamoto S, Mizoue T, Tanaka A, Oshiro Y, Inamura N, Konishi M, Ozeki M, Miyo K, Sugiura W, Sugiyama H, Ohmagari N.	Obesity (Silver Spring). 2022 May;30(5):999-1003. doi: 10.1002/oby.23417. Epub 2022 Apr 12.	Yamamoto S	Obesity (Silver Spring)	2022	2/28/2022	PMC9088326		10.1002/oby.23417
35029310	Innovative vaccine approaches-a Keystone Symposia report	https://pubmed.ncbi.nlm.nih.gov/35029310/	J&J,Moderna,and Pfize	COVID-19 vaccine	N/A	N/A	No	N/A	Cable J, Rappuoli R, Klemm EJ, Kang G, Mutreja A, Wright GJ, Pizza M, Castro SA, Hoffmann JP, Alter G, Carfi A, Pollard AJ, Krammer F, Gupta RK, Wagner CE, Machado V, Modjarrad K, Corey L, B Gilbert P, Dougan G, Lurie N, Bjorkman PJ, Chiu C, Nemes E, Gordon SB, Steer AC, Rudel T, Blish CA, Sandberg JT, Brennan K, Klugman KP, Stuart LM, Madhi SA, Karp CL.	Ann N Y Acad Sci. 2022 May;1511(1):59-86. doi: 10.1111/nyas.14739. Epub 2022 Jan 14.	Cable J	Ann N Y Acad Sci	2022	1/14/2022			10.1111/nyas.14739
34896446	The role of nanoparticle format and route of administration on self-amplifying mRNA vaccine potency	https://pubmed.ncbi.nlm.nih.gov/34896446/	Unknown	COVID-19 vaccinen and saRNA	Other Study type	N/A	No	N/A	Anderluzzi G, Lou G, Woods S, Schmidt ST, Gallorini S, Brazzoli M, Johnson R, Roberts CW, O'Hagan DT, Baudner BC, Perrie Y.	J Control Release. 2022 Feb;342:388-399. doi: 10.1016/j.jconrel.2021.12.008. Epub 2021 Dec 10.	Anderluzzi G	J Control Release	2022	12/13/2021	PMC8660137		10.1016/j.jconrel.2021.12.008
34990709	Pfizer-BioNTech and Oxford AstraZeneca COVID-19 vaccine effectiveness and immune response amongst individuals in clinical risk groups	https://pubmed.ncbi.nlm.nih.gov/34990709/	Pfizer-BioNTech and Oxford AstraZeneca	mRNA and ChAdOx1 nCoV-19 adenoviral AZD1222	Other Study type	N/A	No	N/A	Whitaker HJ, Tsang RSM, Byford R, Andrews NJ, Sherlock J, Sebastian Pillai P, Williams J, Button E, Campbell H, Sinnathamby M, Victor W, Anand S, Linley E, Hewson J, DArchangelo S, Otter AD, Ellis J, Hobbs RFD, Howsam G, Zambon M, Ramsay M, Brown KE, de Lusignan S, Amirthalingam G, Lopez Bernal J.	J Infect. 2022 May;84(5):675-683. doi: 10.1016/j.jinf.2021.12.044. Epub 2022 Jan 3.	Whitaker HJ	J Infect	2022	1/6/2022	PMC8720678		10.1016/j.jinf.2021.12.044
35465948	Increased resistance of SARS-CoV-2 Omicron variant to neutralization by vaccine-elicited and therapeutic antibodies	https://pubmed.ncbi.nlm.nih.gov/35465948/	Unknown	Unknown	Other Study type	N/A	No	N/A	Tada T, Zhou H, Dcosta BM, Samanovic MI, Chivukula V, Herati RS, Hubbard SR, Mulligan MJ, Landau NR.	EBioMedicine. 2022 Apr;78:103944. doi: 10.1016/j.ebiom.2022.103944.	Tada T	EBioMedicine	2022	4/25/2022	PMC9021600		10.1016/j.ebiom.2022.103944
34260716	Evaluating Vaccine Efficacy Against Severe Acute Respiratory Syndrome Coronavirus 2 Infection	https://pubmed.ncbi.nlm.nih.gov/34260716/	Pfizer and Moderna	COVID-19 vaccinen and saRNA	Other Study type	N/A	No	N/A	Lin DY, Gu Y, Zeng D, Janes HE, Gilbert PB.	Clin Infect Dis. 2022 Feb 11;74(3):544-552. doi: 10.1093/cid/ciab630.	Lin DY	Clin Infect Dis	2022	7/14/2021	PMC8406869		10.1093/cid/ciab630
35441203	COVID-19 Vaccination for Frail Older Adults in Singapore - Rapid Evidence Summary and Delphi Consensus Statements	https://pubmed.ncbi.nlm.nih.gov/35441203/	Pfizer-BioNTech, Moderna, and Sputnik, AstraZeneca	COVID-19 vaccinen and saRNA	Other Study type	N/A	No	N/A	Gao J, Lun P, Ding YY, George PP.	J Frailty Aging. 2022;11(2):236-241. doi: 10.14283/jfa.2022.12.	Gao J	J Frailty Aging	2022	4/20/2022	PMC8853208		10.14283/jfa.2022.12
34953607	Cohort study of Covid-19 vaccine effectiveness among healthcare workers in Finland, December 2020 - October 2021	https://pubmed.ncbi.nlm.nih.gov/34953607/	Covid-19 vaccine	mRNA and ADV	Cohort Study	N/A	No	N/A	Poukka E, Baum U, Palmu AA, Lehtonen TO, Salo H, Nohynek H, Leino T.	Vaccine. 2022 Jan 31;40(5):701-705. doi: 10.1016/j.vaccine.2021.12.032. Epub 2021 Dec 18.	Poukka E	Vaccine	2022	12/26/2021	PMC8683266		10.1016/j.vaccine.2021.12.032
35216664	SARS-CoV-2 Omicron Spike recognition by plasma from individuals receiving BNT162b2 mRNA vaccination with a 16-week interval between doses	https://pubmed.ncbi.nlm.nih.gov/35216664/	Pfizer-BioNTech	mRNA	Other Study type	N/A	No	N/A	Chatterjee D, Tauzin A, Marchitto L, Gong SY, Boutin M, Bourassa C, Beaudoin-Bussières G, Bo Y, Ding S, Laumaea A, Vézina D, Perreault J, Gokool L, Morrisseau C, Arlotto P, Fournier É, Guilbault A, Delisle B, Levade I, Goyette G, Gendron-Lepage G, Medjahed H, De Serres G, Tremblay C, Martel-Laferrière V, Kaufmann DE, Bazin R, Prévost J, Moreira S, Richard J, Côté M, Finzi A.	Cell Rep. 2022 Mar 1;38(9):110429. doi: 10.1016/j.celrep.2022.110429. Epub 2022 Feb 8.	Chatterjee D	Cell Rep	2022	2/26/2022	PMC8823958		10.1016/j.celrep.2022.110429
35441174	Immune Correlates Analysis of a Single Ad26.COV2.S Dose in the ENSEMBLE COVID-19 Vaccine Efficacy Clinical Trial	https://pubmed.ncbi.nlm.nih.gov/35441174/	COVID-19 vaccinen and saRNA	COVID-19 vaccinen and saRNA	Cohort Study	N/A	No	N/A	Fong Y, McDermott AB, Benkeser D, Roels S, Stieh DJ, Vandebosch A, Gars ML, Van Roey GA, Houchens CR, Martins K, Jayashankar L, Castellino F, Amoa-Awua O, Basappa M, Flach B, Lin BC, Moore C, Naisan M, Naqvi M, Narpala S, Oá Connell S, Mueller A, Serebryannyy L, Castro M, Wang J, Petropoulos CJ, Luedtke A, Hyrien O, Lu Y, Yu C, Borate B, van der Laan LWP, Hejazi NS, Kenny A, Carone M, Wolfe DN, Sadoff J, Gray GE, Grinsztejn B, Goepfert PA, Little SJ, Paiva de Sousa L, Maboa R, Randhawa AK, Andrasik MP, Hendriks J, Truyers C, Struyf F, Schuitemaker H, Douoguih M, Kublin JG, Corey L, Neuzil KM, Carpp LN, Follmann D, Gilbert PB, Koup RA, Donis RO; Janssen Team; Coronavirus Vaccine Prevention Network (CoVPN)/ENSEMBLE Team; United States Government (USG)/CoVPN Biostatistics Team.	medRxiv. 2022 Apr 12:2022.04.06.22272763. doi: 10.1101/2022.04.06.22272763. Preprint.	Fong Y	medRxiv	2022	4/20/2022	PMC9016647		10.1101/2022.04.06.22272763
35706739	COVID-19 Vaccines and the Efficacy of Currently Available Vaccines Against COVID-19 Variants	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9187843/	Pfizer, Moderna and AstraZenecax	BNT162b2,MRNA	Other Study type	N/A	No	N/A	Panneer Selvam S, Ramani P, R R, Sundar S, T A L.	Cureus. 2022 May 11;14(5):e24927. doi: 10.7759/cureus.24927. eCollection 2022 May.	Panneer Selvam S	Cureus	2022	6/16/2022	PMC9187843		10.7759/cureus.24927
35140406	Vaccine effectiveness of heterologous CoronaVac plus BNT162b2 in Brazil	https://pubmed.ncbi.nlm.nih.gov/35140406/	Sinovac Biotech, AstraZeneca, Janssen and Pfizer-BioNTech	CoronaVac, ChAdOx1, Ad26.COV2.S and BNT162b2	Other Study type	N/A	No	N/A	Cerqueira-Silva T, Katikireddi SV, de Araujo Oliveira V, Flores-Ortiz R, Júnior JB, Paixão ES, Robertson C, Penna GO, Werneck GL, Barreto ML, Pearce N, Sheikh A, Barral-Netto M, Boaventura VS.	Nat Med. 2022 Apr;28(4):838-843. doi: 10.1038/s41591-022-01701-w. Epub 2022 Feb 9.	Cerqueira-Silva T	Nat Med	2022	2/10/2022	PMC9018414		10.1038/s41591-022-01701-w
35353846	Communication about vaccine efficacy and COVID-19 vaccine choice: Evidence from a survey experiment in the United States	https://pubmed.ncbi.nlm.nih.gov/35353846/	Pfizer and Moderna, AstraZeneca and Johnson & Johnson/Janssen	COVID-19 vaccine	Other Study type	N/A	No	N/A	Kreps S, Kriner DL.	PLoS One. 2022 Mar 30;17(3):e0265011. doi: 10.1371/journal.pone.0265011. eCollection 2022.	Kreps S	PLoS One	2022	3/30/2022	PMC8967042		10.1371/journal.pone.0265011
35298453	Effectiveness of 2-Dose BNT162b2 (Pfizer BioNTech) mRNA Vaccine in Preventing SARS-CoV-2 Infection Among Children Aged 5 to 11 Years and Adolescents Aged 12-15 Years - PROTECT Cohort, July 2021-February 2022	https://pubmed.ncbi.nlm.nih.gov/35298453/	Pfizer-BioNTech	BNT162b2	Cohort Study	N/A	No	N/A	Fowlkes AL, Yoon SK, Lutrick K, Gwynn L, Burns J, Grant L, Phillips AL, Ellingson K, Ferraris MV, LeClair LB, Mathenge C, Yoo YM, Thiese MS, Gerald LB, Solle NS, Joddy Z, Odame-Bamfo L, Mak J, Hegmann KT, Gerald JK, Ochoa JS, Berry M, Rose S, Lamberte JM, Madhivanan P, Pubillones FA, Rai RP, Dunnigan K, Jones JT, Krupp K, Edwards LJ, Bedrick EJ, Sokol BE, Lowe A, McLeland-Wieser H, Jovel KS, Fleary DE, Khan SM, Poe B, Hollister J, Lopez J, Rivers P, Beitel S, Tyner HL, Naleway AL, Olsho LEW, Caban-Martinez AJ, Burgess JL, Thompson MG, Gaglani M.	MMWR Morb Mortal Wkly Rep. 2022 Mar 18;71(11):422-428. doi: 10.15585/mmwr.mm7111e1.	Fowlkes AL	MMWR Morb Mortal Wkly Rep	2022	3/17/2022	PMC8942308		10.15585/mmwr.mm7111e1
35015054	Studies Suggest COVID-19 Vaccine Boosters Save Lives	https://pubmed.ncbi.nlm.nih.gov/35015054/	Unknown	COVID-19 vaccine	Other Study type	N/A	No	N/A	Abbasi J.	JAMA. 2022 Jan 11;327(2):115. doi: 10.1001/jama.2021.23455.	Abbasi J	JAMA	2022	1/11/2022			10.1001/jama.2021.23455

PMID	Title	Link	Type of vaccine	Class of Vaccine	Type of study (Case Report/Cohort or any other study type)	About Infection	Relevant	Comment (Only for Relevant ones)	Authors	Citation	First Author	Journal/Book	Publication Year	Create Date	PMCID	NIHMS ID	DOI
35409724	Evaluation of BNT162b2 Vaccine Effectiveness in Galicia, Northwest Spain	https://pubmed.ncbi.nlm.nih.gov/35409724/	Pfizer-BioNTech	BNT162b2	Other Study type	N/A	No	N/A	Pardo-Seco J, Mallah N, López-Pérez LR, González-Pérez JM, Rosón B, Otero-Barrós MT, Durán-Parrondo C, Rodríguez-Tenreiro C, Rivero-Calle I, Gómez-Carballa A, Salas A, Martinón-Torres F.	Int J Environ Res Public Health. 2022 Mar 29;19(7):4039. doi: 10.3390/ijerph19074039.	Pardo-Seco J	Int J Environ Res Public Health	2022	4/12/2022	PMC8998680		10.3390/ijerph19074039
35354425	Demystifying mRNA vaccines: an emerging platform at the forefront of cryptic diseases	https://pubmed.ncbi.nlm.nih.gov/35354425/	(Pfizer/BioNTech, Moderna, Oxford/Astrazeneca, Johnson & Johnson/Janssen, Sinovac, Sinopharm	BNT162b2, mRNA, ChAdOx1-S/ AZD1222, Ad26.COV2.S, CoronaVac, BBIBP-CorV	Other Study type	N/A	No	N/A	Rouf NZ, Biswas S, Tarannum N, Oishee LM, Muna MM.	RNA Biol. 2022;19(1):386-410. doi: 10.1080/15476286.2022.2055923. Epub 2021 Dec 31.	Rouf NZ	RNA Biol	2022	3/31/2022	PMC8973339		10.1080/15476286.2022.2055923
35112973	COVID-19 vaccine effectiveness among immunocompromised populations: a targeted literature review of real-world studies	https://pubmed.ncbi.nlm.nih.gov/35112973/	Pfizer/BioNTech, Moderna, Janssen, Oxford/AstraZeneca	BNT162b2, mRNA-1273, Ad26.COV2.S, ChAdOx1 nCoV-19	Other Study type	N/A	No	N/A	Di Fusco M, Lin J, Vaghela S, Lingohr-Smith M, Nguyen JL, Scassellati Sforzolini T, Judy J, Cane A, Moran MM.	Expert Rev Vaccines. 2022 Apr;21(4):435-451. doi: 10.1080/14760584.2022.2035222. Epub 2022 Feb 3.	Di Fusco M	Expert Rev Vaccines	2022	2/3/2022	PMC8862165		10.1080/14760584.2022.2035222
35536258	mRNA Booster Improves a COVID-19 Vaccine's Effectiveness	https://pubmed.ncbi.nlm.nih.gov/35536258/	Janssen/Johnson & Johnson	Ad26.COV2.S and COVID-19 vaccine	Other Study type	N/A	No	N/A	Kuehn BM.	JAMA. 2022 May 10;327(18):1749. doi: 10.1001/jama.2022.6891.	Kuehn BM	JAMA	2022	5/10/2022			10.1001/jama.2022.6891
35321895	COVID-19 vaccine effectiveness among healthcare workers in Albania (COVE-AL): protocol for a prospective cohort study and cohort baseline data	https://pubmed.ncbi.nlm.nih.gov/35321895/	Pfizer-BioNTech	BNT162b2	Prospective Cohort Study	N/A	No	N/A	Sridhar S, Fico A, Preza I, Hatibi I, Sulo J, Kissling E, Daja R, Ibrahim R, Lemos D, Rubin-Smith J, Schmid A, Vasili A, Valenciano M, Jorgensen P, Pebody R, Lafond KE, Katz MA, Bino S.	BMJ Open. 2022 Mar 23;12(3):e057741. doi: 10.1136/bmjopen-2021-057741.	Sridhar S	BMJ Open	2022	3/24/2022	PMC8943479		10.1136/bmjopen-2021-057741
35032087	Platelet and immune signature associated with a rapid response to the BNT162b2 mRNA COVID-19 vaccine	https://pubmed.ncbi.nlm.nih.gov/35032087/	Pfizer-BioNTech	BNT162b2and mRNA	Other Study type	N/A	No	N/A	Flego D, Cesaroni S, Romiti GF, Corica B, Marrapodi R, Scafa N, Maiorca F, Lombardi L, Pallucci D, Pulcinelli F, Raparelli V, Visentini M, Cangemi R, Piconese S, Alvaro D, Polimeni A, Basili S, Stefanini L; Vax-SPEED-IT Study Group.	J Thromb Haemost. 2022 Apr;20(4):961-974. doi: 10.1111/jth.15648. Epub 2022 Jan 26.	Flego D	J Thromb Haemost	2022	1/15/2022			10.1111/jth.15648
35595662	Assessing vaccine effectiveness against severe COVID-19 disease caused by omicron variant. Report from a meeting of the World Health Organization	https://pubmed.ncbi.nlm.nih.gov/35595662/	Sinovac, AstraZeneca, Moderna, Pfizer	CoronaVac, Vaxzevria, Spikevax, Comirnaty	Other Study type	N/A	No	N/A	Feikin DR, Abu-Raddad LJ, Andrews N, Davies MA, Higdon MM, Orenstein WA, Patel MK.	Vaccine. 2022 Jun 9;40(26):3516-3527. doi: 10.1016/j.vaccine.2022.04.069. Epub 2022 May 2.	Feikin DR	Vaccine	2022	5/20/2022	PMC9058052		10.1016/j.vaccine.2022.04.069
35693807	Reduced Antibodies and Innate Cytokine Changes in SARS-CoV-2 BNT162b2 mRNA Vaccinated Transplant Patients With Hematological Malignancies	https://pubmed.ncbi.nlm.nih.gov/35693807/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Bergamaschi C, Pagoni M, Rosati M, Angel M, Tzannou I, Vlachou M, Darmani I, Ullah A, Bear J, Devasundaram S, Burns R, Baltadakis I, Gigantes S, Dimopoulos MA, Pavlakis GN, Terpos E, Felber BK.	Front Immunol. 2022 May 25;13:899972. doi: 10.3389/fimmu.2022.899972. eCollection 2022.	Bergamaschi C	Front Immunol	2022	6/13/2022	PMC9174567		10.3389/fimmu.2022.899972
34903372	Early effectiveness of BNT162b2 Covid-19 vaccine in preventing SARS-CoV-2 infection in healthcare personnel in six Israeli hospitals (CoVEHPI)	https://pubmed.ncbi.nlm.nih.gov/34903372/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Katz MA, Harlev EB, Chazan B, Chowers M, Greenberg D, Peretz A, Tshori S, Levy J, Yacobi M, Hirsch A, Amichay D, Weinberger R, Dor AB, Taraday EK, Reznik D, Chayat CB, Sagas D, Zvi HB, Berdinstein R, Rashid G, Avni YS, Mandelboim M, Zuckerman N, Rainy N, Akriv A, Dagan N, Kepten E, Barda N, Balicer RD.	Vaccine. 2022 Jan 24;40(3):512-520. doi: 10.1016/j.vaccine.2021.11.092. Epub 2021 Dec 10.	Katz MA	Vaccine	2022	12/14/2021	PMC8662353		10.1016/j.vaccine.2021.11.092
35262410	Vaccine-Induced Antibody Responses against SARS-CoV-2 Variants-Of-Concern Six Months after the BNT162b2 COVID-19 mRNA Vaccination	https://pubmed.ncbi.nlm.nih.gov/35262410/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Jalkanen P, Kolehmainen P, Haveri A, Huttunen M, Laine L, Österlund P, Tähtinen PA, Ivaska L, Maljanen S, Reinholm A, Belik M, Smura T, Häkkinen HK, Ortamo E, Kantele A, Julkunen I, Lempainen J, Kakkola L.	Microbiol Spectr. 2022 Apr 27;10(2):e0225221. doi: 10.1128/spectrum.02252-21. Epub 2022 Mar 9.	Jalkanen P	Microbiol Spectr	2022	3/9/2022	PMC9045126		10.1128/spectrum.02252-21
34586934	High level of protection against COVID-19 after two doses of BNT162b2 vaccine in the working age population - first results from a cohort study in Southern Sweden	https://pubmed.ncbi.nlm.nih.gov/34586934/	Pfizer	BNT162b2 mRNA vaccine	Cohort Study	N/A	No	N/A	Björk J, Inghammar M, Moghaddassi M, Rasmussen M, Malmqvist U, Kahn F.	Infect Dis (Lond). 2022 Feb;54(2):128-133. doi: 10.1080/23744235.2021.1982144. Epub 2021 Sep 29.	Björk J	Infect Dis (Lond)	2022	9/29/2021	PMC8500302		10.1080/23744235.2021.1982144
35146780	Efficacy of inactivated vaccines in patients treated with immunosuppressive drug therapy	https://pubmed.ncbi.nlm.nih.gov/35146780/	Unkown	COVID-19 vaccine	Other Study type	N/A	No	N/A	Bemben NM, Berg ML.	Pharmacotherapy. 2022 Apr;42(4):334-342. doi: 10.1002/phar.2671. Epub 2022 Feb 18.	Bemben NM	Pharmacotherapy	2022	2/11/2022	PMC9088666		10.1002/phar.2671
35085490	SARS-CoV-2 infection and vaccine effectiveness in England (REACT-1): a series of cross-sectional random community surveys	https://pubmed.ncbi.nlm.nih.gov/35085490/	AstraZeneca, Pfizer, Moderna	ChAdOx1 nCov-19, BNT162b2 and mRNA-1273	Other Study type	N/A	No	N/A	Chadeau-Hyam M, Wang H, Eales O, Haw D, Bodinier B, Whitaker M, Walters CE, Ainslie KEC, Atchison C, Fronterre C, Diggle PJ, Page AJ, Trotter AJ, Ashby D, Barclay W, Taylor G, Cooke G, Ward H, Darzi A, Riley S, Donnelly CA, Elliott P; COVID-19 Genomics UK consortium.	Lancet Respir Med. 2022 Apr;10(4):355-366. doi: 10.1016/S2213-2600(21)00542-7. Epub 2022 Jan 24.	Chadeau-Hyam M	Lancet Respir Med	2022	1/27/2022	PMC8786320		10.1016/S2213-2600(21)00542-7
35560036	Association of Prior BNT162b2 COVID-19 Vaccination With Symptomatic SARS-CoV-2 Infection in Children and Adolescents During Omicron Predominance	https://pubmed.ncbi.nlm.nih.gov/35560036/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Fleming-Dutra KE, Britton A, Shang N, Derado G, Link-Gelles R, Accorsi EK, Smith ZR, Miller J, Verani JR, Schrag SJ.	JAMA. 2022 Jun 14;327(22):2210-2219. doi: 10.1001/jama.2022.7493.	Fleming-Dutra KE	JAMA	2022	5/13/2022	PMC9107063		10.1001/jama.2022.7493
35227415	Comparative vaccine effectiveness against severe COVID-19 over time in US hospital administrative data: a case-control study	https://pubmed.ncbi.nlm.nih.gov/35227415/	moderna and Janssen, Pfizer-BioNTech	mRNA-1273 and Ad26.COV2, BNT162b2	control study	N/A	No	N/A	Wright BJ, Tideman S, Diaz GA, French T, Parsons GT, Robicsek A.	Lancet Respir Med. 2022 Jun;10(6):557-565. doi: 10.1016/S2213-2600(22)00042-X. Epub 2022 Feb 25.	Wright BJ	Lancet Respir Med	2022	3/1/2022	PMC8881000		10.1016/S2213-2600(22)00042-X
35178857	mRNA COVID-19 vaccine effectiveness against SARS-CoV-2 infection in a prospective community cohort, rural Wisconsin, November 2020 to December 2021	https://pubmed.ncbi.nlm.nih.gov/35178857/	Moderna and Pfizer	COVID-19 vaccine	Cohort Study	Yes	LOE	This study demonstrates that two doses of mRNA vaccine reduce the risk of SARS-CoV-2 infection. However, vaccinated persons continue to be at risk for infection in the community, serving as a reminder of the importance of layered prevention measures to break chains of transmission.	McLean HQ, McClure DL, King JP, Meece JK, Pattinson D, Neumann G, Kawaoka Y, Rolfes MA, Belongia EA.	Influenza Other Respir Viruses. 2022 Jul;16(4):607-612. doi: 10.1111/irv.12970. Epub 2022 Feb 18.	McLean HQ	Influenza Other Respir Viruses	2022	2/18/2022	PMC9111813		10.1111/irv.12970
35131133	Efficacy and safety of the BNT162b2 mRNA COVID-19 vaccine in participants with a history of cancer: subgroup analysis of a global phase 3 randomized clinical trial	https://pubmed.ncbi.nlm.nih.gov/35131133/	Pfizer	BNT162b2 mRNA vaccine	randomized clinical trial	N/A	No	N/A	Thomas SJ, Perez JL, Lockhart SP, Hariharan S, Kitchin N, Bailey R, Liau K, Lagkadinou E, Türeci Ö, Şahin U, Xu X, Koury K, Dychter SS, Lu C, Gentile TC, Gruber WC.	Vaccine. 2022 Mar 1;40(10):1483-1492. doi: 10.1016/j.vaccine.2021.12.046. Epub 2021 Dec 24.	Thomas SJ	Vaccine	2022	2/8/2022	PMC8702495		10.1016/j.vaccine.2021.12.046
35241064	Alterations in the oral microbiome of individuals with a healthy oral environment following COVID-19 vaccination	https://pubmed.ncbi.nlm.nih.gov/35241064/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Uehara O, Abiko Y, Nagasawa T, Morikawa T, Hiraki D, Harada F, Kawano Y, Toraya S, Matsuoka H, Paudel D, Shimizu S, Yoshida K, Asaka M, Furuichi Y, Miura H.	BMC Oral Health. 2022 Mar 3;22(1):50. doi: 10.1186/s12903-022-02093-6.	Uehara O	BMC Oral Health	2022	3/4/2022	PMC8892109		10.1186/s12903-022-02093-6
35183387	The effect of the E484K mutation of SARS-CoV-2 on the neutralizing activity of antibodies from BNT162b2 vaccinated individuals	https://pubmed.ncbi.nlm.nih.gov/35183387/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Uwamino Y, Yokoyama T, Shimura T, Nishimura T, Sato Y, Wakui M, Kosaki K, Hasegawa N, Murata M.	Vaccine. 2022 Mar 18;40(13):1928-1931. doi: 10.1016/j.vaccine.2022.02.047. Epub 2022 Feb 14.	Uwamino Y	Vaccine	2022	2/20/2022	PMC8841208		10.1016/j.vaccine.2022.02.047

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34936758	Effects of BNT162b2 Covid-19 Vaccine Booster in Long-Term Care Facilities in Israel	https://pubmed.ncbi.nlm.nih.gov/34936758/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Muhsen K, Maimon N, Mizrahi A, Varticovschi B, Bodenheimer O, Gelbshtein U, Grotto I, Cohen D, Dagan R.	N Engl J Med. 2022 Jan 27;386(4):399-401. doi: 10.1056/NEJMc2117385. Epub 2021 Dec 22.	Muhsen K	N Engl J Med	2022	12/22/2021	PMC8757568		10.1056/NEJMc2117385
35752951	Assessing real-world vaccine effectiveness against severe forms of SARS-CoV-2 infection: an observational study from routine surveillance data in Switzerland	https://pubmed.ncbi.nlm.nih.gov/35752951/	Pfizer and Moderna	mRNA vaccines	observational study	N/A	No	N/A	Anderegg N, Althaus CL, Colin S, Hauser A, Laube A, Mäusezahl M, Wagner M, Zaffora B, Riou J.	Swiss Med Wkly. 2022 Apr 19;152:w30163. doi: 10.4414/smw.2022.w30163. eCollection 2022 Apr 11.	Anderegg N	Swiss Med Wkly	2022	6/26/2022			10.4414/smw.2022.w30163
35562366	Heterologous immunization with inactivated vaccine followed by mRNA-booster elicits strong immunity against SARS-CoV-2 Omicron variant	https://pubmed.ncbi.nlm.nih.gov/35562366/	Unkown	COVID-19 vaccine	Other Study type	N/A	No	N/A	Zuo F, Abolhassani H, Du L, Piralla A, Bertoglio F, de Campos-Mata L, Wan H, Schubert M, Cassaniti I, Wang Y, Sammartino JC, Sun R, Vlachiotis S, Bergami F, Kumagai-Braesch M, Andréll J, Zhang Z, Xue Y, Wenzel EV, Calzolai L, Varani L, Rezaei N, Chavoshzadeh Z, Baldanti F, Hust M, Hammarström L, Marcotte H, Pan-Hammarström Q.	Nat Commun. 2022 May 13;13(1):2670. doi: 10.1038/s41467-022-30340-5.	Zuo F	Nat Commun	2022	5/13/2022	PMC9106736		10.1038/s41467-022-30340-5
35634013	Attitudes toward coronavirus disease 2019 vaccination in people with multiple sclerosis	https://pubmed.ncbi.nlm.nih.gov/35634013/	Pfizer and Moderna	COVID-19 vaccine	Other Study type	N/A	No	N/A	Marrie RA, Dolovich C, Cutter GR, Fox RJ, Salter A.	Mult Scler J Exp Transl Clin. 2022 May 22;8(2):20552173221102067. doi: 10.1177/20552173221102067. eCollection 2022 Apr-Jun.	Marrie RA	Mult Scler J Exp Transl Clin	2022	5/31/2022	PMC9131385		10.1177/20552173221102067
35732172	Temporal associations of B and T cell immunity with robust vaccine responsiveness in a 16-week interval BNT162b2 regimen	https://pubmed.ncbi.nlm.nih.gov/35732172/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Nayrac M, Dubé M, Sannier G, Nicolas A, Marchitto L, Tastet O, Tauzin A, Brassard N, Lima-Barbosa R, Beaudoin-Bussières G, Vézina D, Gong SY, Benlarbi M, Gasser R, Laumaea A, Prévost J, Bourassa C, Gendron-Lepage G, Medjahed H, Goyette G, Ortega-Delgado GG, Laporte M, Niessl J, Gokool L, Morrisseau C, Arlotto P, Richard J, Bélair J, Prat A, Tremblay C, Martel-Laferrière V, Finzi A, Kaufmann DE.	Cell Rep. 2022 Jun 28;39(13):111013. doi: 10.1016/j.celrep.2022.111013. Epub 2022 Jun 13.	Nayrac M	Cell Rep	2022	6/22/2022	PMC9189142		10.1016/j.celrep.2022.111013
35182795	Immunogenicity of a Third Dose of the BNT162b2 mRNA Covid-19 Vaccine in Patients with Impaired B Cell Reconstitution After Cellular Therapy-A Single Center Prospective Cohort Study	https://pubmed.ncbi.nlm.nih.gov/35182795/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Ram R, Freund T, Halperin T, Ben-Ami R, Amit O, Bar-On Y, Beyar-Katz O, Eilaty N, Gold R, Kay S, Glait-Santar C, Hagin D.	Transplant Cell Ther. 2022 May;28(5):278.e1-278.e4. doi: 10.1016/j.jtct.2022.02.012. Epub 2022 Feb 16.	Ram R	Transplant Cell Ther	2022	2/19/2022	PMC8848544		10.1016/j.jtct.2022.02.012
34876271	Fast COVID-19 vaccine effectiveness estimation on the basis of recovered individual propensity to be vaccinated	https://pubmed.ncbi.nlm.nih.gov/34876271/	Unkown	COVID-19 vaccine	Other Study type	N/A	No	N/A	Guerriero V, Carriero F, Terrazzano G.	Public Health. 2022 Apr;205:e6-e7. doi: 10.1016/j.puhe.2021.10.014. Epub 2021 Nov 9.	Guerriero V	Public Health	2022	12/8/2021	PMC8576069		10.1016/j.puhe.2021.10.014
35015053	Homing In On a SARS-CoV-2 Correlate of Protection	https://pubmed.ncbi.nlm.nih.gov/35015053/	Moderna	mRNA-1273	Other Study type	N/A	No	N/A	Abbasi J.	JAMA. 2022 Jan 11;327(2):115. doi: 10.1001/jama.2021.24117.	Abbasi J	JAMA	2022	1/11/2022			10.1001/jama.2021.24117
34746991	Immune response to SARS-CoV-2 vaccination among renal replacement therapy patients with CKD: a single-center study	https://pubmed.ncbi.nlm.nih.gov/34746991/	Unkown	COVID-19 vaccine	Other Study type	N/A	No	N/A	Matsunami M, Suzuki T, Terao T, Kuji H, Matsue K.	Clin Exp Nephrol. 2022 Mar;26(3):305-307. doi: 10.1007/s10157-021-02156-y. Epub 2021 Nov 8.	Matsunami M	Clin Exp Nephrol	2022	11/8/2021	PMC8572646		10.1007/s10157-021-02156-y
35158452	Effect of cladribine on COVID-19 serology responses following two doses of the BNT162b2 mRNA vaccine in patients with multiple sclerosis	https://pubmed.ncbi.nlm.nih.gov/35158452/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Brill L, Rechtman A, Zveik O, Haham N, Levin N, Shifrin A, Rozenberg A, Vaknin-Dembinsky A.	Mult Scler Relat Disord. 2022 Jan;57:103343. doi: 10.1016/j.msard.2021.103343. Epub 2021 Oct 23.	Brill L	Mult Scler Relat Disord	2022	2/15/2022	PMC8539216		10.1016/j.msard.2021.103343
35314261	Physical and chemical advances of synthetic delivery vehicles to enhance mRNA vaccine efficacy	https://pubmed.ncbi.nlm.nih.gov/35314261/	Unkown	mRNA	Other Study type	N/A	No	N/A	Kim HJ, Seo SK, Park HY.	J Control Release. 2022 May;345:405-416. doi: 10.1016/j.jconrel.2022.03.029. Epub 2022 Mar 18.	Kim HJ	J Control Release	2022	3/22/2022			10.1016/j.jconrel.2022.03.029
35123065	Bacteria-enabled oral delivery of a replicon-based mRNA vaccine candidate protects against ancestral and delta variant SARS-CoV-2	https://pubmed.ncbi.nlm.nih.gov/35123065/	Pfizer-BioNTech and Moderna	mRNA-1273 and BNT162b2	Other Study type	N/A	No	N/A	Jawalagatti V, Kirthika P, Hewawaduge C, Yang MS, Park JY, Oh B, Lee JH.	Mol Ther. 2022 May 4;30(5):1926-1940. doi: 10.1016/j.ymthe.2022.01.042. Epub 2022 Feb 3.	Jawalagatti V	Mol Ther	2022	2/5/2022	PMC8810265		10.1016/j.ymthe.2022.01.042
34923608	Immunogenicity of the BNT162b2 mRNA COVID-19 vaccine in older residents of a long-term care facility: relation with age, frailty and prior infection status	https://pubmed.ncbi.nlm.nih.gov/34923608/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Seiffert P, Konka A, Kasperczyk J, Kawa J, Lejawa M, Mašlanka-Seiffert B, Zembala-John J, Bugdol M, Romanik M, Buldak R, Marcisz C, Derejczyk J, Religa D.	Biogerontology. 2022 Feb;23(1):53-64. doi: 10.1007/s10522-021-09944-9. Epub 2021 Dec 19.	Seiffert P	Biogerontology	2022	12/19/2021	PMC8684786		10.1007/s10522-021-09944-9
35459558	Vaccine effectiveness against onward transmission of SARS-CoV2-infection by variant of concern and time since vaccination, Belgian contact tracing, 2021	https://pubmed.ncbi.nlm.nih.gov/35459558/	Pfizer, Moderna and AstraZenecax	f Ad26.COV2.S, ChAdOx1, BNT162b2, mRNA1273	Other Study type	N/A	No	N/A	Braeye T, Catteau L, Brondeel R, van Loenhout JAF, Proesmans K, Cornelissen L, Van Oyen H, Stouten V, Hubin P, Billuart M, Djiena A, Mahieu R, Hammami N, Van Cauteren D, Wyndham-Thomas C.	Vaccine. 2022 May 11;40(22):3027-3037. doi: 10.1016/j.vaccine.2022.04.025. Epub 2022 Apr 12.	Braeye T	Vaccine	2022	4/23/2022	PMC9001203		10.1016/j.vaccine.2022.04.025
35173720	Successful Induction of Specific Immunological Tolerance by Combined Kidney and Hematopoietic Stem Cell Transplantation in HLA-Identical Siblings	https://pubmed.ncbi.nlm.nih.gov/35173720/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Fehr T, Hübel K, de Rougemont O, Abela I, Gaspert A, Güngör T, Hauri M, Helmchen B, Linsenmeier C, Müller T, Nilsson J, Riesterer O, Scandling JD, Schanz U, Cippà PE.	Front Immunol. 2022 Jan 31;13:796456. doi: 10.3389/fimmu.2022.796456. eCollection 2022.	Fehr T	Front Immunol	2022	2/17/2022	PMC8841472		10.3389/fimmu.2022.796456
34652831	Receptor binding domain-IgG levels correlate with protection in residents facing SARS-CoV-2 B.1.1.7 outbreaks	https://pubmed.ncbi.nlm.nih.gov/34652831/	Unknown	COVID-19 vaccine	Other Study type	N/A	No	N/A	Blain H, Tuaillon E, Gamon L, Pisoni A, Miot S, Delpui V, Si-Mohamed N, Niel C, Rolland Y, Montes B, Groc S, Rafasse S, Dupuy AM, Gros N, Muriaux D, Picot MC, Bousquet J.	Allergy. 2022 Jun;77(6):1885-1894. doi: 10.1111/all.15142. Epub 2021 Oct 29.	Blain H	Allergy	2022	10/15/2021	PMC8652754		10.1111/all.15142
35214599	The Population-Wide Risk-Benefit Profile of Extending the Primary COVID-19 Vaccine Course Compared with an mRNA Booster Dose Program	https://pubmed.ncbi.nlm.nih.gov/35214599/	Moderna and Pfizer-BioNTech	mRNA-1273 and COVID-19 vaccine	Other Study type	N/A	No	N/A	Shiri T, Evans M, Talarico CA, Morgan AR, Mussad M, Buck PO, McEwan P, Strain WD.	Vaccines (Basel). 2022 Jan 18;10(2):140. doi: 10.3390/vaccines10020140.	Shiri T	Vaccines (Basel)	2022	2/26/2022	PMC8880242		10.3390/vaccines10020140
35345646	Efficacy of approved vaccines to prevent COVID-19: a systematic review and network meta-analysis of reconstructed individual patient data from randomized trials	https://pubmed.ncbi.nlm.nih.gov/35345646/	Pfizer/BioNTech, AstraZeneca, MODERNA, Siopharm, Moscow City Health Department, y Janssen/Johnson & Johnson, Novavax, Turkish Health Institutes Association/Sinovac Research & Development	ChAdOx1 nCoV-19, BNT162b2, mRNA-1273, HB02, Gam-COVID-Vac, Ad26.COV2.S, NVX-CoV2373, CoronaVac	randomized trials	N/A	No	N/A	Diallo A, Carlos-Bolumbu M, Diallo MH, Makinson A, Galtier F.	Z Gesundh Wiss. 2022 Mar 23:1-10. doi: 10.1007/s10389-022-01707-1. Online ahead of print.	Diallo A	Z Gesundh Wiss	2022	3/29/2022	PMC8942153		10.1007/s10389-022-01707-1
35169127	Incidence of COVID-19 infection in hospital workers from March 1, 2020 to May 31, 2021 routinely tested, before and after vaccination with BNT162B2	https://pubmed.ncbi.nlm.nih.gov/35169127/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Larese Filon F, Rui F, Ronchese F, De Michieli P, Negro C.	Sci Rep. 2022 Feb 15;12(1):2533. doi: 10.1038/s41598-021-04665-y.	Larese Filon F	Sci Rep	2022	2/16/2022	PMC8847551		10.1038/s41598-021-04665-y
35507482	Effectiveness of Ad26.COV2.S and BNT162b2 Vaccines against Omicron Variant in South Africa	https://pubmed.ncbi.nlm.nih.gov/35507482/	Pfizer and johnson & Johnson–Janssen	Ad26.COV2.S and BNT162b2	Other Study type	N/A	No	N/A	Gray G, Collie S, Goga A, Garrett N, Champion J, Seocharan I, Bamford L, Moultrie H, Bekker LG.	N Engl J Med. 2022 Jun 9;386(23):2243-2245. doi: 10.1056/NEJMc2202061. Epub 2022 May 4.	Gray G	N Engl J Med	2022	5/4/2022	PMC9093716		10.1056/NEJMc2202061
35227416	Vaccine efficacy against severe COVID-19 in relation to delta variant (B.1.617.2) and time since second dose in patients in Scotland (REACT-SCOT): a case-control study	https://pubmed.ncbi.nlm.nih.gov/35227416/	Pfizer, Modern	mRNA-1273	control study	N/A	No	N/A	McKeigue PM, McAllister DA, Hutchinson SJ, Robertson C, Stockton D, Colhoun HM.	Lancet Respir Med. 2022 Jun;10(6):566-572. doi: 10.1016/S2213-2600(22)00045-5. Epub 2022 Feb 25.	McKeigue PM	Lancet Respir Med	2022	3/1/2022	PMC8880999		10.1016/S2213-2600(22)00045-5
34912946	Risk Factors Associated With an Impaired Antibody Response in Kidney Transplant Recipients Following 2 Doses of the SARS-CoV-2 mRNA Vaccine	https://pubmed.ncbi.nlm.nih.gov/34912946/	Pfizer-BioNTech or Moderna	mRNA-1273	control study	N/A	No	N/A	Yi SG, Moore LW, Eagar T, Graviss EA, Nguyen DT, Ibrahim H, Huang HJ, Hobeika M, McMillan R, Saharia A, Mobley C, Podder H, Drews A, Ghobrial RM, Gaber AO, Knight RJ.	Transplant Direct. 2021 Dec 13;8(1):e1257. doi: 10.1097/TXD.0000000000001257. eCollection 2022 Jan.	Yi SG	Transplant Direct	2021	12/16/2021	PMC8670582		10.1097/TXD.0000000000001257
35044205	Antibody Responses to BNT162b2 Vaccination in Japan: Monitoring Vaccine Efficacy by Measuring IgG Antibodies against the Receptor-Binding Domain of SARS-CoV-2	https://pubmed.ncbi.nlm.nih.gov/35044205/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Fujigaki H, Yamamoto Y, Koseki T, Banno S, Ando T, Ito H, Fujita T, Naruse H, Hata T, Moriyama S, Takahashi Y, Suzuki T, Murakami T, Yoshida Y, Yagura Y, Oyamada T, Takemura M, Kondo M, Iwata M, Saito K.	Microbiol Spectr. 2022 Feb 23;10(1):e0118121. doi: 10.1128/spectrum.01181-21. Epub 2022 Jan 19.	Fujigaki H	Microbiol Spectr	2022	1/19/2022	PMC8768797		10.1128/spectrum.01181-21
35660546	Evaluation of antibody titer kinetics and SARS-CoV-2 infections in a large cohort of healthcare professionals ten months after administration of the BNT162b2 vaccine	https://pubmed.ncbi.nlm.nih.gov/35660546/	Pfizer	BNT162b2 mRNA vaccine	Cohort Study	N/A	No	N/A	Ferrari D, Ambrosi A, Di Resta C, Tomaiuolo R, Locatelli M, Banfi G.	J Immunol Methods. 2022 Jul;506:113293. doi: 10.1016/j.jim.2022.113293. Epub 2022 Jun 2.	Ferrari D	J Immunol Methods	2022	6/6/2022	PMC9161676		10.1016/j.jim.2022.113293

PMID	Title	Link	Type of vaccine	Class of Vaccine	Type of study (Case Report/Cohort or any other study type)	About Infection	Relevant	Comment (Only for Relevant ones)	Authors	Citation	First Author	Journal/Book	Publication Year	Create Date	PMCID	NIHMS ID	DOI
35121642	Cutting Edge: Serum but Not Mucosal Antibody Responses Are Associated with Pre-Existing SARS-CoV-2 Spike Cross-Reactive CD4(+) T Cells following BNT162b2 Vaccination in the Elderly	https://pubmed.ncbi.nlm.nih.gov/35121642/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Meyer-Arndt L, Schwarz T, Loyal L, Henze L, Kruse B, Dingeldey M, Gürcan K, Uyar-Aydin Z, Müller MA, Drosten C, Paul F, Sander LE, Demuth I, Lauster R, Giesecke-Thiel C, Braun J, Corman VM, Thiel A.	J Immunol. 2022 Mar 1;208(5):1001-1005. doi: 10.4049/jimmunol.2100990. Epub 2022 Feb 4.	Meyer-Arndt L	J Immunol	2022	2/5/2022			10.4049/jimmunol.2100990
35314351	Oxidative stress and endogenous DNA damage in blood mononuclear cells may predict anti-SARS-CoV-2 antibody titers after vaccination in older adults	https://pubmed.ncbi.nlm.nih.gov/35314351/	Pfizer/BioNTech, Moderna, Astra-Zeneca/Oxford and Janssen	BNT162B2-mRNA vaccine,	Other Study type	N/A	No	N/A	Ntouros PA, Kravvariti E, Vlachogiannis NI, Pappa M, Trougakos IP, Terpos E, Tektonidou MG, Souliotis VL, Sfikakis PP.	Biochim Biophys Acta Mol Basis Dis. 2022 Jun 1;1868(6):166393. doi: 10.1016/j.bbadis.2022.166393. Epub 2022 Mar 18.	Ntouros PA	Biochim Biophys Acta Mol Basis Dis	2022	3/22/2022	PMC8930778		10.1016/j.bbadis.2022.166393
35077960	Antibody titres before and after a third dose of the SARS-CoV-2 BNT162b2 vaccine in patients with cancer	https://pubmed.ncbi.nlm.nih.gov/35077960/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Debie Y, Vandamme T, Goossens ME, van Dam PA, Peeters M.	Eur J Cancer. 2022 Mar;163:177-179. doi: 10.1016/j.ejca.2021.12.025. Epub 2021 Dec 29.	Debie Y	Eur J Cancer	2022	1/25/2022	PMC8714294		10.1016/j.ejca.2021.12.025
35173736	Healthcare Workers in South Korea Maintain a SARS-CoV-2 Antibody Response Six Months After Receiving a Second Dose of the BNT162b2 mRNA Vaccine	https://pubmed.ncbi.nlm.nih.gov/35173736/	Pfizer	BNT162b2 mRNA vaccine	Other Study type	N/A	No	N/A	Choi JH, Kim YR, Heo ST, Oh H, Kim M, Lee HR, Yoo JR.	Front Immunol. 2022 Jan 31;13:827306. doi: 10.3389/fimmu.2022.827306. eCollection 2022.	Choi JH	Front Immunol	2022	2/17/2022	PMC8842222		10.3389/fimmu.2022.827306
34991780	Vaccine effectiveness against severe acute respiratory infections (SARI) COVID-19 hospitalisations estimated from real-world surveillance data, Slovenia, October 2021	https://pubmed.ncbi.nlm.nih.gov/34991780/	Pfizer, Modern	mRNA-1273	Other Study type	N/A	No	N/A	Grgič Vitek M, Klavs I, Učakar V, Serdt M, Mrzel M, Vrh M, Fafangel M.	Euro Surveill. 2022 Jan;27(1):2101110. doi: 10.2807/1560-7917.ES.2022.27.1.2101110.	Grgič Vitek M	Euro Surveill	2022	1/7/2022	PMC8739341		10.2807/1560-7917.ES.2022.27.1.2101110
35222380	A Detailed Overview of Immune Escape, Antibody Escape, Partial Vaccine Escape of SARS-CoV-2 and Their Emerging Variants With Escape Mutations	https://pubmed.ncbi.nlm.nih.gov/35222380/	Moderna and Pfizer-BioNTech	mRNA-1273 and COVID-19 vaccine	Cohort Study	N/A	No	N/A	Chakraborty C, Sharma AR, Bhattacharya M, Lee SS.	Front Immunol. 2022 Feb 9;13:801522. doi: 10.3389/fimmu.2022.801522. eCollection 2022.	Chakraborty C	Front Immunol	2022	2/28/2022	PMC8863680		10.3389/fimmu.2022.801522
35324878	Effectiveness of mRNA Vaccination in Preventing COVID-19-Associated Invasive Mechanical Ventilation and Death - United States, March 2021-January 2022	https://pubmed.ncbi.nlm.nih.gov/35324878/	Pfizer-BioNTech or Moderna	OVID-19 mRNA	Other Study type	N/A	No	N/A	Tenforde MW, Self WH, Gaglani M, Ginde AA, Douin DJ, Talbot HK, Casey JD, Mohr NM, Zepeski A, McNeal T, Ghamande S, Gibbs KW, Files DC, Hager DN, Shehu A, Prekker ME, Frosch AE, Gong MN, Mohamed A, Johnson NJ, Srinivasan V, Steingrub JS, Peltan ID, Brown SM, Martin ET, Monto AS, Khan A, Hough CL, Busse LW, Duggal A, Wilson JG, Qadir N, Chang SY, Mallow C, Rivas C, Babcock HM, Kwon JH, Exline MC, Botros M, Lauring AS, Shapiro NI, Halasa N, Chappell JD, Grijalva CG, Rice TW, Jones ID, Stubblefield WB, Baughman A, Womack KN, Rhoads JP, Lindsell CJ, Hart KW, Zhu Y, Adams K, Surie D, McMorrow ML, Patel MM; IVY Network.	MMWR Morb Mortal Wkly Rep. 2022 Mar 25;71(12):459-465. doi: 10.15585/mmwr.mm7112e1.	Tenforde MW	MMWR Morb Mortal Wkly Rep	2022	3/24/2022	PMC8956334		10.15585/mmwr.mm7112e1
35085218	Effectiveness of a Third Dose of Pfizer-BioNTech and Moderna Vaccines in Preventing COVID-19 Hospitalization Among Immunocompetent and Immunocompromised Adults - United States, August-December 2021	https://pubmed.ncbi.nlm.nih.gov/35085218/	Pfizer-BioNTech or Moderna	OVID-19 mRNA	Other Study type	N/A	No	N/A	Tenforde MW, Patel MM, Gaglani M, Ginde AA, Douin DJ, Talbot HK, Casey JD, Mohr NM, Zepeski A, McNeal T, Ghamande S, Gibbs KW, Files DC, Hager DN, Shehu A, Prekker ME, Erickson HL, Gong MN, Mohamed A, Johnson NJ, Srinivasan V, Steingrub JS, Peltan ID, Brown SM, Martin ET, Monto AS, Khan A, Hough CL, Busse LW, Duggal A, Wilson JG, Qadir N, Chang SY, Mallow C, Rivas C, Babcock HM, Kwon JH, Exline MC, Botros M, Lauring AS, Shapiro NI, Halasa N, Chappell JD, Grijalva CG, Rice TW, Jones ID, Stubblefield WB, Baughman A, Womack KN, Rhoads JP, Lindsell CJ, Hart KW, Zhu Y, Naioti EA, Adams K, Lewis NM, Surie D, McMorrow ML, Self WH; IVY Network.	MMWR Morb Mortal Wkly Rep. 2022 Jan 28;71(4):118-124. doi: 10.15585/mmwr.mm7104a2.	Tenforde MW	MMWR Morb Mortal Wkly Rep	2022	1/27/2022			10.15585/mmwr.mm7104a2
35189624	Effectiveness of mRNA-1273 against SARS-CoV-2 Omicron and Delta variants	https://pubmed.ncbi.nlm.nih.gov/35189624/	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Tseng HF, Ackerson BK, Luo Y, Sy LS, Talarico CA, Tian Y, Bruxvoort KJ, Tubert JE, Florea A, Ku JH, Lee GS, Choi SK, Takhar HS, Aragones M, Qian L.	Nat Med. 2022 May;28(5):1063-1071. doi: 10.1038/s41591-022-01753-y. Epub 2022 Feb 21.	Tseng HF	Nat Med	2022	2/21/2022	PMC9117141		10.1038/s41591-022-01753-y
34911691	Effectiveness of mRNA-1273 against delta, mu, and other emerging variants of SARS-CoV-2: test negative case-control study	https://pubmed.ncbi.nlm.nih.gov/34911691/	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Bruxvoort KJ, Sy LS, Qian L, Ackerson BK, Luo Y, Lee GS, Tian Y, Florea A, Aragones M, Tubert JE, Takhar HS, Ku JH, Paila YD, Talarico CA, Tseng HF.	BMJ. 2021 Dec 15;375:e068848. doi: 10.1136/bmj-2021-068848.	Bruxvoort KJ	BMJ	2021	12/16/2021	PMC8671836		10.1136/bmj-2021-068848
35249272	Covid-19 Vaccine Effectiveness against the Omicron (B.1.1.529) Variant	https://pubmed.ncbi.nlm.nih.gov/35249272/	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Andrews N, Stowe J, Kirsebom F, Toffa S, Rickeard T, Gallagher E, Gower C, Kall M, Groves N, O'Connell AM, Simons D, Blomquist PB, Zaidi A, Nash S, Iwani Binti Abdul Aziz N, Thelwall S, Dabrera G, Myers R, Amirthalingam G, Gharbia S, Barrett JC, Elson R, Ladhani SN, Ferguson N, Zambon M, Campbell CNJ, Brown K, Hopkins S, Chand M, Ramsay M, Lopez Bernal J.	N Engl J Med. 2022 Apr 21;386(16):1532-1546. doi: 10.1056/NEJMoa2119451. Epub 2022 Mar 2.	Andrews N	N Engl J Med	2022	3/6/2022	PMC8908811		10.1056/NEJMoa2119451
	Protection against Omicron re-infection conferred by prior heterologous SARS-CoV-2 infection, with and without mRNA vaccination		Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Sara Carazo, Danuta M. Skowronski, Marc Brisson, Chantal Sauvageau, Nicholas Brousseau, Rodica Gilca, Manale Ouakki, Sapha Barkati, Judith Fafard, Denis Talbot, Vladimir Gilca, Geneviève Deceuninck, Christophe Garenc, Alex Carignan, Philippe De Wals, Gaston De Serres	BMJ Yale	Sara Carazo	Protection against Omicron re-infection conferred by prior heterologous SARS-CoV-2 infection, with and without mRNA vaccination Sara Carazo, Danuta M. Skowronski, Marc Brisson, Chantal Sauvageau, Nicholas Brousseau, Rodica Gilca, Manale Ouakki, Sapha Barkati, Judith Fafard, Denis Talbot, Vladimir Gilca, Geneviève Deceuninck, Christophe Garenc, Alex Carignan, Philippe De Wals, Gaston De Serres medRxiv 2022.04.29.22274455; doi: https://doi.org/10.1101/2022.04.29.22274455	2022				medRxiv 2022.04.29.22274455; doi: https://doi.org/10.1101/2022.04.29.22274455
35297591	Efficacy of a Fourth Dose of Covid-19 mRNA Vaccine against Omicron	https://pubmed.ncbi.nlm.nih.gov/35297591/	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Please see the PBRER Section	Regev-Yochay G, Gonen T, Gilboa M, Mandelboim M, Indenbaum V, Amit S, Meltzer L, Asraf K, Cohen C, Fluss R, Biber A, Nemet I, Kliker L, Joseph G, Doolman R, Mendelson E, Freedman LS, Harats D, Kreiss Y, Lustig Y.	N Engl J Med. 2022 Apr 7;386(14):1377-1380. doi: 10.1056/NEJMc2202542. Epub 2022 Mar 16.	Regev-Yochay G	N Engl J Med	2022	3/17/2022	PMC9006792		10.1056/NEJMc2202542

Appendix 11.28g Lack of Efficacy/Vaccine failure: Additional literature search strategy

((((("Vaccine Efficacy"[MeSH Terms]) OR ("Vaccine efficacy"[Text Word])) OR ("Lack of efficacy"[Text Word])) AND (("mrna vaccines"[MeSH Terms] OR "2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "mRNA 1273"[All Fields] OR "mRNA 1273"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "mrna1273"[All Fields]) OR ("modernatx"[All Fields] AND "1273"[All Fields]) OR "1273"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "m 1273"[All Fields]) OR "m 1273"[All Fields] OR ("moderna"[All Fields] AND ("covid 19 vaccines"[MeSH Terms] OR ("covid 19"[All Fields] AND "vaccines"[All Fields]) OR "covid 19 vaccines"[All Fields] OR ("covid19"[All Fields] AND "vaccine"[All Fields]) OR "covid19 vaccine"[All Fields])) OR "moderna covid 19 vaccine"[All Fields] OR "moderna covid 19 vaccine"[All Fields] OR "moderna covid 19 vaccine"[All Fields] OR "SPIKEVAX"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields] AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields] OR "elasomeran"[All Fields]) OR "CX-024414"[All Fields] OR "tak 919"[All Fields] OR "tak 919"[All Fields] OR ("2019 ncov vaccine mrna 1273"[MeSH Terms] OR ("2019 ncov"[All Fields]) OR (SARS-CoV-2 vaccination) AND "vaccine"[All Fields] AND "mRNA 1273"[All Fields]) OR "2019 ncov vaccine mrna 1273"[All Fields])))))) AND (("2022/01/01"[Date - Publication] : "2022/06/18"[Date - Publication]))

Appendix 11.29a Elderly: Fatal case listings

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	GERMANY	Sudden death	90.00	Male			4.1(b)	
	HUNGARY	Cardiogenic shock	65.00	Male	Emphysema(H); Arteriosclerosis(H); Cirrhosis alcoholic(H); Cardiomyopathy alcoholic(H); Alcoholism(H)			3003659
	KOREA, REPUBLIC OF	Cardiac arrest, Syncope	70.00	Male	Large intestine polyp(H)			
	TAIWAN, PROVINCE OF CHINA	Decreased appetite, Oedema peripheral	70.00	Male				3003184-CDC
	TAIWAN, PROVINCE OF CHINA	Thrombocytopenia	74.00	Female				
	PHILIPPINES	Pyrexia	70.00	Female				
	SWITZERLAND	COVID-19, Diarrhoea, Dyspnoea, Oxygen saturation decreased, Vaccination failure	86.00	Female	Asthma(C); Myocardial ischaemia(C); Hypertension(C); Hypothyroidism(C); Small cell lung cancer(C)	CLOPIDOGREL; ESOMEPRAZOLE; EUTHYROX; LISINOPRIL; NEBILET; ZOLPIDEM; SERETIDE; LAXOBERON; PURSANA; ATOZET; KALCIPOS D3; LERCANIDIPINE; FLUIMUCIL; DOMPERIDONE; CO-DAFALGAN; TRAMADOL		
	AUSTRIA	COVID-19, Vaccination failure	67.00	Male				3001177; 3000493
	SWITZERLAND	Apnoea, Cardiac arrest	86.00	Male	Pulmonary fibrosis(C); Myocardial infarction(H)			
	GERMANY	Sudden death	85.00	Female	Myocardial ischaemia(H); Chronic obstructive pulmonary disease(H)			
	SWITZERLAND	Death	85.00	Female	Hypertension(C); Peripheral venous disease(H); Malignant melanoma(H); Skin laceration(C)	AMLODIPINA ACC; VALSARTAN		
	LUXEMBOURG	Asthenia, General physical health deterioration	76.00	Female	Breast cancer(H); Malignant neoplasm progression(H); Metastases to central nervous system(H); Ovarian cancer(H); Gastrooesophageal reflux disease(H); Cholelithiasis(H); Osteoporosis(H); Hypercholesterolaemia(H); Hypothyroidism(H); Metastases to bone(H); Fracture(H); Metastases to lung(H); Metastases to liver(H); Metastases to skin(H)	D-CURE; CRESTOR; AROMASIN; RELVAR; XELODA; NEXIAM [ESOMEPRAZOLE MAGNESIUM]; XGEVA; VENTOLIN [SALBUTAMOL SULFATE]; EUTHYROX		3000493; 300042721
	GERMANY	Acute pulmonary oedema, Pulmonary embolism	85.00	Female	VAXZEVRIA; VAXZEVRIA			092F21A
	AUSTRIA	COVID-19, Vaccination failure	69.00	Female				3001939; 3001531
	ITALY	Cerebrovascular accident	92.00	Female				3001442
	SPAIN	Cardio-respiratory arrest, Pulmonary thrombosis	72.00	Female				
	TAIWAN, PROVINCE OF CHINA	Altered state of consciousness	75.00	Male				
	TAIWAN, PROVINCE OF CHINA	Asthma	72.00	Male				939599-CDC
	BRUNEI DARUSSALAM	Asthenia, Back pain, Death, Decreased appetite, Pyrexia, Sepsis	79.00	Female	Hypertension(C); Diabetes mellitus(C); Back pain(C); Osteoporosis(C); Hypercalcaemia(C); Hyperlipidaemia(C); Oedema(H); Anaemia folate deficiency(H)			3004736
	BRUNEI DARUSSALAM	Haemorrhagic stroke	82.00	Male	Hypertension(C); Tobacco user(C)			3004736
	GREECE	Back pain, Cardiac arrest, Cerebral thrombosis, Death, Diarrhoea, Loss of consciousness, Musculoskeletal chest pain, Neck pain, Pulmonary oedema, Pulmonary thrombosis, Pyrexia, Respiratory distress, Syncope, Vomiting	65.00	Unknown				
	UNITED STATES	Death	80.00	Female				
	FRANCE	Death	98.00	Female	Asthma(H); Hypertension(C); Dementia Alzheimer's type(C); Hypercholesterolaemia(H); Type 2 diabetes mellitus(C)			018G21A
	GERMANY	Sudden death	86.00	Male	SPIKEVAX; SPIKEVAX			3004951
	AUSTRIA	COVID-19, Vaccination failure	79.00	Male				3002188; 3000493
	GERMANY	Breast pain, Sudden death	67.00	Male	COVID-19 VACCINE ASTRAZENECA(H); COMIRNATY(H)			
	SWEDEN	Acute myocardial infarction, Cardiac failure	93.00	Male	COVID-19 immunisation(H); COVID-19 immunisation(H)			DOS 3: 3005835
	FRANCE	Vaccination failure	74.00	Male	Rheumatoid arthritis(H); Hypertension(H); Diabetes mellitus(H); Transient ischaemic attack(H)	TRESIBA; METFORMINE [METFORMIN]; AMLODIPINE; KARDEGIC; METHOTREXATE; PERINDOPRIL; ALLOPURINOL; BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE; REPAGLINIDE; ACIDE FOLIQUE		
	AUSTRIA	Death	73.00	Male	Diabetes mellitus(C); Hypertension(C); COVID-19 VACCINE MODERNA(H); COVID-19 VACCINE MODERNA(H)			
	SWITZERLAND	Acute disseminated encephalomyelitis, Death, Depressed level of consciousness, Epilepsy	82.00	Male				
	UNITED STATES	Death	70.00	Female				
	UNITED STATES	Death	98.00	Female				
	UNITED STATES	Acute respiratory distress syndrome, COVID-19 pneumonia, Vaccine induced antibody absent	70.00	Male	End stage renal disease(H); Left ventricular failure(C); Type 1 diabetes mellitus(C); Renal transplant	MYCOPHENOLATE; TACROLIMUS; PREDNISONE		
	THAILAND	Chest discomfort, Chest pain, Loss of consciousness, Seizure	84.00	Male				3005841
	THAILAND	Death, Dyspnoea, Fatigue, Pyrexia	84.00	Male	Osteoporosis(C); Bedridden(C); Hip fracture(H)			021F21A

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	THAILAND	Dyspnoea, Mouth haemorrhage	85.00	Male	Embolic stroke(H); Atrial fibrillation(H)		4.1(b)	3005841
	THAILAND	Cerebrovascular accident	77.00	Male				021F21A
	FRANCE	Pulmonary embolism	68.00	Male				
	PORTUGAL	Ischaemic stroke	70.00	Female	Goitre(H); Syncope(H); Nicotine dependence(H); Hypertension(C); Dyslipidaemia(H); Meningioma(C); Tobacco user(H)	COVERSYL [PERINDOPRIL ERBUMINE]; LIPOCOMB; TRAUSAN; METIBASOL; ACETYLSALICYLIC ACID		017G21A
	ITALY	Aphasia, Facial spasm, Hemiparesis, Loss of consciousness	97.00	Male	Ischaemic stroke(H)			94f21a
	THAILAND	Cardiac arrest	72.00	Male	Myocardial ischaemia(C)			TRC3005841
	NETHERLANDS	Malaise, Myalgia, Sudden cardiac death	73.00	Male	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	ACETYLSALICYLZUUR		044G21ABS
	THAILAND	COVID-19 pneumonia, Respiratory failure	91.00	Female	Hypertension(C); Dyslipidaemia(C); Insomnia(H); Coronary artery disease(H)			TRC3005841
	THAILAND	Cardiac arrest	66.00	Female				049F21A
	CZECH REPUBLIC	Dyspnoea, Leukaemia, Pain, Pain in extremity, Rash macular, Spinal pain	72.00	Female	Cardiac disorder(C)			
	GERMANY	General physical health deterioration, Hypophagia, Somnolence	91.00	Female	SPIKEVAX; SPIKEVAX(H)			3005291
	AUSTRIA	COVID-19, Vaccination failure	73.00	Male				3002545; 3001938
	FINLAND	Anxiety, Back pain, Balance disorder, Confusional state, Decreased appetite, Dehydration, Dementia, Emotional distress, Erysipelas, Eyelid ptosis, Fall, Fear, Haematoma, Urinary tract infection, Vomiting	88.00	Female				
	FRANCE	Immunisation reaction, Sudden death	80.00	Female	Obesity(H); Hypertension(C)	COMIRNATY		3005242
	THAILAND	Cerebral haemorrhage, Fall	85.00	Female		ASTRAZENECA COVID-19 VACCINE		
	AUSTRIA	COVID-19, Vaccination failure	74.00	Female				3004218
	GREECE	Drug ineffective, Haemorrhage intracranial, Hypertensive crisis	71.00	Female				
	FRANCE	Death	85.00	Male	Cardiac failure(C); Diabetes mellitus(C); Hypertension(C); Arrhythmia(H); Hypoacusis(H); Silicosis(H); Hepatic mass(H); Ventricular dysfunction(C); Inguinal hernia(H)	COMIRNATY		3005242
	UNITED STATES	Arthralgia, Cerebral thrombosis, Death, Fall, Incoherent, Joint swelling, Neurological symptom	77.00	Female	Hypertension(C); Depression(C); Disability(C); Obesity(C)	NEURONTIN; INFLUENZA VACCINE		939909
	FRANCE	Death	86.00	Male	Osteoporotic fracture(H); Polymyalgia rheumatica(H); Peripheral arterial occlusive disease(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE			057G21A
	UNITED KINGDOM	Circulatory collapse, Cough, Delirium, Empyema, Pyrexia	83.00	Male	Diabetes mellitus(C); Chronic obstructive pulmonary disease(C); Suspected COVID-19(C)			
	ITALY	Pyrexia, Tremor, Vomiting	90.00	Male	Osteoarthritis(H); Arrhythmia(H)			
	UNITED STATES	Lung neoplasm malignant, Pneumonia	70.00	Male	Ex-tobacco user(H)			038A21A; 026A21A
	ITALY	Abdominal distension, Asthenia, Cardiac arrest, Chest discomfort, Confusional state, Headache, Insomnia, Nausea, Vomiting	72.00	Female	Nicotine dependence(H); Bronchitis chronic(H); Cachexia(H); Pain(H); Anxiety(H); Eating disorder(H); Back pain(H); Depression(C); Toxic nodular goitre(H)	DUROGESIC; FOSTERA; TAPAZOLE; PARACETAMOLO; MOVICOLON; OMEPRAZOLE; ZOLOFT; DIBASE; XANAX; HALCION		3006322
	ITALY	Intestinal infarction, Malaise, Vomiting	84.00	Male				3005887
	SPAIN	Haemolytic anaemia	71.00	Male				300042722
	ITALY	Asthenia, Blood pressure decreased, Dyspnoea, Retching	81.00	Male				3002545
	ITALY	Cardiac arrest, Respiratory arrest	72.00	Female	VAXZEVRIA			000004A
	TAIWAN, PROVINCE OF CHINA	Haemophagocytic lymphohistiocytosis, Stevens-Johnson syndrome, Toxic epidermal necrolysis	77.00	Female	Mouth ulceration(H); Perineal ulceration(H)			
	TAIWAN, PROVINCE OF CHINA	Cardiac discomfort, Insomnia	68.00	Female				
	GERMANY	Death	89.00	Female	Bronchial carcinoma(C); COVID-19(H); Chronic obstructive pulmonary disease(C); Diabetes mellitus(C); Pulmonary resection(C); Pulmonary embolism(H)			045921A
	GERMANY	Death	72.00	Male				
	TAIWAN, PROVINCE OF CHINA	Rectal cancer	75.00	Male	Prostatic disorder(H); Colorectal cancer(C)			
	FRANCE	Cardio-respiratory arrest, Myocardial infarction	83.00	Female	Atrial fibrillation(C); Myocardial ischaemia(C); Hypertension(C); Dyslipidaemia(C)			
	GERMANY	Myocardial infarction	65.00	Male	Hyperuricaemia(C); Hypercholesterolaemia(C); Tobacco user(C)			3004951
	GERMANY	Cerebrovascular accident	82.00	Female				
	GERMANY	Death	66.00	Male	Coronary artery disease(C); Coronary artery bypass			
	GERMANY	Death, Loss of consciousness	89.00	Female				
	GERMANY	Cardiac arrest	90.00	Male	Cardiac failure(C)			000117A

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	DENMARK	Cardiac arrest	67.00	Female	SPIKEVAX; SPIKEVAX	PANODIL; LANSOPRAZOL CF; EFASTAD; ZARATOR MAX; CARDIOSTAD PLUS; VENLAFAXIN KRKA; IBUPROFEN DH; KLORZOXAZON; METFORMIN BOIE	4.1(b)	3004959
	GERMANY	Cerebrovascular accident	96.00	Male				
	PORTUGAL	Chills, Respiratory distress	85.00	Male	Chronic kidney disease(H); Cardiovascular disorder(H)			3005885
	GERMANY	Cerebrovascular accident	92.00	Male	Cardiac assistance device user(C)			
	GERMANY	Death	90.00	Female	COMIRNATY; Dementia(C)			
	ITALY	Bronchitis chronic, Pyrexia	92.00	Female				
	GERMANY	Arrhythmia	85.00	Female	COMIRNATY(H)			000128A
	GERMANY	Myocardial infarction	66.00	Male				216044
	GERMANY	Sudden death	81.00	Male				
	AUSTRIA	Cardiac arrest, Chills, Pyrexia	80.00	Male	Bedridden(C); Myocardial infarction(H); Hip surgery; Hip surgery; Cardiac pacemaker insertion; Decreased immune responsiveness(C); Medical device site joint infection(H)	ELIQUIS; OLEOVIT A; ANXIOLIT; LASIX P; SERTRALINE A; DOXYCYCLINE RIA; TRITTICO; RISPERIDONA; PANTOPRAZOLE; MOLAXOLE; HYDAL; HYDAL; BISOPROLOL EG		3005897
	GERMANY	Death, Syncope	89.00	Female				092F21A
	FRANCE	Cardiac arrest	86.00	Female	Cardiac valve disease(C); Depression(H); Hypertension(C)			018G21A
	GERMANY	Cerebral haemorrhage, Thrombosis	81.00	Male				
	AUSTRIA	COVID-19, Vaccination failure	90.00	Male				
	NETHERLANDS	Abdominal pain, Blood glucose fluctuation, Circulatory collapse, Diarrhoea, Gastrointestinal pain, Haematochezia, Headache, Rectal haemorrhage, Resuscitation, Sinusitis, Vomiting	77.00	Female	Pancreatitis(H); Obesity(H); Radius fracture(H); Dyspnoea(H); Type 1 diabetes mellitus(H); Trigger finger(H); Cholangitis(H); Tibia fracture(H); Tendon sheath incision(H); Agoraphobia(H); Cholelithiasis(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; Hypertension(C); Neurolysis	AZITROMYCINE; INSULIN; HYDROCHLOORTHIAZIDE		
	UNITED KINGDOM	COVID-19, Ruptured cerebral aneurysm	76.00	Female				000014A
	NETHERLANDS	Myocardial infarction	80.00	Female	Atrial fibrillation(C); Diabetes mellitus(C); Obesity(C); Vertigo positional(C); Hypertension(C); Dizziness postural(C); Myocardial infarction(H); COMIRNATY; COMIRNATY	METFORMINE [METFORMIN]; FRUSEMIDE [FUROSEMIDE]; ACENOCOUMAROL; INSULINE NPH; OMEPRAZOL A; ATORVASTATINE [ATORVASTATIN]; GLIMEPIRIDE; VALSARTAN; PAROXETIN [PAROXETINE]; METOPROLOL;MORPHINE; BARNIDIPINE		
	GREECE	Chills, Coronary artery occlusion, Death, Dyspnoea, Fatigue, Feeling cold, Myocardial infarction, Pyrexia	73.00	Male	Hypertension(H); Diabetes mellitus(H)			
	JAPAN	Pneumonia aspiration, Respiratory failure	82.00	Male	Cardiac failure(C); Chronic obstructive pulmonary disease(C)			3005700
	KOREA, REPUBLIC OF	Sudden death	66.00	Male				
	CROATIA	Agonal respiration, Death	93.00	Female	Cor pulmonale chronic(C); Chronic respiratory failure(C); Goitre(C); Scoliosis(C); Cholecystectomy; Hypertension(C); Delusion(C); VAXZEVRIA; VAXZEVRIA; Neurosis(H); OXYGEN(H)	ATROVENT N; KALINORM; LEXILLIUM; NEBILET; RISSET; FUROSEMIDA MK [FUROSEMIDE]		3004952
	ITALY	Carotid artery occlusion, Cerebral artery occlusion, Ischaemic stroke	71.00	Male	Hypertension(C); Nicotine dependence(H)			017G21A
	UNITED STATES	Discomfort, Dizziness, Feeling of body temperature change, Pulmonary thrombosis	66.00	Female	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	PLAVIX		
	UNITED KINGDOM	Death, Fatigue, Syncope	78.00	Male				3005287
	GERMANY	Asthenia, Death, Dehydration, Diarrhoea, Dizziness, Malaise, Nausea	78.00	Female	Adrenal insufficiency(H); Autoimmune thyroiditis(H); Vitamin B12 deficiency(H); VAXZEVRIA; COMIRNATY			
	GERMANY	Cardiac arrest	79.00	Female	Hypertension(C); Hiatus hernia(C); B-cell small lymphocytic lymphoma(C); Hyperlipidaemia(C); Spinal osteoarthritis(C)			3005291
	ITALY	Cardiac arrest, Dyspnoea, Hyperhidrosis, Loss of consciousness, Orthopnoea	86.00	Female	Hypertensive heart disease(H)	SERTRALINE; COTAREG		044G21A
	FINLAND	Brain injury, Myocardial ischaemia, Ventricular fibrillation	86.00	Male				3006274
	ITALY	Cerebrovascular accident	81.00	Female	Hypertension(H); Diabetes mellitus(H)			
	GERMANY	Cardiac arrest, Pulmonary oedema	72.00	Female	Arrhythmia(H); Renal failure(H); Chronic obstructive pulmonary disease(H); SPIKEVAX(H)			000120A
	SPAIN	Sudden death	69.00	Female				
	GERMANY	Death, General physical health deterioration, Muscle spasms, Pulmonary oedema, Pyrexia	81.00	Female				
	JAPAN	Arrhythmia, Cardio-respiratory arrest, Myocardial infarction, Respiratory arrest	96.00	Female	Dementia(C); Gastritis(C); Cerebral infarction(H)	LANSOPRAZOLE; MEMANTINE HYDROCHLORIDE; MEMANTINE HYDROCHLORIDE; EXCEGRAN; ENSURE H		3005701
	GERMANY	Death, Fatigue, Influenza, Paraesthesia, Vomiting	81.00	Female	Heart valve calcification(C)			000114AM
	JAPAN	Aortic dissection, Cardio-respiratory arrest, Dyspnoea	68.00	Female	COMIRNATY; COMIRNATY			3005840

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	UNITED KINGDOM	Hypertension, Oxygen saturation decreased, Pyrexia, Tachycardia	79.00	Male	Pulmonary fibrosis(H); Lower respiratory tract infection(H); Dyspnoea(H); Hypertension(C); Oxygen saturation decreased(H); Arthritis(H); (H); COVID-19(H)	ATORVASTATIN; PFIZER BIONTECH COVID-19 VACCINE; DOXYCYCLINE; MORPHINE; SALBUTAMOL	4.1(b)	
	GERMANY	Atonic seizures, Drop attacks, Pyrexia, Sudden death	83.00	Male	COVID-19 VACCINE(H); COVID-19 VACCINE(H)			30001651
	FRANCE	Myocardial infarction	80.00	Female	Osteoarthritis(H)			
	GERMANY	Sudden death	65.00	Male	Coronary artery disease(H); Atrial fibrillation(H); Hypertension(H)			000105A
	GERMANY	Coagulopathy, COVID-19, Hepatic failure, Multiple organ dysfunction syndrome, Shock haemorrhagic, Thrombocytopenia	69.00	Female	COVID-19(C); VAXZEVRIA; COMIRNATY			000105A
	ITALY	Fatigue, Thrombosis, Vertigo	65.00	Female	Cardiac failure(C); Atrial fibrillation(C); Tricuspid valve incompetence(C)			
	UNITED STATES	COVID-19, Respiratory failure	80.00	Male	Liver transplant; Hepatic cirrhosis(C); Cardiomyopathy(C); Atrial fibrillation(C); Chronic kidney disease(C)	TACROLIMUS		
	UNITED STATES	COVID-19 pneumonia, Respiratory failure	82.00	Male	Liver transplant; Coronary artery disease(C); Diabetes mellitus(C); Chronic kidney disease(C)	TACROLIMUS		
	FRANCE	Vaccination failure	76.00	Male	Sleep apnoea syndrome(C); Renal transplant; Gout(C); Deafness bilateral(C); Deep vein thrombosis(C); Myocardial ischaemia(C); Dyslipidaemia(C); Hypertension(C); Coronary artery bypass; Optic ischaemic neuropathy(C); Atrioventricular block complete(C)			300042722 & UNK; 300042722 & UNK
	SINGAPORE	Head injury	65.00	Male				
	GERMANY	Diarrhoea, Malaise, Nausea, Pyrexia, Vomiting	89.00	Male				
	FRANCE	Haemorrhagic stroke	79.00	Male	Myalgia(H); Cerebrovascular accident(H); Hypertension(H); Ex-tobacco user(H); Dyslipidaemia(H); Arrhythmia(H)	ASPIRINETAS; RAMIPRIL; VAXZEVRIA		006G21A
	GERMANY	Sudden death	70.00	Female	COVID-19 VACCINE ASTRAZENECA; COMIRNATY			
	GERMANY	Sudden death	67.00	Male	VAXZEVRIA; COMIRNATY			3004951
	NETHERLANDS	Pneumonia	84.00	Male	Pulmonary embolism(H); Arrhythmia(H); Pneumonia(H); Pulmonary oedema(H); Oesophageal cancer metastatic(C); COMIRNATY; COMIRNATY	LENDORMIN; OXYCODON; B IJZER NUTRIDOSES; ANTICOAGULANT CITRATE DEXTROSE; CODEINE SULPHATE		
	PORTUGAL	Acute pulmonary oedema	69.00	Male		ULTIBRO BREEZHALER; XARELTO; OMEPRAZOLE; MONTELUKAST; CONCOR		
	GERMANY	Chest pain, Coronary arterial stent insertion, Electrocardiogram abnormal	67.00	Male	Hyperlipidaemia(H); Atrial fibrillation(C); Coronary artery disease(C); Hypertension(C)			
	NETHERLANDS	Cerebral infarction, Dysarthria, Dysphagia, Loss of consciousness, Pneumonia	84.00	Female	Hypersensitivity; Fall(H); Urinary bladder polyp(H); Breast cancer(H); Intermittent claudication(H); Stent placement; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; Cataract(H); Urogenital prolapse(H); Hypertension(H); Cognitive disorder(H)	PAROXETIN [PAROXETINE]; METOPROLOL SUCCINAT BETA; ACETYLSALICYLZUUR; CHLOORTALIDON		093F21A
	SPAIN	Chest pain	69.00	Male	Ischaemic cardiomyopathy(H); Chronic kidney disease(H); Alcohol use(H); Hypertension(C); Tobacco abuse(H); Type 2 diabetes mellitus(C); Hyperlipidaemia(C)			3006276; ABY1328; ABW7197
	FRANCE	Sudden death	88.00	Male	Coronary artery disease(H); Diabetes mellitus(C)			007G21A
	BELGIUM	Arthralgia, Chills, Death, Extensive swelling of vaccinated limb, Fatigue, Feeling cold, Injection site induration, Injection site movement impairment, Injection site pain, Injection site reaction, Limb immobilisation, Lymphoma, Malaise, Myalgia, Plasma cell myeloma recurrent, Pyrexia, Skin fissures, Tinnitus	74.00	Female	Plasma cell myeloma(H)			3000494; 3000494
	SPAIN	COVID-19 pneumonia, Vaccination failure	65.00	Male		VAXZEVRIA		216001
	ITALY	Asthenia, Coma, Confusional state, Dysphagia, Dysphonia, Emergency care	69.00	Male		ADALAT; ESKIM; DEPAKIN; TOTALIP; RIVOTRIL; PRITORPLUS		3005884
	GERMANY	Death	85.00	Male				042G21A
	PHILIPPINES	Cough	79.00	Male				PCA0030
	GERMANY	Cerebral infarction, Cerebrovascular accident, Hemiparesis	80.00	Male	Atrial fibrillation(C); BNT162B2; BNT162B2			092F21A
	JAPAN	Drowning, Listless, Somnolence	77.00	Female	Uterine cancer(C); Rectal cancer(C); Metastases to lymph nodes(C); COMIRNATY; COMIRNATY	TEGAFUR;URACIL		3006279
	NETHERLANDS	Bradykinesia, Cerebral haemorrhage, Incoherent	72.00	Male				
	JAPAN	Acidosis, Arthralgia, Cardiac arrest, Listless, Oedema peripheral, Pericarditis, Pleural effusion, Pulmonary congestion	94.00	Female	Diabetes mellitus(C); Chronic kidney disease(C); Cardiac failure chronic(C); Dementia(C); Chronic sinusitis(C); Bronchitis chronic(C); Angina pectoris(C); Hyperuricaemia(C); Constipation(C); Subarachnoid haemorrhage(H); CELECOX(H); KAKKONTOKASENKYUSHIN'I [CINNAMOMUM CASSIA BARK;CNIDIUM OFFICINALE RHIZOME;EPHEDRA SPP. HERB;GLYCYRRHIZA SPP. ROOT;MAGNOLIA SPP. FLOWER;PAEONIA LACTIFLORA ROOT;PUERARIA LOBATA ROOT;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA FRUIT](H); Spinal operation	CALONAL; TRAZENTA; AMLODIN; LASIX P; ALDACTONE A; FEBURIC; MEMARY; BISOLVON; GASMOTIN SR; YODEL-S		3005840
	JAPAN	Chills, Depressed level of consciousness, Feeling cold, Pallor, Pyrexia, Respiratory arrest	87.00	Female	Gastrooesophageal reflux disease(C); Constipation(C); Decreased appetite(C); Decreased activity(C); COMIRNATY; COMIRNATY	RABEPRAZOLE SODIUM; MAGMITT; NINJIN'YOEITO		3005694
	GERMANY	Death, Dehydration	82.00	Male	Cardiac failure(C)			000117A
	SPAIN	Death	68.00	Male		VAXZEVRIA		031G21A
	ITALY	Acute kidney injury, Cardiomegaly, Generalised oedema, Shock	77.00	Female	Cholelithiasis(H); Acute myeloid leukaemia(H); Type 2 diabetes mellitus(C); Hypothyroidism(C); Chronic kidney disease(C); Cardiac failure(C); Humerus fracture(H); Cerebrovascular accident(H); COMIRNATY; COMIRNATY	TRITTICO; LASIX P; TORVAST; FLUVION; CETIRIZINE; COUMADIN; LANSOX; ZAROXOLYN; CALCITRIOL; ZOLOFT; BISOPROLOL; ABASAGLAR; EUTIROX		3005887

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	TAIWAN, PROVINCE OF CHINA	Cardiac arrest	71.00	Female	Diabetes mellitus(C); Hypertension(C)		4.1(b)	
	TAIWAN, PROVINCE OF CHINA	Fatigue, Myalgia, Vaccination site pain	71.00	Female				
	TAIWAN, PROVINCE OF CHINA	Altered state of consciousness, Respiratory rate decreased	66.00	Male				
	TAIWAN, PROVINCE OF CHINA	Asthma, Bradycardia, Hypotension	99.00	Female	Hypertension(H)			
	TAIWAN, PROVINCE OF CHINA	Altered state of consciousness	77.00	Female				006K21A_1110208-CDC
	TAIWAN, PROVINCE OF CHINA	Chest discomfort	77.00	Male				
	TAIWAN, PROVINCE OF CHINA	Death	92.00	Female				
	JAPAN	Acute myocardial infarction, Cardio-respiratory arrest, Feeling abnormal, Malaise	86.00	Male	Hypertension(C); Diabetes mellitus(C); COMIRNATY; COMIRNATY; Eczema(C); Dementia(C); Insomnia(C); Cerebral infarction(C); Cardiac failure chronic(C); Back pain(C); Femoral neck fracture(H); Spinal compression fracture(H)	NEXIUM EBB; RUPAFIN; MEMANTINE HYDROCHLORIDE OD; SERTRALINE; BAYASPIRIN; ZOLPIDEM TARTRATE; CELECOXIB; AMLODIPINE		3005786
	ITALY	Cardio-respiratory arrest, Haemorrhage, Loss of consciousness	72.00	Male	Myocardial infarction(H)	ZOLOFT; CARDIOASPIRIN; ACESISTEM		000033A
	TAIWAN, PROVINCE OF CHINA	Abdominal pain, Abdominal pain upper, Chest pain, Syncope	73.00	Female	Diabetes mellitus(C); Hypertension(C); Cardiac failure(H)			
	TAIWAN, PROVINCE OF CHINA	Headache, Syncope, Vomiting	72.00	Female	Diabetes mellitus(C); Dialysis; ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE			
	TAIWAN, PROVINCE OF CHINA	Altered state of consciousness	87.00	Male	Diabetes mellitus(C); End stage renal disease(C); Dialysis; Coronary artery disease(C); Stent placement			
	TAIWAN, PROVINCE OF CHINA	Asthma, Chest discomfort	72.00	Male	Transplant failure(H); Coronary artery disease(C); Mitral valve incompetence(C); Coronary artery bypass; Coronary arterial stent insertion; End stage renal disease(C); Stent placement; ASTRAZENECA COVID-19 VACCINE; Dialysis; Stent placement(H)			
	TAIWAN, PROVINCE OF CHINA	Death	70.00	Male				
	TAIWAN, PROVINCE OF CHINA	Chest pain	80.00	Female				
	TAIWAN, PROVINCE OF CHINA	Death	69.00	Male				
	TAIWAN, PROVINCE OF CHINA	Cerebral haemorrhage, Pyrexia, Thrombocytopenia	72.00	Female				
	TAIWAN, PROVINCE OF CHINA	Abdominal pain, Altered state of consciousness	75.00	Male	Myocardial ischaemia(H); Essential hypertension(H); End stage renal disease(H); Colon cancer stage II(H); Haemodialysis			050F21A_1110124-CDC
	TAIWAN, PROVINCE OF CHINA	Altered state of consciousness, Syncope	72.00	Female				006K21A_1110208-CDC
	TAIWAN, PROVINCE OF CHINA	Myocarditis	65.00	Female	Hypertension(C); Parkinson's disease(C)			
	TAIWAN, PROVINCE OF CHINA	Apnoea, Cardiac arrest, Loss of consciousness	72.00	Male				050F21A-1110124-CDC
	TAIWAN, PROVINCE OF CHINA	Decreased appetite, Pyrexia	86.00	Female	Bronchiectasis(C); ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE			072F21A_1110129-CDC
	TAIWAN, PROVINCE OF CHINA	Cough	72.00	Male				939599-CDC
	NETHERLANDS	Cardiac arrest, Chills, Malaise	82.00	Female	Short stature(C); Embolism venous(H); Gastrooesophageal reflux disease(H); Epilepsy(C); Post herpetic neuralgia(H); Hypertension(C); Osteoporosis(C); Renal impairment(H); Syncope(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; INFLUENZA VACCIN	CALCIUMCARBIMIDUM; FENTANYL CT; IPRATROPIUM BR; LIDOCAINE NMD; SIMVASTATINE; DENOSUMAB; GABAPENTINE; LEVETIRACETAM TEVA		
	GERMANY	Death, Influenza like illness	78.00	Female	Atrial fibrillation(H); Quadriplegia(H); Pulmonary fibrosis(H); COVID-19(H); Venous thrombosis limb(H); Myopathy(H); COMIRNATY			216045
	SPAIN	Hyperthermia malignant	75.00	Female	Obesity(C); Depression(C); Atrial fibrillation(C); Hypoacusis(C); Chronic obstructive pulmonary disease(C); Arteriosclerosis(C); Dyslipidaemia(C); Diabetes mellitus(C)	TRANGOREX; DOBUPAL; BISOPROLOL EG; SPIOLTO; SPIRONOLACTONE; TRUSOPT; DEPRAX [FLUOXETINE HYDROCHLORIDE]; ATORVASTATINA MK; VESICARE; AMLODIPINO RAAM		W0539-1
	UNITED STATES	Anaphylactic reaction	68.00	Female	Hypertension(C); Hypersensitivity; Bronchial hyperreactivity(C); Anaphylactic reaction(H); ALBUTEROL HFA(H); ALBUTEROL HFA(H)			
	NETHERLANDS	Circulatory collapse, Dyspnoea, Myocardial infarction, Pallor	77.00	Male	COMIRNATY; COMIRNATY; Cerebrovascular accident(H)			094F21A

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4.1(b)	ITALY	Death	79.00	Male	SPIKEVAX		4.1(b) 4.1(b)	VVJAQDD2LBC5H
	SWITZERLAND	Cardiac arrest, Sudden cardiac death	80.00	Female	Dementia Alzheimer's type(C)	EXELON [RIVASTIGMINE]; ESCITALOPRAM		
	NETHERLANDS	Sudden death	87.00	Female	COMIRNATY; COMIRNATY; Skin ulcer(H); Hypertension(C); Hypoacusis(H); Parkinsonian gait(C); Walking aid user(C); Weight decreased(H); Hypothyroidism(H); Cataract(H); METOPROLOL(H); HYDROCHLOORTHIAZIDE(H); HYDROCHLOORTHIAZIDE(H)			216041
	SWITZERLAND	Death	77.00	Male	Tobacco user(C); Lung neoplasm malignant(C); Colon cancer(C); Hypercholesterolaemia(C); Diabetes mellitus(H)	PREDNISONE TEVA; ACIDUM FOLICUM; SIMCORA; DUODART; EFFORTIL; SOLARAZE; DAFALGAN		
	SWITZERLAND	COVID-19 pneumonia, Vaccination failure	86.00	Male	Tobacco abuse(H); Chronic kidney disease(C)	ASPIRIN CARDIO; ELIQUIS; ACIDUM FOLICUM HAENSELER; TORASEMID SANDOZ; CALCIMAGON D3; PANTOPRAZOL SANDOZ; DUODART; JAKAVI		
	FRANCE	Death	73.00	Male	Arterial stent insertion; Cardiac failure(H); Hypertensive heart disease(H); Pulmonary oedema(H)			057G21A
	NETHERLANDS	Cerebellar haemorrhage, Cerebral haemorrhage, Cerebral infarction, Device dislocation, Partial seizures	69.00	Female	Throat cancer(H); Hypertension(C); Basal cell carcinoma(H); Tobacco user(C); Breast cancer(H); COMIRNATY; COMIRNATY	PERINDOPRIL GA; LORAZEPAMUM		
	SWITZERLAND	Asthenia, Death, Head injury	85.00	Male	Renal impairment(C); Metastatic malignant melanoma(C); Hypochromic anaemia(C); Urinary tract infection(H); Ischaemic cardiomyopathy(H); Cardiac pacemaker insertion; Gout(H); Drug hypersensitivity; Peripheral venous disease(C); Peripheral arterial occlusive disease(H)			
	GERMANY	Circulatory collapse, Shock, Sudden death	65.00	Male	Tobacco user(H)			216045
	GERMANY	Cough, Haemoptysis, Sudden death	65.00	Male	Hypertension(H); Chronic obstructive pulmonary disease(H)			092F21A
	ITALY	Intestinal pseudo-obstruction, Muscular weakness, Narcolepsy	74.00	Male	Parkinsonism(C)			3001655-01
	JAPAN	Cardio-respiratory arrest, Drowning, Vaccination site pain	90.00	Female	Hypertension(C); Diabetes mellitus(C); Lacunar infarction(C); Gastrooesophageal reflux disease(C); Spinal compression fracture(H)	ATELEC; MICARDIS; ALDACTONE A; TAKEPRON; PLETAAL; METGLUCO; GASMOTIN SR; RIKKUNSHITO [ATRACTYLODES LANCEA RHIZOME;CITRUS AURANTIUM PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA FRUIT]		000008A
	ITALY	Acute kidney injury, Aphasia, Bladder sphincter atony, Cerebrovascular accident, Coma, Pneumonia, Respiratory failure, Septic shock	87.00	Male	Chronic obstructive pulmonary disease(C); Hypertension(C); Cognitive disorder(H); Chronic kidney disease(C); COMIRNATY; COMIRNATY	NORVASC; KANRENOL; TRITTICO; QUETIAPINE; FOSTER [PIROXICAM]		3006322
	JAPAN	Angina pectoris, Death	72.00	Male				
	ICELAND	COVID-19 immunisation, COVID-19 pneumonia, Deep vein thrombosis, Immune system disorder, Organ failure, Pneumonia, Pulmonary embolism, Pyrexia, Respiratory failure, SARS-CoV-2 test positive	74.00	Male				
	TAIWAN, PROVINCE OF CHINA	Cardiac arrest	71.00	Female				
	TAIWAN, PROVINCE OF CHINA	Insomnia	66.00	Male				
	TAIWAN, PROVINCE OF CHINA	Death, Sepsis, Thrombocytopenia	67.00	Female				
	TAIWAN, PROVINCE OF CHINA	Cold sweat, Presyncope	84.00	Male	Hypertension(C); Diabetes mellitus(C)			
	TAIWAN, PROVINCE OF CHINA	Cardiac arrest	78.00	Female	Atrial fibrillation(C); Hypertensive heart disease(C)			
	TAIWAN, PROVINCE OF CHINA	Abdominal pain	65.00	Male				
	TAIWAN, PROVINCE OF CHINA	Death	67.00	Female				
	TAIWAN, PROVINCE OF CHINA	Asthma, Muscular weakness	71.00	Female	Cerebrovascular accident(H); Muscular weakness(H); Diabetes mellitus(C); Hypertension(C); Hyperlipidaemia(C)			072F21A_1110129
	TAIWAN, PROVINCE OF CHINA	Pyrexia	83.00	Male	Cerebrovascular accident(C); Hypertension(C)			
	TAIWAN, PROVINCE OF CHINA	Cardio-respiratory arrest	65.00	Male				

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	AUSTRIA	Accident, Contusion, Craniocerebral injury, Haemorrhage intracranial, Pupil fixed, Subdural haemorrhage, Unresponsive to stimuli	81.00	Female	Fall(H); Hospitalisation(H); Contusion(H); Gait disturbance(H); COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; Hyperlipidaemia(C); Escherichia infection(H); Hepatic lesion(C); Atrial fibrillation(C); Hiatus hernia(C); Condition aggravated(H); Hallucination(H); Decreased appetite(H); Loss of personal independence in daily activities(H); Movement disorder(H); Wound infection staphylococcal(C); Hypoproteinaemia(C); Skin ulcer(C); Cognitive disorder(C); Goitre(C); Memory impairment(H); Cerebrovascular disorder(C); Cholelithiasis(C); Anticoagulant therapy; Urinary tract infection(H); Cardiac failure(C); Dementia(H); Cognitive disorder(C); Malaise(H); Peripheral venous disease(C); Hypertension(C); Tobacco abuse(H); Wound infection staphylococcal(H); Urinary tract infection bacterial(H); Nutritional condition abnormal(H); Cardiac failure(H); Hypothyroidism(C); Peripheral arterial occlusive disease(C); Staphylococcal infection(C); Hip arthroplasty(C); Renal hamartoma(C); Chronic kidney disease(C); Sarcopenia(H); Chronic gastritis(C); COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; COVID-19 VACCINE MODERNA; Goitre(C)	NOVALGINA; PROTIFAR; CONCOR; FOLSAN; EXELON [RIVASTIGMINE]; XARELTO; DAFLON 1000; PANTOLOC; LASIX SPECIAL; ROSUMIBE [ROSUVASTATIN]; OLEOVIT [RETINOL]	4.1(b)	3004218
	ITALY	Dysarthria, Hemiplegia	68.00	Female	Thrombophlebitis(H)			030G21A
	GERMANY	Death, Thrombosis	79.00	Female				3004235
	JAPAN	Apnoea, Cardiac arrest, Cardiac failure acute, Depressed level of consciousness, Near drowning, Pulmonary oedema	80.00	Female	Craniotomy(H); Intra-cerebral aneurysm operation(H)			
	JAPAN	Arrhythmia, Arteriosclerosis, Cardio-respiratory arrest	73.00	Female	Chronic kidney disease(C); Glomerulonephritis(C); Haemodialysis; Spinal stenosis(C)	RIZEN; MEVALOTIN; FEBURIC; MAINTATE; PLAVIX; TAKECAB; ORKEDIA; CEROCRAL; DOPS; TARLIGE		3006279
	JAPAN	Arrhythmia, Cardio-respiratory arrest, Visceral congestion	81.00	Female				3006279
	GERMANY	Death	67.00	Male				000128A
	GERMANY	Abscess drainage, Abscess limb, Caregiver, Death, Dementia, Syncope, Vaccination site reaction, Weight decreased	67.00	Female				
	PHILIPPINES	Chest discomfort	88.00	Female				
	NORWAY	Atrial fibrillation, Cardiac failure, COVID-19 immunisation, Endotracheal intubation, Renal failure, Respiratory failure, Staphylococcal sepsis, Tachycardia	71.00	Male	Chronic kidney disease(H); Chronic obstructive pulmonary disease(H); Cardiac failure(H); Emphysema(H); Plasma cell myeloma(H); Comirnaty; Comirnaty	DARATUMUMAB; BORTEZOMIB; DEXAMETHASONE		
	FRANCE	COVID-19 pneumonia, Vaccination failure	89.00	Male	Aortic aneurysm(H); Coronary arterial stent insertion; Carotid arteriosclerosis(H); Hypertension(H); Myocardial infarction(H); Cardiac assistance device user(H); Atrial fibrillation(H); Nicotine dependence(C)	KARDEGIC; LOVENOX HP; PANTOPRAZOLE; BISOCE; FINASTERIDE; TAHOR		3004834
	JAPAN	Altered state of consciousness, Cerebral infarction, Heat illness, Movement disorder, Multiple organ dysfunction syndrome, Shock	76.00	Male	COMIRNATY; COMIRNATY; Diabetes mellitus(C); Atrial fibrillation(C)			
	JAPAN	Death, Pyrexia, Respiratory arrest, Sputum increased	88.00	Male	Neoplasm malignant(C); Comirnaty; Comirnaty; Prostate cancer(C); Cerebral infarction(H)			3006279
	ITALY	Anuria, Multiple organ dysfunction syndrome, Septic shock	74.00	Male	Respiratory failure(H); Amnestic disorder(H); Ex-tobacco user(H); Diabetic retinopathy(C); Sepsis(H); Diaphragmatic hernia(H); Peripheral arterial occlusive disease(H); Aortic valve replacement(H); Lactic acidosis(H); Hypertensive heart disease(H); Anaemia(H); Insulin-requiring type 2 diabetes mellitus(C); Hypertension(C); Hyperuricaemia(H); Atrial fibrillation(C); Hepatic steatosis(H); Acute pulmonary oedema(H); Cerebral infarction(H); Femur fracture(H); COMIRNATY; COMIRNATY	TOUJEO; TORVAST; CARDIOASPIRIN; LANOXIN; ELIQUIS; LASIX P; SERTRALINE; KANRENOL; SEQUACOR; LANSOX; NOVORAPID		3005887
	GERMANY	Cardiac death, Death	67.00	Male				
	GERMANY	Death, Nausea, Vaccination site pain, Vomiting	85.00	Female				
	FRANCE	COVID-19 pneumonia, Vaccination failure	91.00	Male	Hypertension(H); Myocardial ischaemia(C); Coronary artery disease(C); Vascular device user(H); Atrial fibrillation(H); Colon cancer(H); Cardiac murmur(C); Hyperthyroidism(C); Benign prostatic hyperplasia(H)	PERINDOPRIL; ATENOLOL; DIFFU K; FINASTERIDE; RIVAROXABAN; ALFUZOSINE UNO; FUROSEMIDE		091F21A
	ITALY	Intracranial aneurysm	71.00	Female				045G21A
	SWITZERLAND	Cerebral haemorrhage	71.00	Male	Hypertension(C); Coronary artery disease(C); Acute myocardial infarction(H); Peripheral arterial occlusive disease(C); Sleep apnoea syndrome(C); Hypercholesterolaemia(C); Gout(C)	TAMSULOSIN MEPHA; CANDESARTAN; ASPIRIN CARDIO; ROSUVASTATIN MEPHA LACTAB; PANTOPRAZOL SANDOZ		3002917/ 3003606; 3002917/ 3003606
	GERMANY	Cardiac arrest, Death	83.00	Male	Dementia(C); Cardiac failure(C); Myocardial infarction(H)			216046
	JAPAN	Acute myocardial infarction, Angiopathy, Cardio-respiratory arrest, Product storage error	90.00	Female	Hypertension(C)			000009A
	JAPAN	Dyspnoea, Interstitial lung disease, Pneumonia bacterial	91.00	Male	Hypertension(C); Interstitial lung disease(C); Cardiac failure chronic(C); Atrial fibrillation(C); Femur fracture(H)	PREDONINE-1; VASOLANDE; CARVEDILOL; FRANDOL S		000018A
	JAPAN	Acidosis, Brain stem infarction, Cardio-respiratory arrest, Cerebral arteriosclerosis, Disseminated intravascular coagulation, Hepatic function abnormal, Hyperkalaemia, Ischaemic cerebral infarction, Malaise, Near drowning, Pleural effusion, Thrombosis with thrombocytopenia syndrome	77.00	Female	Cerebral infarction(C); Osteoporosis(C); Constipation(C); Glaucoma(H)	LIXIANA		

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4.1(b)	JAPAN	Cardiac failure, Death, Pallor	86.00	Male	Diabetes mellitus(C); Hypertension(C); Prostatism(C)	INSULIN	4.1(b)	000018A
	HUNGARY	COVID-19 pneumonia	85.00	Female	Hypertension(H); COVID-19 pneumonia(H)			
	SWITZERLAND	Chest pain, Death	84.00	Male	Cardiomyopathy(C); Myelodysplastic syndrome(C)	ASPIRIN CARDIO; CANDESARTANUM; BELOC ZOK; ZANIDIP; TORASEMIDE; CORDARONE; EUTHYROX; PANTOPRAZOLE; SINOPIL		3005704
	SLOVAKIA	Coronary artery disease, Dyspnoea, Visual impairment	68.00	Female				
	GERMANY	Condition aggravated, Decreased appetite, Vomiting, Weight decreased	81.00	Male	COMIRNATY			3004235
	UNITED STATES	Death, Dyspnoea, Gait disturbance, Inappropriate schedule of product administration	75.00	Male	Cardiac pacemaker insertion; Seasonal allergy; Heart rate decreased(H); FLU; Hospitalisation(H); Thrombosis(H); Pulmonary thrombosis(H); Lung opacity(H); Dyspnoea(H)	BABY ASPIRIN; PREDNISONE; ELIQUIS; OMEPRAZOLE		029A21A; 007M20A
	GERMANY	Death	87.00	Female	Hypertension(C)			3004494
	CZECH REPUBLIC	Asthenia, Back pain, Cardiac death, Dyspnoea, Fall, Pain, Syncope	73.00	Female	Dementia Alzheimer's type(C); Chronic obstructive pulmonary disease(C); Cachexia(C); Hypertension(C)	KALNORMIN; CONCOR; CALTRATE MINI CALS; AGEN; PRESTARIUM A; CONTROLOC		
	FRANCE	Drug ineffective, Vaccination failure	66.00	Male	Abdominal hernia(C); Non-Hodgkin's lymphoma(C); Psoriasis(C); Hypercholesterolaemia(C); Cyst(C); Carpal tunnel syndrome(C); Sinusitis(C); Aortic valve incompetence(C); Tendon disorder(C)			214022
	JAPAN	Drowning	69.00	Female	Schizophrenia(H)	SENNOSIDE A+B; PZC [PERPHENAZINE HYDROCHLORIDE]; SULPIRIDE; METOCLOPRAMIDE; ARTANE [ARTEMETHER]; MOSAPRIDE; GASMOTIN [LEVOSULPIRIDE]; PARIET		3006279
	JAPAN	Cerebral haemorrhage, Circulatory collapse, Hepatic function abnormal, Multiple organ dysfunction syndrome, Pancytopenia, Pneumonia, Pyrexia, Renal impairment, Septic shock, Urinary tract infection	79.00	Female	Cerebral haemorrhage(H); Subdural haemorrhage(H)			
	JAPAN	Cardio-respiratory arrest, Contusion, Epistaxis	85.00	Male	Hypertension(C); Cerebral infarction(H); COMIRNATY; COMIRNATY			3005786
	JAPAN	Cardio-respiratory arrest, Decreased appetite, Loss of consciousness, Myocardial infarction, Pyrexia	97.00	Male	Myocardial infarction(H); Emphysema(C); Cardiac failure(C); Pulmonary tuberculosis(C); Hypertension(C); Dementia Alzheimer's type(C)	CLOPIDOGREL; MEMANTINE; METHYCOBAL; VITAMEDIN S		000021A
	JAPAN	Arrhythmia, Cardio-respiratory arrest	80.00	Male	Angina pectoris(C); COMIRNATY; COMIRNATY			
	UNITED STATES	Death, Neurological symptom, Speech disorder, Tremor	75.00	Male				
	GERMANY	Pulmonary embolism, Resuscitation, Thrombophlebitis	67.00	Male	Tobacco user(C); Infection(C)			
	JAPAN	Cardiac arrest, Cardiac death, Myocardial infarction, Poriomania, Thrombosis, Wound	73.00	Male	Diabetes mellitus(C); Hypertension(C); Cerebral infarction(C); COMIRNATY; COMIRNATY	NIFEDIPINE; GLIMEPIRIDE; APRINDINE HYDROCHLORIDE; METFORMIN HYDROCHLORIDE; VOGLIBOSE		000020A
	JAPAN	Myocarditis, Shock	81.00	Male	COMIRNATY(H); COMIRNATY(H)			000021A
	ITALY	Asthenia, Cardiac arrest, Decreased appetite, Diarrhoea, Vomiting	67.00	Male				007G21A
	SWEDEN	Death, Interchange of vaccine products, Off label use	95.00	Female				016G21A
	UNITED KINGDOM	Myocardial infarction, Thrombosis	66.00	Male				
	UNITED STATES	COVID-19	66.00	Female	Lung disorder(C); Rheumatoid arthritis(C); B-cell depletion therapy	LEFLUNOMIDE		
	JAPAN	Cardio-respiratory arrest, Death, Pyrexia	89.00	Female	Dementia(C); Femur fracture(C); Central venous catheterisation(H); Pneumonia aspiration(C)	FULCALIQ; MINERAMIC		3005786
	FRANCE	Dyspnoea, General physical health deterioration, Idiopathic pulmonary fibrosis, Infection, Pneumonitis, Pyrexia	77.00	Male	Dyslipidaemia(H); Hypertension(H); Prostate cancer(H); Rheumatoid arthritis(H); Atrial fibrillation(H); Pulmonary fibrosis(H); Lung lobectomy; Myocardial infarction(H); Lung neoplasm malignant(H)	ELIQUIS; AMIODARONE; CORTANCYL; SPECIAFOLDINE; EUPANTOL; TIMETH; BISOPROLOL EG		
	FRANCE	Death	65.00	Male	Hypertension(C); Benign prostatic hyperplasia(C); Osteoarthritis(C); COMIRNATY; COMIRNATY	COMIRNATY		091F21A
	JAPAN	Death	81.00	Female		LIMAPROST ALFADEX; SARPOGRELATE HYDROCHLORIDE		3005786
	NETHERLANDS	Asthenia, Chills, Cough, Insomnia, Malaise, Myalgia, Nasopharyngitis, Nausea, Peripheral coldness, Vomiting	72.00	Male	Pneumonia(H); Tobacco user(C); Aortic aneurysm(H); Chronic obstructive pulmonary disease(C); Renal cancer(H); COMIRNATY; COMIRNATY			
	NETHERLANDS	Cerebrovascular accident, Respiratory acidosis	82.00	Male	Hypertension(C); Resuscitation(H); Aortic aneurysm(H); Atrial fibrillation(C); Coronary artery bypass; Cardiac assistance device user(C); Percutaneous coronary intervention; Wheelchair user(C); Ex-tobacco user(H); Drug hypersensitivity; Aortic aneurysm repair; Plasmacytoma(C); COMIRNATY; COMIRNATY; COMIRNATY; COMIRNATY	METOPROLOL-BC; SALBUTAMOL A; TIOTROPIUM; ACETYLSALICYLZUUR		216036
	JAPAN	Aortic arteriosclerosis, Cardiac failure acute, Lacunar infarction	81.00	Female	Gastric cancer(H); Gastrectomy; Cholelithiasis(H); Cholecystectomy; Uterine cancer(H); Hysterosalpingo-oophorectomy			3006279
	JAPAN	Aortic dissection, Cardio-respiratory arrest, Fall, Headache, Loss of consciousness	102.00	Female	COMIRNATY; COMIRNATY			000012A
	JAPAN	Cardio-respiratory arrest	86.00	Female	Hypertension(C); Hypercholesterolaemia(C)			
	FRANCE	Haemorrhagic stroke	72.00	Female	Peripheral ischaemia(H); Hypertension(H); Dyslipidaemia(H); Cerebrovascular accident(H)			
	GERMANY	Meningitis, Multiple organ dysfunction syndrome	69.00	Male	COVID-19 VACCINE ASTRAZENECA; COMIRNATY			
	FRANCE	Cardio-respiratory arrest	74.00	Male				006G21A

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	CZECH REPUBLIC	Apathy, Cardiac failure, Communication disorder, Disorientation, General physical health deterioration, Mobility decreased, Sepsis	90.00	Female	Bacterial infection(C); Culture wound(H); Breast cancer(C); Peripheral arterial occlusive disease(C); Skin ulcer(C); Multimorbidity(C); Depression(C)	CITALEC; DOLFORIN	4.1(b)	
	JAPAN	Death	80.00	Female	Hypertension(C); Atrial fibrillation(C); Osteoporosis(C); Cardiac failure(C); Spinal compression fracture(H); Hypercholesterolaemia(C); Muscle spasms(H); Oedema peripheral(H); KETAS(H)	BONALON; FUROSEMIDE; AMLODIPINE; PITAVASTATIN CA; SHAKUYAKUKANZOTO; ELIQUIS; TAKAVENSU; AZILVA		
	CZECH REPUBLIC	Decreased appetite, Diarrhoea, Ileus, Intestinal haemorrhage, Intestinal infarction, Mesenteric arterial occlusion, Nausea	77.00	Male	Myocardial ischaemia(C); Peripheral artery bypass; Vascular pseudoaneurysm(H); Arterial stenosis(C); Vascular graft occlusion(H); Prosthetic vessel implantation; Hypertension(C); Abstains from alcohol(H); Tobacco user(H); Hypertension(H); Peripheral artery bypass(H)	PRESTARIUM NEO COMBI; EBRANTIL KAKEN; ISOPTINO; STACYL		
	GERMANY	Ataxia, Confusional state, Pyrexia, Urosepsis	79.00	Male	Asthma(C); Hyperchromic anaemia(C); Type 2 diabetes mellitus(C); Cardiac failure(C); Hepatic cirrhosis(C)			216045
	FRANCE	Vaccination failure	71.00	Female	Hypertension(C); Dyslipidaemia(H); Diffuse large B-cell lymphoma(H)			3002616; 214004
	ITALY	Ventricular fibrillation	78.00	Female	Acute coronary syndrome(H); Arteriosclerosis(H)			3001941
	TAIWAN, PROVINCE OF CHINA	Decreased appetite, Incontinence, Muscular weakness	84.00	Male				
	TAIWAN, PROVINCE OF CHINA	Neuroleptic malignant syndrome	86.00	Female				
	TAIWAN, PROVINCE OF CHINA	Abdominal pain, Dyspnoea, Muscular weakness	83.00	Male				006K21A_1110210-CDC
	TAIWAN, PROVINCE OF CHINA	Pyrexia	86.00	Male				
	TAIWAN, PROVINCE OF CHINA	Asthenia, Chest discomfort, Depressed level of consciousness, Dizziness	85.00	Female				
	TAIWAN, PROVINCE OF CHINA	Altered state of consciousness	95.00	Female				050F21A_1110124-CDC
	TAIWAN, PROVINCE OF CHINA	Headache	65.00	Male	Diabetes mellitus(C)			006K21A_1110214-CDC
	TAIWAN, PROVINCE OF CHINA	Cardiac failure, Respiratory failure	93.00	Male				
	TAIWAN, PROVINCE OF CHINA	Acute kidney injury, Hepatitis	75.00	Male	Hepatocellular carcinoma(C); Therapeutic embolisation; High frequency ablation; Hepatitis viral(H); Percutaneous ethanol injection therapy	SORAFENIB		
	TAIWAN, PROVINCE OF CHINA	Myocarditis	84.00	Female				
	TAIWAN, PROVINCE OF CHINA	Consciousness fluctuating	79.00	Female				
	TAIWAN, PROVINCE OF CHINA	Feeling cold, Headache	93.00	Male				2100685_1110308-CDC
	TAIWAN, PROVINCE OF CHINA	Death	72.00	Female				
	GERMANY	Cerebrovascular accident	67.00	Male	Cerebrovascular accident(H); JANSSEN COVID-19 VACCINE			3004951
	LUXEMBOURG	COVID-19 immunisation, Dyspnoea, Hypoxia, Pyrexia	83.00	Female	Lymphoma(C); Coagulopathy(H); Cerebrovascular accident(H); Thyroidectomy; Transfusion; Transient ischaemic attack(H); COMIRNATY			017G21A
	SWITZERLAND	Death, Extensive swelling of vaccinated limb, Pneumonitis	95.00	Female	Diabetes mellitus(C); Dementia Alzheimer's type(C); Normochromic normocytic anaemia(C); Chronic kidney disease(C); Cardiomyopathy(C); Hypertension(C); Dyslipidaemia(C); Femur fracture(H)	NOVALGINA; CLEXANE; SEQUASE; CANDESARTAN TAKEDA; CONCOR; DULOXETIN MEPHA; METFORMIN-MEPHA; RISPERIDON MEPHA; TRAJENTA; RYZODEG		
	UNITED STATES	Death, Expired product administered	87.00	Unknown	Atrial fibrillation(H); Acute kidney injury(H)			050E21A
	UNITED STATES	Death, Expired product administered	77.00	Male				050E21A
	PHILIPPINES	Gun shot wound	65.00	Male				061621A
	PHILIPPINES	Pyrexia	65.00	Male				
	JAPAN	Arrhythmia, Cardio-respiratory arrest, Decreased appetite	69.00	Female	Diabetes mellitus(H); Osteoarthritis(H); Parkinson's disease(C); Epilepsy(C); Hypertension(C); Insomnia(C); Osteoporosis(C); Dyslipidaemia(C)	DOPACOL; ROPINIROLE; TRERIEF; VALPROATE SODIUM; DAYVIGO; ELDECALCITOL; AZELNIDIPINE; AZILVA; TRICHLORMETHIAZIDE; LUPRAC; ATORVASTATIN		3005785
	JAPAN	Cardiac valve disease	88.00	Female	Rhinitis allergic(C); Diabetes mellitus(C); Hypertension(C); Dyslipidaemia(C); Osteoporosis(C); Cerebral infarction(H); Cerebral haemorrhage(H); Diabetes mellitus(C); Hypertension(C); Dyslipidaemia(H); Hypertonic bladder(H); Gastrooesophageal reflux disease(H); Neuropathy peripheral(C); Neuralgia(C); COMIRNATY; COMIRNATY; Peripheral vascular disorder(C)	AMLODIPINE; ALFAROL; DEBERZA; OLMETEC; BETANIS; OMEPRALAN; BILANOA; PARMODIA; METHYCOBAL; TARLIGE; JUVELA N		3005785
	GERMANY	Brain injury, Encephalitis, Status epilepticus	69.00	Female				

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4.1(b)	SWEDEN	COVID-19 immunisation, Pulmonary embolism	74.00	Female	COVID-19 immunisation(H); Hypertension(C); COVID-19 immunisation(H)	LOSARTAN/HYDROCHLOROTHIAZIDE; AMLODIPINE; METOPROLOL	4.1(b)	023F21A
	CANADA	Agitation, Apnoea, Breath sounds abnormal, Cheyne-Stokes respiration, Erythema, Haematoma, Hypotension, Jugular vein distension, Lethargy, Moaning, Oedema peripheral, Pulmonary embolism, Stupor, Tachypnoea	85.00	Female				
	NETHERLANDS	Myocardial infarction	92.00	Female	SPIKEVAX; SPIKEVAX			000121A
	CANADA	Sudden death	72.00	Male				
	CANADA	Haemorrhage, Lethargy, Loss of consciousness	94.00	Male				
	ITALY	Cerebrovascular accident	75.00	Male	Hypertension(C); Leukaemia(C)			000030A
	JAPAN	Death	74.00	Female	COMIRNATY; COMIRNATY			3005786
	FRANCE	Drug ineffective, Vaccination failure	66.00	Male	Blood cholesterol increased(C); Abdominal hernia(H); Carpal tunnel syndrome(H); Tendon disorder(H); Sinusitis(H); Psoriasis(H); Cyst(H); Aortic valve incompetence(H)			214022
	JAPAN	Acute kidney injury, Altered state of consciousness, Cardiac arrest, Cyanosis, Gastrointestinal haemorrhage, Hyperkalaemia, Pyrexia	77.00	Female	Diabetes mellitus(C)			000011A
	JAPAN	Acute myocardial infarction, Death	82.00	Male	Hypertension(C); Prinzmetal angina(C)	CANDESARTAN; AMLODIPINE; BENIDIPINE HYDROCHLORIDE; PRAVASTATIN NA; NICORANDIL; SENNOSIDE A+B; MAGNESIUM OXIDE; BETAHISTINE MESILATE; IFENPRODIL TARTRATE; TRIAZOLAM; ADETPHOS; FRANDOL S; ESOMEPRAZOLE MAGNESIUM; NITOROL		000028A
	SPAIN	Creutzfeldt-Jakob disease	71.00	Male				3002183; 3001532
	NETHERLANDS	Cerebral haemorrhage	84.00	Male	COMIRNATY; COMIRNATY			094F21ABS
	ITALY	Cardio-respiratory arrest	80.00	Male				000004A
	FINLAND	Purulent pericarditis	91.00	Male				
	GERMANY	Acute myocardial infarction, Atrioventricular block, Cardiogenic shock	93.00	Female	COMIRNATY; COMIRNATY			
	FINLAND	COVID-19 immunisation, Dementia Alzheimer's type, Pneumonia, Pyrexia, Sputum increased, Vomiting	73.00	Male		MEMANTIN ORION; CLOPIDOGREL TEVA [CLOPIDOGREL HYDROCHLORIDE]; LIPCUT; EXELON PATCH 5		
	LUXEMBOURG	COVID-19 immunisation, Diabetes mellitus inadequate control, Feeling abnormal, Pulmonary embolism	79.00	Female	Cataract operation; Hypothyroidism(C); Hypertension(C); Pain(C); Type 2 diabetes mellitus(C); Gastrooesophageal reflux disease(H); Thyroidectomy(H); Breast cancer(H); COVID-19 VACCINE JANSSEN			017G21A
	LATVIA	Death, Nausea, Pyrexia	75.00	Female	Goitre(C); Hypertension(C); Hypercholesterolaemia(C)	MOXONIDIN; CONCOR; TRIPLIXAM; ROSULIP F; PREDNISOLONE V		000027BA
	NETHERLANDS	Arrhythmia, Cardiac arrest, Paraesthesia	76.00	Male	Arrhythmia(H); PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE	SEMINIET		018J21ABS
	JAPAN	Cardiac disorder	92.00	Female	Hypertension(C); Oedema(C)	VESICARE; EDIROL; OPALMON; SELARA		000018A
	JAPAN	Cardiac failure congestive, Hypertension	81.00	Male	Angina pectoris(C); Diverticulum intestinal haemorrhagic(C); Hypertension(C); Diabetes mellitus(C); Dyslipidaemia(C); Cardiac failure chronic(C)	AMLODIPINE BESILATE;AZILSARTAN; ATORVASTATIN; FORXIGA; TAKELDA; PIOGLITAZONE; FERRUM [IRON]; LIMAPROST ALFADEX; GOSHAJINKIGAN; OLOPATADINE HYDROCHLORIDE		000225A
	JAPAN	Cardiac arrest, Interstitial lung disease, Loss of consciousness	74.00	Male	Renal impairment(C); Hypertension(C); Hypocalcaemia(C); Hyperphosphataemia(C); Hyperkalaemia(C); Dialysis(H)	AMLODIPINE; LOSARTAN POTASSIUM; PRECIPITATED CALCIUM CARBONATE; P TOL; LOKELMA; BIOFERMIN T; AZILVA; CARDENALIN; DARBEPOETIN ALFA; MAXACALCITOL		
	JAPAN	Drowning	87.00	Male	COMIRNATY; COMIRNATY			
	JAPAN	Arrhythmia	76.00	Male	Myocardial infarction(H); Chronic myeloid leukaemia(C); Hypothyroidism(H); Hyperuricaemia(H); Anaemia(H); Gastrooesophageal reflux disease(C); Constipation(C); Insomnia(C); Thrombocytosis(C); COMIRNATY; Comirnaty; Thyradin(H)	BAYASPIRIN; LANSOPRAZOLE; MAGNESIUM OXIDE; BELSOMRA; TRAZODONE HYDROCHLORIDE		000005A
	FRANCE	Mallory-Weiss syndrome	65.00	Male	Dyslipidaemia(C); Hypertension(C); Hepatic cirrhosis(C)			3006320
	GERMANY	Death, Deep vein thrombosis, Pulmonary embolism	87.00	Female	COMIRNATY; COMIRNATY; COMIRNATY			
	JAPAN	Cardiac failure acute, Cardio-respiratory arrest	82.00	Male	Myocardial ischaemia(C); Angina pectoris(C); Peripheral arterial occlusive disease(C); Leg amputation; Stent placement; Cardiovascular disorder(C)	BAYASPIRIN		000025A
	TAIWAN, PROVINCE OF CHINA	Fatigue	70.00	Male				
	TAIWAN, PROVINCE OF CHINA	Acute myocardial infarction	70.00	Male				
	TAIWAN, PROVINCE OF CHINA	Chest pain, Hypoaesthesia, Muscular weakness, Palpitations	66.00	Male	Hypertension(H); Polypectomy			
	JAPAN	Cardio-respiratory arrest, Pneumonia, Sepsis	87.00	Female	Hypertension(C); Dementia Alzheimer's type(C); COMIRNATY; COMIRNATY; Dyslipidaemia(C); Osteoporosis(C); Back pain(C)	EDIROL; NORVASC; LOCHOLES; CELECOX; ARICEPT		
	TAIWAN, PROVINCE OF CHINA	Asthma, Fatigue, Somnolence	89.00	Female	Osteoporosis(H); ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE			

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4.1(b)	TAIWAN, PROVINCE OF CHINA	Sepsis, Syncope	78.00	Male			4.1(b)	2100685
	TAIWAN, PROVINCE OF CHINA	Fatigue	68.00	Male	Surgery; Hypertension(C)			
	TAIWAN, PROVINCE OF CHINA	Pyrexia	89.00	Male				
	TAIWAN, PROVINCE OF CHINA	Death	80.00	Male				
	TAIWAN, PROVINCE OF CHINA	Altered state of consciousness, Headache, Muscular weakness, Myalgia	92.00	Female				072F21A-1101207-CDC
	ARGENTINA	Embolism, Haemorrhage	67.00	Female				022d21a
	ARGENTINA	COVID-19, Immunisation reaction	66.00	Male				080C21A
	ARGENTINA	Immunisation reaction, Pyrexia, Syncope	80.00	Female				022D21A
	ARGENTINA	Immunisation reaction	88.00	Female				022D21A
	ARGENTINA	Immunisation reaction, SARS-CoV-2 test positive	75.00	Male				022D21A
	ARGENTINA	Cardiovascular disorder	77.00	Female				NK0084
	NORWAY	Cardiac arrest, COVID-19 immunisation, Pulmonary embolism	78.00	Male				3004498
	JAPAN	Acute kidney injury, Arrhythmia, Blood glucose decreased, Cardio-respiratory arrest, Dehydration, Hyperkalaemia, Hyponatraemia, Rhabdomyolysis	70.00	Female	Cirrhosis alcoholic(H); Hyperuricaemia(H); Hypertension(C); Depression(H)	LOSARTAN K; ALLOPURINOL; BEHYD		000211A
	JAPAN	Blood disorder, Cardio-respiratory arrest, Fracture, Internal haemorrhage, Loss of consciousness, Pain, Peripheral swelling	71.00	Female	Dysaesthesia(C); Diabetes mellitus(C); Hypertension(C); COMIRNATY; COMIRNATY	EQUMET; AMLODIPINE; CIMETIDINE; LANDSEN; MIRTAZAPINE; BROTIZOLAM; BIPERIDEN HYDROCHLORIDE; ABILIFY		
	FRANCE	Henoch-Schonlein purpura	71.00	Female	Adenocarcinoma of colon(H); Chronic kidney disease(C); Lung carcinoma cell type unspecified stage 0(H); Thyroidectomy; Obesity(C); Hypertension(C); Hypercholesterolaemia(C)	UVEDOSE; RESIKALI; AMLODIPINE; RENVELA; CALCIDIA; BICARBONATE NA; UN-ALFA; LEVOTHYROX; FUROSEMIDE; ATORVASTATINE EG		2104025
	FRANCE	Myocardial infarction	69.00	Male	Hypercholesterolaemia(C); Hypertrophic cardiomyopathy(C); Gastroduodenal ulcer(H); Pelvic kidney(H); Peripheral arterial occlusive disease(C); Chronic obstructive pulmonary disease(C); Muscle spasms(H); Transplant; Hypertension(C)	KARDEGIC; COVERSYL AM; AVAMYS; PANTOPRAZOLE; CRESTOR		214030
	FRANCE	Cardiac arrest, Rash, Vomiting	72.00	Female	Multiple allergies; Dyslipidaemia(C); Supraventricular tachycardia(C)			3001653
	JAPAN	Diarrhoea, Myocardial infarction	75.00	Male	Hypertension(C); Diabetes mellitus(C); Atrial fibrillation(C)			
	JAPAN	Altered state of consciousness, Blood pressure decreased, Fall, Haematoma, Intracranial aneurysm, Obstructive airways disorder, Respiratory arrest, Subarachnoid haemorrhage, Vomiting	68.00	Female				000024A
	GERMANY	Cerebral haemorrhage	83.00	Female	Cardiac disorder(C)			
	JAPAN	Cardio-respiratory arrest	75.00	Male	Hypertension(C); Benign prostatic hyperplasia(C); Hypertonic bladder(C)	LISINOPRIL; AMLODIPINE; NATRIX; BETANIS; CERNILTON N		3006343
	JAPAN	Blood pressure decreased, Cerebral infarction, Death, Depressed level of consciousness, Pyrexia	73.00	Female	Chronic kidney disease(C); Haemodialysis(H); Diabetes mellitus(C); Comirnaty(H); Comirnaty(H)	BUFFERIN C2; CILOSTAZOL; INSULIN		000028A
	HUNGARY	Chest pain, Death	89.00	Male	Arteriosclerosis(C); Hypertension(C); Aortic stenosis(C)	COVEREX AS KOMB; CARDURA XL		G26761A
	JAPAN	Pneumonia	93.00	Female	Dementia(C)			
	AUSTRIA	Cardiac failure acute, COVID-19 immunisation	67.00	Male	Pulmonary embolism(H); Hypertension(C); COMIRNATY; COMIRNATY; Cardiac hypertrophy(C); Hepatic steatosis(C); Anxiety disorder(C); Cardiomegaly(C); Hypertension(C)			3004670
	PHILIPPINES	Death	74.00	Male				3004960
	GERMANY	Acute myocardial infarction, Death	73.00	Male	Type 2 diabetes mellitus(C); Hypertension(C); VAXZEVRIA; VAXZEVRIA			000153A
	JAPAN	Arrhythmia, Cardio-respiratory arrest, Headache, Malaise, Myocardial infarction, Near drowning	74.00	Male	COMIRNATY; COMIRNATY; Diabetes mellitus(C); Dyslipidaemia(C); Benign prostatic hyperplasia(C)			3005787
	GERMANY	Cerebral haemorrhage	84.00	Female				3005690
	JAPAN	Acute respiratory failure, Cardio-respiratory arrest	93.00	Male	Cerebral infarction(C); Chronic kidney disease(C); Rheumatoid arthritis(C); Food allergy(H); Bile duct stone(H); Choledocholithotomy; Pneumonia aspiration(H)			000009A
	SWEDEN	Hemiplegia, Lethargy, Myocardial infarction, Nervous system disorder	77.00	Male	Cerebrovascular accident(H); Myalgia(H); Diabetes mellitus(C); Aphasia(C)			3005835
	JAPAN	Anaemia, Cardiac failure, Cardio-respiratory arrest, Depressed level of consciousness, Dyspnoea, Haematochezia, Polyp	86.00	Female	Cardiac failure congestive(C)			3005786
	ITALY	Myocarditis	81.00	Female	Depression(H); Osteoarthritis(H); Cognitive disorder(H); Hypertensive heart disease(C); Arthropathy(C); Obesity(C); Diabetes mellitus(C); SPIKEVAX	METFORMIN; OMEPRAZOLE; PAROXETINE; DELECIT; VALSARTAN D; CARDIOASPIRIN		214003
	FRANCE	COVID-19, Vaccination failure	80.00	Male	Alcohol use(H); Arterial disorder(H)			214011
	JAPAN	Death, Depressed level of consciousness	76.00	Male	Cerebral infarction(C); Diabetes mellitus(C); Cerebral infarction(H); COMIRNATY; COMIRNATY			3005786
	ITALY	Cerebral haemorrhage, Headache, Loss of consciousness	80.00	Male				030g21a
	JAPAN	Death, Loss of consciousness	83.00	Female	Diabetes mellitus(C); Hypertension(C); Dementia(C); Aortic valve stenosis(C); Delirium(H); COMIRNATY; COMIRNATY	SEIBULE; METGLUCO; TRADIANCE; MICAMLO; AMLODIPINE; YOKUKANSAN		000025A
	GERMANY	Granulomatosis with polyangiitis	77.00	Female	Granulomatosis with polyangiitis(C); COMIRNATY; COMIRNATY			000087A

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4.1(b)	TAIWAN, PROVINCE OF CHINA	Asthma, Chest discomfort	87.00	Female	Diabetes mellitus(C); Hypoacusis(C)		4.1(b)	
	TAIWAN, PROVINCE OF CHINA	Acute myocardial infarction	85.00	Female				006K21A 1110210-CDC
	TAIWAN, PROVINCE OF CHINA	Fatigue, Headache, Myalgia, Pain in extremity	75.00	Male				
	TAIWAN, PROVINCE OF CHINA	Pulmonary mass	65.00	Female	MODERNA COVID-19 VACCINE			082F21B
	TAIWAN, PROVINCE OF CHINA	Acute myeloid leukaemia, Pyrexia	68.00	Female				
	GERMANY	Pulmonary embolism	84.00	Female				
	GERMANY	Cardiac failure	91.00	Male	Aortic valve incompetence(H); Lymphoma(H); Atrial fibrillation(H); Aortic valve stenosis(H); Goitre(H); Cardiac failure(H); Cataract(H)			007G21A
	ITALY	Ataxia, Confusional state, Dysphagia, Dystonia, Hallucination, Myoclonus, Nervous system disorder, Prion disease, Psychomotor hyperactivity, Respiratory failure, Sopor	80.00	Male	COMIRNATY; COMIRNATY			000030A
	JAPAN	Fall, Interstitial lung disease	91.00	Female	Hypertension(C); Diabetes mellitus(C); Dyslipidaemia(C); Osteoarthritis(C)	AMLODIPINE; GLICLAZIDE; ATORVASTATIN; FAMOTIDINE; ALPRAZOLAM; BIOFERMIN [LACTOMIN]		000020A
	CANADA	Feeding disorder, General physical health deterioration, Herpes zoster, Hypokinesia, Lethargy, Neuralgic amyotrophy, Oedema peripheral, Psychomotor retardation	71.00	Male		ADVAGRAF; APRESOLINE; COREG; INNOHEP; LIPITOR; LYRICA; MAGNESIUM; NORVASC T; ONE ALPHA; OSCALVIT; PANTOLOC; PREDNISONE; PROLOPA; TYLENOL [PARACETAMOL]; VALTREX		
	JAPAN	Basilar artery occlusion, Brain stem infarction, Coma, Cyanosis, Pneumonia aspiration, Pyrexia, Renal infarct, Thalamic infarction, Thrombosis, Vaccination site swelling	79.00	Female	Hyperlipidaemia(C)			
	GERMANY	Cerebral haemorrhage	91.00	Female	COMIRNATY; COMIRNATY			000125A
	JAPAN	Aortic dissection, Cardio-respiratory arrest	80.00	Female	Aortic dissection(H)			000001A
	GERMANY	Death, Dizziness, Fatigue, Pain in extremity, Vaccination site pain	85.00	Female	SPIKEVAX(H)			000112A
	FRANCE	Death	81.00	Female	Glaucoma(C)			
	PHILIPPINES	Cardiogenic shock	66.00	Male				010G21B
	PHILIPPINES	Chest pain	67.00	Male				
	PHILIPPINES	Electrolyte imbalance	77.00	Female				055E21A
	SPAIN	COVID-19 pneumonia, Dyspnoea, Vaccination failure	68.00	Male	Type 1 diabetes mellitus(C); Solid organ transplant; Chronic kidney disease(C); Angina pectoris(H); Myocardial ischaemia(H); COVID-19(H)			3005790; 300042722; 3000494
	PHILIPPINES	Asthenia	66.00	Female				
	PHILIPPINES	Seizure	85.00	Female				
	PHILIPPINES	Loss of consciousness	72.00	Female				057D21A
	PHILIPPINES	Dyspnoea	86.00	Female				055E21A
	NETHERLANDS	Death, Thrombosis	86.00	Female	COVID-19 VACCINE; COVID-19 VACCINE			018J21A
	PHILIPPINES	Death	71.00	Male				05621A
	NETHERLANDS	Headache, Hypoxia, Pyrexia	78.00	Female	Endometrial cancer(C); PFIZER BIONTECH COVID-19 VACCINE; SPIKEVAX; Cerebrovascular accident(H); COVID-19(H)	CLOPIDOGREL; CANDESARTAN; ROSUVASTATINE CF		000060ABS
	UNITED STATES	Acute disseminated encephalomyelitis, Shock haemorrhagic	81.00	Male				
	GERMANY	Hyperpyrexia, Leukopenia	79.00	Male				
	UNITED KINGDOM	Cardiac death	75.00	Male				000074A
	FRANCE	Pancreatic carcinoma	90.00	Female	MODERNA COVID-19 VACCINE; MODERNA COVID-19 VACCINE; Depression(C); Blepharospasm(C); Microcytic anaemia(C); Hypertension(C)			3002616; 214009; 057G21A
	JAPAN	Acute myocardial infarction, Arrhythmia, Cardiac arrest, Loss of consciousness, Pulmonary congestion	69.00	Female	Hypertension(C); Hyperlipidaemia(C); Back pain(C)			
	UNITED KINGDOM	Death	83.00	Female	Neoplasm(C); Chemotherapy; Hypertension(C); Squamous cell carcinoma(C); Gastrointestinal neoplasm(C); SARS-COV-2 VACCINE(H); SARS-COV-2 VACCINE(H); SARS-COV-2 VACCINE(H); Radiotherapy; Benign pleural neoplasm(C)	ALLOPURINOL; ATENOLOL; DONEPEZIL; FLUOXETINE; LANSOPRAZOLE; MEMANTINE; MIRTAZAPINE; SENNA [SENNA ALEXANDRINA]; SIMVASTATIN; PARACETAMOL		000076A
	UNITED STATES	Death, Myocardial infarction	85.00	Male	Cerebrovascular accident(H)			
	GERMANY	Cardiac failure	86.00	Male	Chronic obstructive pulmonary disease(C); Hypertension(C); Tricuspid valve incompetence(C); Cardiac failure(C); Cardiac failure(C); Urinary incontinence(C); Dyspnoea exertional(C); Hypoxia(C); Atrial fibrillation(C); COMIRNATY; COMIRNATY			000114A
	JAPAN	Acute respiratory distress syndrome, Pneumonia	79.00	Male	Hypertension(C); Urticaria chronic(C)	LOSARTAN K; PREDONINE-1; ZOLPIDEM TARTRATE		000009A

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	TAIWAN, PROVINCE OF CHINA	Myocardial infarction	68.00	Male			4.1(b)	
	AUSTRIA	Altered state of consciousness, Anisocoria, Coma, Headache, Respiration abnormal, Respiratory arrest, Ruptured cerebral aneurysm, Subarachnoid haemorrhage	79.00	Male	Ischaemic stroke(H); Renal transplant; DOXAZOSIN(H); FUROSEMID [FUROSEMIDE](H); ADVAGRAF(H); MYFORTIC(H); COVID-19 VACCINE MODERNA; ATORVASTATIN(H); Carotid arteriosclerosis(C); Tubulointerstitial nephritis(H); Coronary arterial stent insertion(H); Prostatic adenoma(C); Hypertensive crisis(H); Hemiparaesthesia(H); Arteriosclerosis coronary artery(C); Chronic obstructive pulmonary disease(C); Folate deficiency(H); Transient ischaemic attack(H); Nephrogenic anaemia(C); Actinic keratosis(C); Obstructive sleep apnoea syndrome(C); Haemodialysis(H); Cardiac failure(H); Atrial fibrillation(H); Axonal and demyelinating polyneuropathy(C); Renal transplant(H); Meniere's disease(C); Hypertension(C); Hypercholesterolaemia(H); Overweight(H); Aphasia(H); Epilepsy(H); Renal oncocytoma(C); Iron deficiency anaemia(C); Epilepsy(H); Chronic sinusitis(C); AMLODIPINE(H); NORVASC(H)	CLOPIDOGREL; CANDESARTAN; MYFORTIC; ADVAGRAF; LEVETIRACETAM; CALCIDURAN VIT. D3; MAGNESIUM HYDROXID; APREDNISLON; FUROSEMIDA SALA; ATORVASTATIN; DOXAZOSIN; ELIQUIS; SPIOLTO RESPIMAT; NOMEXOR; ZANIDIP; NEPHROTRANS		3005241
	SWEDEN	COVID-19 immunisation, Nausea, Sudden death	90.00	Female	COVID-19 immunisation; Hypertension(C); Ileus(H); COVID-19 immunisation; Memory impairment(C); Cerebrovascular accident(H); Chronic obstructive pulmonary disease(C); COVID-19 immunisation			3006270
	FRANCE	COVID-19, Drug ineffective	90.00	Male	COVID-19(H)			018G21A
	PHILIPPINES	Dyspnoea	86.00	Female				055E21A
	ITALY	Acute kidney injury, Autoimmune pancreatitis, Death, Drug reaction with eosinophilia and systemic symptoms, Eosinophil count increased, Rash, Thrombocytopenia, Transaminases increased, Vasculitis	73.00	Female	Osteoporosis(H); Hypothyroidism(H); Parkinson's disease(C); Chronic kidney disease(C)	ROLDAP; CARBOLITHIUM; PANTOPRAZOLO		
	ITALY	Asthenia, Back pain, Dysentery, Fatigue	94.00	Male		CARDIOASPIRIN; LASIX M; ZYLORIC; PANTORC; SEQUACOR; TRIATEC [CAFFEINE CITRATE;CODEINE PHOSPHATE;PARACETAMOL]; ALDACTONE [POTASSIUM CANRENOATE]		3005887
	UNITED STATES	Creutzfeldt-Jakob disease	70.00	Female				
	ITALY	Cerebral haemorrhage	76.00	Male	Hypertension(H); Emphysema(H)			
	GERMANY	Acute myocardial infarction, Dyspnoea, Malaise, Ventricular fibrillation	72.00	Female	Cardiac failure(H); Supraventricular extrasystoles(H); Type 2 diabetes mellitus(C); Hypertension(C); Guillain-Barre syndrome(C); Diaphragmatic paralysis(H); COMIRNATY; COMIRNATY			21046
	UNITED KINGDOM	Cardiac arrest	87.00	Male	Cerebrovascular accident(H); Cardiac pacemaker insertion			000076A
	UNITED KINGDOM	Pulmonary embolism	86.00	Female				
	FRANCE	Agitation, General physical health deterioration, Haematuria, Hallucination	93.00	Male	Gait disturbance(H); Transient ischaemic attack(H); Lung disorder(H); Starvation(H); Parkinson's disease(H); Atrial fibrillation(H); Osteoarthritis(H); Depression(H); Anxiety(H); Cardiac flutter(H); Dementia(H); Deafness(H); Malnutrition(H); Delusion(H); Cognitive disorder(H); Aggression(H); Apathy(H); Pneumonia(H); Urinary retention(H)			000003A
	GREECE	Death, Infection, Plasma cell myeloma, Pyrexia	72.00	Female	Tobacco user(H)			
	SWITZERLAND	Death, Pneumonia	74.00	Male				3004219
	UNITED KINGDOM	Cardiac arrest	87.00	Male	Myocardial ischaemia(H); Atrial fibrillation(H); Cerebrovascular accident(H); Cardiac assistance device user(H); Obstructive sleep apnoea syndrome(H); Knee arthroplasty	ATORVASTATIN; EDOXABAN; FUROSEMIDE; INDAPAMIDE; OMEPRAZOLE		0000768
	GREECE	Death, Dyspnoea	78.00	Female				
	GERMANY	Pulmonary embolism	85.00	Female	COVID-19(H)			000103A
	GERMANY	Pulmonary embolism	85.00	Female				000103A
	PHILIPPINES	Acute myocardial infarction, COVID-19	68.00	Male				
	JAPAN	Cardio-respiratory arrest, Death, Decreased activity, Incontinence, Pyrexia	65.00	Male	Schizophrenia(C)			3006278
	UNITED KINGDOM	Death	89.00	Female	Dementia Alzheimer's type(C); Asthenia(C)	COMIRNATY; NITROFURANTOIN		000075A
	FRANCE	Chest pain, Discoloured vomit, Dyspnoea, Night sweats, Weight decreased	65.00	Female				
	NETHERLANDS	Condition aggravated, Cough, Dyspnoea, Granulomatosis with polyangiitis, Haemoptysis	86.00	Female	Myocardial infarction(H); Granulomatosis with polyangiitis(H); Chronic obstructive pulmonary disease(H); Coronary artery disease(H); COVID-19 VACCINE; COVID-19 VACCINE; COVID-19 VACCINE	OMEPRAZOL [OMEPRAZOLE]; CARBASALAATCALCIUM; HYDROCHLOORTHIAZIDE; LOSARTAN TEVA; BUDESONIDE AND FORMOTEROL; AMLODIPINE; ATORVASTATINE [ATORVASTATIN]; BISOPROLOL FUMARATE; AZITROMYCINE; METFORMIN [METFORMIN HYDROCHLORIDE]		
	FRANCE	COVID-19 pneumonia, Vaccination failure	78.00	Female	Cardiac hypertrophy(H); Hysterectomy; Enlarged clitoris(H); Type 2 diabetes mellitus(C); Rheumatoid arthritis(C); Respiratory failure(H); Congenital absence of bile ducts(C); Breast mass(H); Vulvectomy; Hypertension(C); Obesity(H); Dyslipidaemia(H)	ACIDE FOLIQUE; SALBUTAMOL; BISOPROLOL LPH; ATORVASTATINE EG; METHOTREXATE; SOLUPRED ORO; CHLORHYDRATE DE PROCAINE		

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	JAPAN	Acute respiratory distress syndrome	88.00	Female	Hysterectomy; Non-tobacco user(C); Hypertension(C); Dyslipidaemia(C); Asthma(C); Neuropathy peripheral(C); Insomnia(C); Uterine leiomyoma(H); Oxygen therapy	AMLODIPINE; PRAVASTATIN; DIHYDROCODEINE; MONTELUKAST; DL-METHYLEPHEDRINE; CHLORPHENIRAMINE [CHLORPHENAMINE]; ZOLPIDEM; MECOBALAMIN	4.1(b)	
	TAIWAN, PROVINCE OF CHINA	Death	72.00	Male	Hypertension(C); Diabetes mellitus(C)			
	TAIWAN, PROVINCE OF CHINA	Fatigue, Pyrexia	83.00	Male	Diabetes mellitus(C); Hypertension(C); Cerebrovascular accident(H); Myocardial infarction(H)			
	JAPAN	Apnoea, Cardiac hypertrophy, Cardio-respiratory arrest, Chills, Feeling hot, Incontinence, Malaise, Muscular weakness, Pain, Pyrexia	65.00	Male	Mitral valve repair; Hypertension(C); COMIRNATY; COMIRNATY			3006278
	UNITED STATES	Death	70.00	Male				
	FRANCE	Vaccination failure	85.00	Female	Chronic obstructive pulmonary disease(C); Hypertension(C); Type 2 diabetes mellitus(C); Cardiac failure(H); Cerebrovascular accident(H); Anaemia(H); Chronic kidney disease(C)			3004234; 3005834
	ITALY	Interstitial lung disease, Loss of consciousness	77.00	Male				3001655 / 3002186
	TAIWAN, PROVINCE OF CHINA	Decreased appetite, Vomiting	75.00	Female				
	TAIWAN, PROVINCE OF CHINA	Fatigue, Headache, Vomiting	70.00	Male				
	TAIWAN, PROVINCE OF CHINA	Pulmonary embolism	95.00	Female	Hypertension(C); Dementia(C)			
	TAIWAN, PROVINCE OF CHINA	Thrombocytopenia	65.00	Female				
	TAIWAN, PROVINCE OF CHINA	Death	69.00	Male				048M21A_1110504
	GERMANY	Death, Influenza	80.00	Female	SPIKEVAX; SPIKEVAX			3004962
	TAIWAN, PROVINCE OF CHINA	Nausea, Vaccination site pain, Vomiting	86.00	Female				048M21A_1110509-CDC
	SWEDEN	Cardiac arrest, COVID-19 immunisation, Decreased appetite, Fatigue, General physical health deterioration, Malnutrition, Mobility decreased, Multiple organ dysfunction syndrome, Personality change	94.00	Female	Upper limb fracture(H); Drug hypersensitivity; Colon cancer(H); Angina pectoris(C); Diarrhoea(H)			016G21A
	FINLAND	Coronary artery disease	85.00	Male				216035
	GERMANY	Cardiac arrest, Dyspnoea, Sudden death	80.00	Male				3005696
	GERMANY	Pulmonary embolism, Pulmonary oedema	85.00	Male	VAXZEVRIA; VAXZEVRIA			092F3AA
	SWEDEN	Aortic dissection, COVID-19 immunisation, Pulmonary embolism	75.00	Male	COVID-19 immunisation(H); Pulmonary embolism(H); Oxygen therapy(C); Hemiparesis(C); Respiratory failure(C); COVID-19 immunisation(H); Cerebrovascular accident(H); Hypertension(C)			3003659
	GERMANY	Aspiration, Asthenia, Atonic seizures, Dementia Alzheimer's type, Dysarthria, Dysphagia, Dyspnoea, Palliative care, Quadriplegia	88.00	Female	Depression(H); Polyneuropathy(C); Hyperlipidaemia(C); Hypertension(C)			092F21A
	UNITED STATES	COVID-19, Death, Drug ineffective, Herpes zoster, Injection site pain, Metastases to central nervous system, Pain, Pulmonary mass, Thrombosis	75.00	Female	Rubber sensitivity			037B21A; 006B21A
	UNITED STATES	Fall	77.00	Male	Plasma cell myeloma(H); Hypertension(H); Gait disturbance(H); Arrhythmia(H); Cardiac pacemaker insertion; Deep vein thrombosis(H)	POMALIDOMIDE; DEXAMETHASONE; NEURONTIN; LACTULOSE		
	FRANCE	Acute coronary syndrome, Cardiogenic shock	74.00	Male				214029; 000138A
	UNITED STATES	Acute kidney injury, Cardiogenic shock, COVID-19, Drug ineffective, Ischaemic cardiomyopathy, Myocardial infarction, Productive cough	69.00	Female	Drug hypersensitivity; Drug hypersensitivity; Hypersensitivity; Diabetes mellitus(C); Stent placement; Stent placement; Vascular graft; Leg amputation	INSULIN		052C21A; 050C21A
	UNITED KINGDOM	Death	82.00	Male	Myocardial ischaemia(H); Cardiac resynchronisation therapy			
	FRANCE	Drug ineffective, Vaccination failure	69.00	Male	Lymphoma(H); Myocardial ischaemia(H)			057G12A
	JAPAN	Blood pressure decreased, Bradycardia, Cardio-respiratory arrest, Chest discomfort, Depressed level of consciousness, Mydriasis, Oxygen saturation decreased, Restlessness, Sudden cardiac death	74.00	Male	Cardiac failure(C); Chronic kidney disease(C); Carotid arteriosclerosis(C); Hypertension(C); Diabetes mellitus(C); Dyslipidaemia(C); Constipation(C); Gastric ulcer haemorrhage(C); COMIRNATY; COMIRNATY(H)			
	ITALY	Asthenia, Injection site pain, Sudden death	66.00	Male	Adrenal insufficiency(C)			3004499
	ITALY	Acute respiratory failure, Guillain-Barre syndrome	76.00	Male	Cardiac assistance device user(C); Type 2 diabetes mellitus(C); Diabetic neuropathy(C); Arteriosclerosis(H); Gait disturbance(H); Chronic kidney disease(C); Dialysis; Atrial fibrillation(C)	COUMADIN; BISOPROLOL FUMARATE; TRAJENTA; UROREC; LASIX [FUROSEMIDE]; AVODART; LANSOX		000060a
	NETHERLANDS	Circulatory collapse, Diarrhoea, Ear haemorrhage, Haematoma, Influenza like illness, Insomnia, Limb discomfort, Malaise, Nausea, Oedema peripheral, Resuscitation	69.00	Female	Diverticulitis(H); Hypothyroidism(H); Chronic obstructive pulmonary disease(C); Polyarthritis(C); Blood cholesterol increased(C); Hypertension(C); Polymyalgia rheumatica(H); Type 2 diabetes mellitus(H); Cerebrovascular accident(H); Gastric bypass(H); Joint prosthesis user(C); Lichen sclerosus(H); MODERNA COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE(H)	CLOPIDOGREL TEV; LISINOPRIL/HYDROCHLOORTHIAZIDE; QUETIAPINE GH; CALCIUMCARBONAAT; ATORVASTATINE EG; APO-BECLOMETHASONE; PANTOPRAZOLO		
	GERMANY	Cerebrovascular accident	80.00	Male	Atrial fibrillation(C); Diabetes mellitus(C); VAXZEVRIA; Food allergy			

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	UNITED KINGDOM	Agitation, Agonal respiration, Cardiac arrest, Choking, Confusional state, Delirium, Fall, Hypotension, Malaise, Personality change, Productive cough, Psychomotor hyperactivity, Seizure	90.00	Female	Heavy menstrual bleeding(H); Hyperparathyroidism(H); Blood pressure fluctuation(H); Syncope(H); Eyelid rash(H); Sarcoma(H); Femur fracture(H); Depression(C); Arthritis(C); Anxiety(C)		4.1(b)	
	ITALY	Syncope	76.00	Male	Diabetes mellitus(C); Pulmonary hypertension(H); COMIRNATY; COMIRNATY	CARDIOASPIRIN; TICAGRELOR; NOVORAPID; PANTOPRAZOLE; XIGDUO; TOUJEO; ATORVASTATIN		3005884 sc 08/05/22
	TAIWAN, PROVINCE OF CHINA	Tachypnoea	81.00	Female	Hypertension(C); Tachypnoea(H)			SP2110-CDC
	TAIWAN, PROVINCE OF CHINA	Cerebral haemorrhage	86.00	Male	Diabetes mellitus(C)			2100686_1110427-CDC
	TAIWAN, PROVINCE OF CHINA	Immune system disorder, Sepsis	72.00	Male	Hypertension(C)			939599-CDC
	PHILIPPINES	Loss of consciousness	74.00	Male				068F21A
	UNITED KINGDOM	Lower respiratory tract infection, Pneumonia	87.00	Male				000081A
	UNITED KINGDOM	Pneumonia	87.00	Male	Left ventricular dysfunction(H); Aortic stenosis(H); Myocardial ischaemia(H); Chronic kidney disease(C); Pulmonary hypertension(C)	APIXABAN; HYDROXOCOBALAMIN; TAMSULOSIN; FINASTERIDE; ATORVASTATIN; LANSOPRAZOLE; EPOETIN NOS		000081A
	JAPAN	Cardiac death	70.00	Male	Hypertension(C); Diabetes mellitus(C); Myocardial infarction(C); Cardiac failure chronic(C); Chronic kidney disease(C); Hyperlipidaemia(C); Myocardial ischaemia(C); Atrial fibrillation(C); Gastrooesophageal reflux disease(C)			000224A
	JAPAN	Bacterial infection, Multiple organ dysfunction syndrome, Pneumonia, Pulmonary alveolar haemorrhage, Respiratory failure, Vasculitis	84.00	Female	Back pain(C); Hypertension(C); Dementia(C); COMIRNATY; COMIRNATY			
	UNITED STATES	Dementia, Interchange of vaccine products, Parkinson's disease, Pyrexia, Seizure	75.00	Male	Alcohol use(H); Drug hypersensitivity; Non-tobacco user(C); Arterial stent insertion; Parkinson's disease(C)	VENLAFAXINE; LORAZEPAM; MIDODRINE; TRAZODONE; MIRALAX; TYLENOL; VITAMIN D2; PREVACID; SEROQUEL		065K21A; 030H21B
	UNITED KINGDOM	Abdominal pain, COVID-19, Death, Fatigue, Thirst, Vomiting	98.00	Male	Suspected COVID-19(H); SARS-COV-2 VACCINE(H); SARS-COV-2 VACCINE; SARS-COV-2 VACCINE	PARACETAMOL		
	UNITED KINGDOM	Pneumonia	82.00	Male	Living in residential institution(H); Hypertension(C); Vascular dementia(C); Atrial fibrillation(C); Type 2 diabetes mellitus(C); Chronic kidney disease(C); SARS-COV-2 VACCINE; SARS-COV-2 VACCINE; SARS-COV-2 VACCINE	BENPERIDOL; BISOPROLOL; GLICLAZIDE; LINAGLIPTIN; MIRTAZAPINE		000018A
	JAPAN	Pulmonary alveolar haemorrhage, Respiratory failure, Vasculitis	82.00	Male	Interstitial lung disease(C); Pulmonary fibrosis(C); COMIRNATY; COMIRNATY			
	NETHERLANDS	Arrhythmia, Chills, Febrile convulsion, Hypoxia, Pneumonia, Pulmonary embolism, Pyrexia, Sepsis	80.00	Male	PFIZER BIONTECH COVID-19 VACCINE; PFIZER BIONTECH COVID-19 VACCINE; Hypertension(C); Bronchitis(C)	SEMINIET		3005789BS
	UNITED STATES	Dementia, Hepatic cirrhosis	87.00	Female	Dementia(C); Hepatic cirrhosis(C)			
	ITALY	Dyspnoea, Non-small cell lung cancer, Pleural effusion	89.00	Female	COMIRNATY; COMIRNATY			214024 sc 09/02/2022
	GERMANY	Cerebral haemorrhage	68.00	Male	Hypertension(C); Parkinson's disease(C); VAXZEVRIA			042G21A
	TAIWAN, PROVINCE OF CHINA	Death	81.00	Male	Hypertension(C); Dialysis; ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE			
	TAIWAN, PROVINCE OF CHINA	Decreased appetite	88.00	Male	Dialysis			
	TAIWAN, PROVINCE OF CHINA	Dyspnoea, Oxygen saturation decreased	85.00	Male	Hypertension(C); Gout(C); Tuberculosis(C); Cerebellar embolism(C)			
	TAIWAN, PROVINCE OF CHINA	Headache, Myalgia, Pyrexia, Vaccination site erythema, Vaccination site pain, Vaccination site swelling	81.00	Male	Chronic kidney disease(C); Pneumoconiosis(C); Pneumothorax(C); Gout(C)			
	TAIWAN, PROVINCE OF CHINA	Death	80.00	Female	Dialysis; COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA			2100696_1110525
	SPAIN	COVID-19 immunisation, COVID-19 pneumonia, Vaccination failure	77.00	Male	Retinopathy hypertensive(H); Atrial fibrillation(H); Type 2 diabetes mellitus(H); Chronic kidney disease(H); Hypertension(H); Cerebrovascular accident(H); Dyslipidaemia(H)			3001532; 3002339
	SWEDEN	Cardiac arrest, Hypoxic-ischaemic encephalopathy	79.00	Female	COVID-19 immunisation; Torticollis(C); COVID-19 immunisation; COVID-19 immunisation; Depression(C)			000037A
	SWEDEN	Lung infiltration	78.00	Female	Rheumatoid arthritis(C); Cognitive disorder(C); Radiotherapy; Progressive multifocal leukoencephalopathy(H); COVID-19 immunisation(H); Pneumonitis(H); Breast cancer(H); Colitis ulcerative(C)			3001177
	UNITED STATES	Interstitial lung disease, Respiratory failure	72.00	Male	Interstitial lung disease(C); Pleuroparenchymal fibroelastosis(C)			
	UNITED KINGDOM	Aortic stenosis, Chronic kidney disease, Pneumonia	87.00	Male	Myocardial ischaemia(C); Aortic stenosis(C); Chronic kidney disease(C); Epistaxis(H); Cardiac failure(H); Pulmonary hypertension(C)	APIXABAN; ATORVASTATIN; FINASTERIDE; LANSOPRAZOLE; TAMSULOSIN; HYDROXOCOBALAMIN; EPOETIN NOS		000081A
	FRANCE	Aspiration, Pneumonia aspiration, Vomiting	74.00	Female	Acromegaly(C); Mixed anxiety and depressive disorder(C); Hypertension(C); Breast cancer(C); Tobacco user(C); Vomiting(H); Cognitive disorder(C)	VALSARTAN/HIDROCLOROTIAZIDA; IMOVANE; DAFALGAN; SERESTA		000080A
	PHILIPPINES	Asthenia, COVID-19, Dyspnoea	81.00	Female				
	PHILIPPINES	Death	72.00	Male				
	PHILIPPINES	Chest pain, Dyspnoea, Hyperhidrosis, Vomiting	70.00	Male				

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	PHILIPPINES	Death	72.00	Male			4.1(b)	
	GERMANY	Brain neoplasm malignant, Cerebrovascular accident, Lung neoplasm malignant, Pancreatic carcinoma	86.00	Female	Tuberculosis(H); Acute lung injury(C); SPIKEVAX			
	GERMANY	Myocardial infarction	66.00	Female	COMIRNATY; COMIRNATY			0001401
	FRANCE	COVID-19 pneumonia, Vaccination failure	96.00	Female	Atrial fibrillation(H); Gastric ulcer(H); Dyslipidaemia(H); Cerebrovascular accident(H); Hypertension(H); Age-related macular degeneration(H); Cardiac failure(H); Femur fracture(H); Cataract(H); Gastrointestinal haemorrhage(H)	CORDARONE; FLUIDABAK; LOXENIL; PLAVIX; DOLIPRANE; COLECALCIFEROL; ATARAXOID; PANTOPRAZOLE; VOGALENE; TIMOLOLO; CALCIUM IPODATE; BRINZOLAMIDE; VOLTARENE LP; COLECALCIFEROL; NORSET		214005
	ITALY	Abdominal pain, Injection site erythema, Injection site pain, Intestinal ischaemia, Muscle contractions involuntary, Renal necrosis, Vomiting	86.00	Female				000054A
	UNITED STATES	Cerebral haemorrhage, Fall, Ischaemic stroke	79.00	Male	Seasonal allergy; Amnesia(H)			018B21A; 011A21A
	ESTONIA	COVID-19, Drug ineffective	84.00	Unknown				
	GERMANY	Bone cancer	88.00	Female	COMIRNATY; COMIRNATY			092F21A
	UNITED KINGDOM	Cerebrovascular accident, Grip strength decreased, Muscular weakness, Status epilepticus	83.00	Male	Vitamin B12 deficiency(H); Hypertension(C)	AMLODIPINE		
	PHILIPPINES	Blood pressure increased	72.00	Male				
	SWEDEN	Asthenia, Cardiac failure, COVID-19 immunisation, Decreased appetite, Dyspnoea, Fatigue, Pulmonary embolism	85.00	Female	COVID-19 immunisation; COVID-19 immunisation; Diabetes mellitus(C); Hypertension(C); COVID-19 immunisation			000037A
	FRANCE	Acute pulmonary oedema	75.00	Male	Cerebrovascular accident(H); Carotid arteriosclerosis(H); Hypertension(H)	COMIRNATY		057G21A
	FRANCE	Death	96.00	Female				44A
	ESTONIA	COVID-19, Vaccination failure	84.00	Female	Osteoporosis(C); Glaucoma(C)	ATORVASTATIN; VITAMIN D 3; CALCIUM		3005243
	GERMANY	Death	67.00	Male	Hypothyroidism(C); COMIRNATY; COMIRNATY			3004951
	CHILE	Anisocoria, Bradycardia, Craniocerebral injury, Pupil fixed, Syncope, Traumatic haematoma	68.00	Female		ATORVASTATIN; CARVEDILOL; SPIRONOLACTONE; ACETYLSALICYLIC ACID; ISOSORBIDE; HYDROCHLOROTHIAZID; LOSARTAN; INSULIN ISOPHANE		

Appendix 11.29b Elderly: Fatal case narratives

Case ID	Narrative (Complete)
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 03-Jan-2022 and was forwarded to Moderna on 03-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death unexplained) in a 90-year-old male patient who received mRNA-1273 (Spikevax) for Prophylactic vaccination. No Medical History information was reported. On 13-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 14-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not provided. Treatment information was not provided. Company Comment This case concerns a 90-year-old male patient with a relevant history of advanced age, who experienced the serious, unexpected event of Sudden Death. The event occurred 1 day after an unspecified dose sequence of mRNA-1273 vaccine. The medical history of advanced age is a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting and retained for consistency with the RA report.
4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of CARDIOGENIC SHOCK (Cardiogenic shock) in a 65-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003659) for COVID-19 vaccination. The patient's past medical history included Emphysema, Arteriosclerosis, Alcoholic cirrhosis, Alcoholic cardiomyopathy and Chronic alcoholism. On 19-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 ml. On 28-Nov-2021, after starting mRNA-1273 (Spikevax), the patient experienced CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death and medically significant). The patient died on 28-Nov-2021. An autopsy was performed. The autopsy-determined cause of death was Cardiogenic shock. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. The patient was died suddenly 9 days after vaccination with Spikevax. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. This is a regulatory authority case concerning a 65-year-old, male patient with medical history of Emphysema, Arteriosclerosis, Alcoholic cirrhosis, Alcoholic cardiomyopath, who experienced the unexpected fatal event of Cardiogenic Shock, which resulted in death. The events occurred approximately 9 days after the unknown dose of mRNA-1273 COVID 19 Vaccine. The rechallenge was not applicable, as information about further dosing was not disclosed. An autopsy determined the casuse of death is Cardiogenic shock. The medical history of Emphysema, Arteriosclerosis, Alcoholic cirrhosis, Alcoholic cardiomyopathy remains a confounder.The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.
4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of CARDIAC ARREST (Cardiac arrest) and SYNCOPE (Suddenly collapsed) in a 7-decade-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Large intestine polyp. In October 2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In November 2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. In December 2021, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and medically significant) and SYNCOPE (Suddenly collapsed) (seriousness criterion medically significant). The patient died in December 2021. The reported cause of death was Cardiac arrest and suddenly collapsed. An autopsy was not performed. At the time of death, SYNCOPE (Suddenly collapsed) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In December 2021, Chest X-ray: result not provided (Inconclusive) Result not provided. In December 2021, SARS-CoV-2 test: result not provided (Inconclusive) Result not provided. Concomitant products were not provided. This case concerns a male patient in his late 60s. The patient seemed to have no specific events following vaccination. After about a month after the receiving the second dose , the patient suddenly collapsed on the street. The paramedics performed cardio-pulmonary resuscitation, but the patient did not resuscitate and therefore was transferred to the emergency room . Upon arrival at the emergency room , the hospital performed tests such as COVID-19 test, chest X-rays, cerebral hemorrhage etc. (results were unknown). The hospital performed cardio-pulmonary resuscitation for 40 minutes but the patient did not resuscitate and eventually died. After reviewing the surveillance cameras, it was reported that the patient seemed healthy with no symptoms or discomfort seconds before he collapsed. According to surveillance cameras, it seemed like the patient was already dead before the ambulance had arrived. According to the doctor, the cause of death was cardiac arrest of an unknown cause. At first the autopsy was requested but eventually was not done since the bereaved thought the causal relationship between the vaccine and the event could not be determined. This case concerns a 7-decade-old male patient with no relevant medical history, who experienced the unexpected serious events of Cardiac Arrest and Syncope. The event of Cardiac Arrest was medically significant and fatal for the patient. The events occurred approximately 1 month after receiving the second dose of mRNA-1273 Vaccine. The patient died the same day on the onset of events, the reported cause of death was Cardiac arrest of an unknown

Case ID	Narrative (Complete)
	cause. An autopsy was not performed. No other clinical or treatment details were given. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of DECREASED APPETITE (Loss of appetite) and OEDEMA PERIPHERAL (Edema of left lower extremity) in a 70-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 3003184-CDC) for an unknown indication. No Medical History information was reported. On 20-Jul-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Jul-2021, the patient experienced DECREASED APPETITE (Loss of appetite) (seriousness criterion death) and OEDEMA PERIPHERAL (Edema of left lower extremity) (seriousness criterion death). The reported cause of death was Appetite lost and Edema of lower extremities. It is unknown if an autopsy was performed. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. On 20-jul-2021 After receiving the Moderna vaccine, the patient visited the Department of Family Medicine of Nantou Hospital on 26-jul-2021due to edema in the left lower extremity, stomach distention and loss of appetite, with no improvement in symptoms. On 30-aug-2021, the patient underwent an abdominal ultrasound examination at Cheung Hong Hepatobiliary Clinic in Yuanlin, with a left liver tumor detected. On 01-sep-2021, the patient visited Changhua Christian Hospital and received an abdominal ultrasound and computed tomography and diagnosed with liver tumor, with recommendation for surgery. 16-sep-2021, the patient was admitted to the hospital for surgery to remove a liver tumor over 35cm. The post-operative oxygenation was approximately 86-90% with a nasal cannula. 02-oct-2021, the patient was discharged from the hospital and returned home, during which time the nasal cannula was supplied with O2:3.5L/min.On 05-nov-2021, due to poor appetite, bloating and vomiting at home, the patient was sent to Changhua Christian Hospital by his family members, and was diagnosed with liver cancer in his right liver after undergoing an abdominal computerized tomography.The patient was admitted to hospital with high white blood cells and his condition was not suitable for reoperation. On 13-Nov-2021, the patient was treated with targeted drugs, and on 15-nov-2021, the patient was treated in the hospice ward. On 17-nov-2021, the patient was transferred back to Nantou Hospital for hospice care, and on December 8, the patient died. Company comment:This is a regulatory case concerning a 70 year-old, male patient with no reported medical history, who experienced the serious Fatal unexpected, events of Decreased appetite and Oedema peripheral. The patient referred Decreased appetite, Oedema peripheral and Gastric dilatation started approximately 6 days after the mRNA-1273 vaccine, dose number not provided. Approximately 1month and a half after vaccination the patient was diagnosed with liver tumor through ultrasound and computed tomography. The patient was hospitalized and surgery performed, 15 days after diagnosis, to remove a liver tumor over 35 cm width. Patient was discharged from hospital with oxygen requirements and was admitted again 3 days after due to Decreased appetite, vomiting, Abdominal distension and white blood cells increased, a diagnosis of hepatic cancer was confirmed, treatment with targeted drugs was started. The patient died approximately 4 months and a half after receiving the mRNA-1273 vaccine, it is unknown whether an autopsy was performed. The rechallenge was not applicable due to the fatal outcome. The concurrent diagnosis of hepatic carcinoma and patient´s advanced age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of THROMBOCYTOPENIA (Thrombocytopenia) in a 74-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 24-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-Dec-2021, the patient experienced THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criteria death and medically significant). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant drug information provided. No treatment drug information provided. The patient received two doses of Moderna vaccine. She was diagnosed with myocardial infarction. The patient was hospitalized for stent surgery and then discharged. No abnormality was found after the discharge, and the patient could still work in the fields. In early December, the youngest son found that the patient had a little stroke and took the patient to Hospital for hospitalization and treatment. Blood test indicated that the platelet count was low, but the patient's condition was stable. On December 14, the Hematology Oncology Department found that the patient's platelet count was still low. Later, the patient was diagnosed with thrombotic thrombocytopenia purpura. Later, the condition became serious and the patient died on December 16. A family member called to ask about applying for VICP. The family member said that the patient had no chronic disease history, and the patient underwent stent surgery due to MI before. Company Comment: This case refers to a 74-year-old female patient with no known medical history who experienced the unexpected event of Thrombocytopenia approximately 10 weeks after the second dose of mRNA-1273 vaccine which. The patient eventually died. No causality assessment was provided by the reporter. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
4.1(b) [redacted]	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (Fever) in a 70-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for an unknown indication. No Medical History information was reported.

Case ID	Narrative (Complete)
	On 14-Dec-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 14-Dec-2021 at 1:00 PM, the patient experienced PYREXIA (Fever) (seriousness criterion death). The reported cause of death was Fever. An autopsy was not performed. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication list was not provided. Treatment medication information was not provided by the reporter. The batch number reported as N/A It was reported that patient experienced fever/muscle or body aches. Company Comment - This regulatory authority case concerns a 70 year old female patient with no relevant medical history, who experienced the serious (death) unexpected event of pyrexia. The event occurred on the same day after the a dose of mRNA-1273 vaccine, and the outcome was fatal. The reported cause of death was fever. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Infection despite vaccination), DIARRHOEA (Watery diarrhoea), DYSPNOEA (Dyspnea), OXYGEN SATURATION DECREASED (Desaturation) and COVID-19 (SARS-CoV-2 infection) in an 86-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concurrent medical conditions included Asthma, Ischemic heart disease, Hypertension arterial, Hypothyroidism (substituted) and Small cell carcinoma of the lung. Concomitant products included CLOPIDOGREL, ESOMEPRAZOLE, LEVOTHYROXINE SODIUM (EUTHYROX), LISINOPRIL, NEBIVOLOL HYDROCHLORIDE (NEBILET), ZOLPIDEM, FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE (SERETIDE), SODIUM PICOSULFATE (LAXOBERON), FICUS CARICA EXTRACT, SORBITOL (PURSANA), ATORVASTATIN CALCIUM, EZETIMIBE (ATOZET), CALCIUM CARBONATE, COLECALCIFEROL (KALCIPOS D3), LERCANIDIPINE, ACETYLCYSTEINE (FLUIMUCIL), DOMPERIDONE, CODEINE PHOSPHATE HEMIHYDRATE, PARACETAMOL (CO-DAFALGAN) and TRAMADOL for an unknown indication. On 12-Feb-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 18-Mar-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 19-Nov-2021, the patient experienced VACCINATION FAILURE (Infection despite vaccination) (seriousness criteria death, hospitalization and medically significant), DIARRHOEA (Watery diarrhoea) (seriousness criteria death, hospitalization and medically significant), DYSPNOEA (Dyspnea) (seriousness criteria death, hospitalization and medically significant), OXYGEN SATURATION DECREASED (Desaturation) (seriousness criteria death, hospitalization and medically significant) and COVID-19 (SARS-CoV-2 infection) (seriousness criteria death, hospitalization and medically significant). The patient died on 28-Nov-2021. The reported cause of death was infection despite vaccination, SARS-CoV-2 infection, Watery diarrhoea, Dyspnea and desaturation. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Nov-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered VACCINATION FAILURE (Infection despite vaccination), DIARRHOEA (Watery diarrhoea), DYSPNOEA (Dyspnea), OXYGEN SATURATION DECREASED (Desaturation) and COVID-19 (SARS-CoV-2 infection) to be possibly related. It was verbally reported that, dyspnea with desaturation as of 22 November. She was hospitalized on 26.11.2021. In continuous care, treatment of dexamethasone and tocilizumab was introduced. The evolution was unfavorable. This patient experienced SARS-CoV-2 infection approximately 8 months after the second injection of Spikevax Moderna vaccine. The Phase 3 study that allowed the registration of the COVID-19 Vaccine Moderna® vaccine included approximately 30,000 people and showed 94% efficacy of the vaccine, based on the number of symptomatic COVID-19 infections reported in each group; 11 out of 14'134 vaccine cases versus 185 cases out of 14,073 placebo (1). The final analysis of this study demonstrated an overall effectiveness in the prevention of COVID-19 disease of 93.2%. The effectiveness in the prevention of severe disease was 98.2%, and the effectiveness in the prevention of asymptomatic infection starting 14 days after the second injection was 63%. In addition, vaccine effectiveness was consistent across all ethnic and racial groups, age groups and participants with co-morbidities such as chronic lung disease, heart disease, obesity, diabetes, liver failure, or HIV (2). In studies conducted in “real life”, high efficacy of more than 90% was also observed after the second dose (3.4). Company Comment - This regulatory authority case concerns an 86 year old female patient with medical history of hypothyroidism and small cell carcinoma of the lung who experienced the serious unexpected events of vaccination failure, diarrhea, dyspnea, oxygen saturation decreased and COVID-19. The events occurred approximately 8 months after the second dose of mRNA-1273 vaccine, and the outcome was fatal, with death occurring 9 days later. The reported causes of death were infection despite vaccination, SARS-CoV-2 infection, diarrhoea, dyspnea and desaturation. Patient's medical history of hypothyroidism and small cell carcinoma of the lung remains a confounder. The rechal
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 (SARS-CoV-2 infection) and VACCINATION FAILURE (Vaccination failure) in a 67-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3001177 and 3000493) for COVID-19 vaccination. No Medical History information was reported. On 25-Mar-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.

Case ID	Narrative (Complete)
	On 22-Apr-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 08-Oct-2021, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criterion death) and VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Oct-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company comment: This is a regulatory authority case concerning a 67-year-old male patient with no medical history reported, who experienced unexpected events of COVID-19 (AESI) and vaccination failure (seriousness criterion death assessed as per Regulatory Authority reporting). The events occurred approximately 5 months 16 days after the administration of second dose of mRNA-1273 vaccine. Clinical course and treatment details were not provided. The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. Very limited information has been provided at this time. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 5-Jan-2022.
4.1(b) [redacted]	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (respiratory arrest and cardiac arrest, unsuccessful resuscitation) and APNOEA (respiratory arrest and cardiac arrest, unsuccessful resuscitation) in an 86-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Myocardial infarction (The patient has had several heart attacks in the past.). Concurrent medical conditions included Lung fibrosis (The patient suffered from pre-existing chronic progressive pulmonary fibrosis.). On 30-Nov-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 50 µg. On 30-Nov-2021 at 12:05 PM, the patient experienced CARDIAC ARREST (respiratory arrest and cardiac arrest, unsuccessful resuscitation) (seriousness criterion death) and APNOEA (respiratory arrest and cardiac arrest, unsuccessful resuscitation) (seriousness criterion death). The patient died on 30-Nov-2021. The cause of death was not reported. It is unknown if an autopsy was performed. The autopsy-determined cause of death was Death from natural causes. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered CARDIAC ARREST (respiratory arrest and cardiac arrest, unsuccessful resuscitation) and APNOEA (respiratory arrest and cardiac arrest, unsuccessful resuscitation) to be possibly related. Treatment information not provided. Concomitant medication not provided. The patient stopped breathing on car after taking of 50 mcg of Spikevax booster vaccination (Elasomeran, lot number unknown) on 30-Nov-2021 at 11:45 a.m. As per the autopsy the patient died of natural death findings by the forensic medicine institute. The Patient had pre-existing chronic progressive pulmonary fibrosis, take oxygen therapy and several heart attacks in the past. Therapy include oxygen therapy for pulmonary fibrosis. Company comment: This Regulatory authority case concerns a 86-year-old, male patient, with medical history of lung fibrosis and myocardial infarction, who experienced the unexpected, serious (fatal) event of apnoea and cardiac arrest. The patient received a dose of mRNA-1273 vaccine, considered as the third dose of the patient's COVID-19 vaccination schedule. It was reported that the patient was vaccinated at 11:45am and after 20 minutes of monitoring, he went to the car on foot independently, however, when the patient was sitting in the car, his son noticed that the patient stopped breathing. Despite immediate resuscitation by doctors, the patient was pronounced dead at 12:15pm, approximately 30 minutes after vaccination. According to the autopsy findings of the forensic medicine institute, the patient died of natural death. The patient suffered from pre-existing chronic progressive pulmonary fibrosis with home oxygen therapy and had several myocardial infarctions in the past. The medical history of lung fibrosis and myocardial infarction remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death unexplained) in an 85-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Chronic ischaemic heart disease, unspecified and COPD. On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The cause of death was not reported. An autopsy was performed, but no results were provided. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. It was reported that patient died 3 days after vaccination, autopsy result not reported. Company comment: This is a regulatory case concerning a 85-year-old, female patient with a history of Myocardial ischaemia and Chronic obstructive pulmonary disease, who experienced the Fatal unexpected , according CCDS, event of Sudden death. The event occurred approximately 3 days after the booster dose of mRNA-1273 vaccine. Cause of death was not further specified; autopsy result not reported. The rechallenge was not applicable due to the fatal outcome. The medical history of Myocardial ischaemia and Chronic obstructive pulmonary disease remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	Narrative (Complete)
	Most recent FOLLOW-UP information incorporated above includes: On 05-Jan-2022: Follow up received wherein suspect product indication updated On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 04-Jan-2022.
4.1(b) [redacted]	This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death) in an 85-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Venous insufficiency (She was suffering from venous insufficiency.) and Melanoma (She suffered from melanoma in the past (2015).) in 2015. Concurrent medical conditions included Hypertension (She was suffering from hypertension.) and Laceration (The day before, the patient went to GCS monitoring after a fall with a a crack crush wound...) since 29-Nov-2021. Concomitant products included AMLODIPINE BESILATE (AMLODIPINA ACC) and VALSARTAN for Hypertension. On 30-Nov-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. Death occurred on 30-Nov-2021 The patient died on 30-Nov-2021. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered DEATH (Death) to be possibly related. Company comment: This is a regulatory case concerning a 85-year-old, female patient with a history of Hypertension, Malignant melanoma and Peripheral venous disease, who experienced the Fatal unexpected, according CCDS, event of Death. The event occurred approximately the same day after the third dose of mRNA-1273 vaccine. The day before, the patient was hospitalized for GCS monitoring after a fall with a crack loss. no abnormalities were detected computed topographically. Cause of death was not further specified; it is unknown if an autopsy was performed. The rechallenge was not applicable due to the fatal outcome. The medical history of Hypertension, Malignant melanoma and Peripheral venous disease remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The day before, the patient was hospitalized for GCS monitoring after a fall with a RissQuetsch wound. none abnormalities were detected computed tomographically.The patient was immunized against COVID-19 with Spikevax (Elasomeran) in March 2021 and April 2021. On 30-Nov-2021, the patient was vaccinated against COVID-19 with Spikevax for the third time. The patient died 6 to 8 hours after vaccination. The day before, the patient was hospitalized for GCS monitoring after a fall with a crack loss. none abnormalities were detected computed tomographically. The patient had not shown none side effects following the first two COVID-19 vaccinations. The patient did not consume or smoke alcohol and had none allergies. Patient suffered from hypertension, venous insufficiency and melanoma in the past (2015). The following medications were also taken Daily amlodipine for hypertension, Daily valsartan for hypertension. The Swiss drug information of amlodipine axapharm (amlodipine, sample preparation) indicates data describing pronounced peripheral vasodilation and possible reflex tachycardia in severe overdose. In addition, there may be a clear and persistent systemic hypertension up to fatal shock. However, an overdose is not mentioned in the patient. According to the Swiss drug information from Valsartan Axapharm (valsartan, sample preparation), patients with severe heart failure whose renal function was dependent on the activity of the renin-angiotensin-aldosterone system were treated with ACE inhibitors and angiotensin II receptor antagonists under treatment with ACE inhibitors and angiotensin II receptor antagonists and/or progressive azotemia and rarely acute renal failure and/or deaths are observed. No evidence of severe heart failure in the patient or acute renal failure is reported. There is a close temporal relationship between the use of Spikevax (Elasomeran) and the onset of symptoms. There is also a temporal correlation between taking amlodipine and valsartan and beginning of complaints. Although the drug information only records deaths from an overdose or in patients with severe heart failure that the patient did not suffer from, but since only Spikevax has been restarted, the other drugs appear etiologically less likely. In exitus letalis, it is not possible to evaluate the subsidence of symptoms in terms of a positive deconhale. In summary, we assess the causality between the use of Spikevax (elasomeran) and the exitus of letalis according to WHO/CIOMS criteria based on the time context, documentation in the WHO database, but possible other non-exclusivable non-drug causes (risk factors, endogenous causes) formally as possible. MEDICAL HISTORY: No treatment medication information was reported
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration) and ASTHENIA (Weakness) in a 76-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3000493 and 300042721) for COVID-19 vaccination. The patient's past medical history included Breast tumor malignant in 2014, Malignant neoplasm progression in 2021, Brain metastases, Ovarian cancer in 2014, Gastrooesophageal reflux (Treated with NEXIAM), Cholelithiasis in 2003, Osteoporosis in 2016, Hypercholesteraemia, Hypothyroidism, Bone metastases, Fracture bone (Pathological fracture bone) in 2016, Lung metastases, Hepatic metastases and Skin metastases. Concomitant products included CAPECITABINE (XELODA) for Metastatic disease, COLECALCIFEROL (D-CURE), ROSUVASTATIN CALCIUM (CRESTOR), EXEMESTANE (AROMASIN), FLUTICASONE FUROATE, VILANTEROL TRIFENATATE (RELVAR), ESOMEPRAZOLE MAGNESIUM (NEXIAM [ESOMEPRAZOLE MAGNESIUM]), DENOSUMAB (XGEVA), SALBUTAMOL SULFATE (VENTOLIN [SALBUTAMOL SULFATE]) and LEVOTHYROXINE SODIUM (EUTHYROX) for an unknown indication. On 11-Mar-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 08-Apr-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. In April 2021, the patient experienced GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration) (seriousness criteria death and hospitalization) and ASTHENIA (Weakness) (seriousness criteria death and hospitalization). The patient died on 26-Jul-2021. The reported cause of death was General physical health deterioration, Macrophage activation and Metastatic disease. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In July 2021, Platelet count: severe thrombopenia (Inconclusive) severe thrombopenia. On 22-Jul-2021, Blood pressure diastolic: 80 mm[hg] (Inconclusive) 80 mm[Hg]. On 22-Jul-2021, Blood pressure systolic: 170 mm[hg] (Inconclusive) 170 mm[Hg]. On 22-Jul-2021, Body temperature: 36.2 degree celsius (Inconclusive) 36.2 degree Celsius.

Case ID	Narrative (Complete)
	On 22-Jul-2021, Heart rate: 88 per minute (Inconclusive) 88 per minute. On 22-Jul-2021, Oxygen saturation: 93 per 100 (Inconclusive) 93 per 100 SaO2 93% in room air. No treatment information was provided. FRENCH IMPUTABILITY METHOD for the events general physical health deterioration and weakness are provided as C2 S1 (I1 dubious) B2. Company Comment This case concerns a 76-year-old female patient with a relevant medical history of Malignant neoplasm progression in 2021 with Lung metastases, Hepatic metastases, and Skin metastases, who experienced the serious unexpected events of General Physical Health Deterioration and Asthenia with fatal outcome. The events occurred on an unspecified date in April after the second dose of mRNA-1273 vaccine. No autopsy report was provided. The medical history of Malignant neoplasm progression in 2021 with Lung metastases, Hepatic metastases and Skin metastases are confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting as death/hospitalization and retained for consistency with the RA report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 05-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (in particular pulmonary embolism) and ACUTE PULMONARY OEDEMA (Acute pulmonary edema) in an 85-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for Prophylactic vaccination. Previously administered products included for Prophylactic vaccination: VAXZEVRIA on 08-Apr-2021 and Vaxzevria COVID-19 Vaccine COVID-19 Vaccine (ChAdOx1-S [recombinant]) COVID-19 Vaccine AstraZeneca suspension for injection COVID-19 Vaccine AstraZeneca on 01-Jul-2021. Past adverse reactions to the above products included No adverse event with VAXZEVRIA and Vaxzevria COVID-19 Vaccine COVID-19 Vaccine (ChAdOx1-S [recombinant]) COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca. On 18-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Dec-2021, the patient experienced PULMONARY EMBOLISM (in particular pulmonary embolism) (seriousness criteria death and life threatening) and ACUTE PULMONARY OEDEMA (Acute pulmonary edema) (seriousness criteria death and life threatening). The patient died on 21-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant Medication use information was not provided by reporter. Treatment Medication use information was not provided by reporter. Company Comment This case concerns an 85-year-old female patient with no relevant medical history, who experienced the serious unexpected events of Pulmonary Embolism (AESI) and Acute Pulmonary Oedema with fatal outcome. The events occurred 3 days after the third dose of mRNA-1273 vaccine. No autopsy report was provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting as death/life-threatening and retained for consistency with the RA report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and COVID-19 (SARS-CoV-2 infection) in a 69-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3001939 and 3001531) for COVID-19 vaccination. No Medical History information was reported. On 03-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 01-May-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 14-Oct-2021, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death) and COVID-19 (SARS-CoV-2 infection) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Oct-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Company Comment: This case concerns a 69-year-old female patient, with no medical history reported, who experienced the unexpected events of COVID-19 (AESI) and Vaccination failure. The events occurred 5 months and 13 days after the second dose of mRNA-1273 vaccine, and had a fatal outcome, with death occurring. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 05-Jan-2022.

Case ID	Narrative (Complete)
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 06-Jan-2022. The most recent information was received on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of CEREBROVASCULAR ACCIDENT (Ictus) in a 92-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3001442) for COVID-19 vaccination. No Medical History information was reported. On 26-Mar-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 27-Mar-2021, the patient experienced CEREBROVASCULAR ACCIDENT (Ictus) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication use information was not provided by reporter. Treatment medication use information was not provided by reporter. Company Comment: This is a regulatory case concerning 92-year-old female patient with no medical history reported, who experienced the serious fatal unexpected AESI event of Cerebrovascular accident approximately 1 day after a dose of mRNA-1273 vaccine. No further information regarding the event and "cause" of death have been provided. The patient´s age remains as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 14-Feb-2022: Follow up received death date, autopsy, event stop date has been deleted and event verbatim has been updated. On 18-Feb-2022: Follow up received and contains No new information
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This case was received via European Medicines Agency (Reference number: 4.1(b)) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) and PULMONARY THROMBOSIS (Pulmonary thrombosis) in a 72-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 24-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .25 ml. On an unknown date, the patient experienced CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) (seriousness criteria death, hospitalization and medically significant) and PULMONARY THROMBOSIS (Pulmonary thrombosis) (seriousness criteria death, hospitalization and medically significant). The patient died on 02-Dec-2021. The reported cause of death was trombosis pulmonar. It is unknown if an autopsy was performed. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 24-Nov-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant information was not provided. Treatment information was not provided.
4.1(b)	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 03-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of ALTERED STATE OF CONSCIOUSNESS (Changes in consciousness) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 08-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-Aug-2021, the patient experienced ALTERED STATE OF CONSCIOUSNESS (Changes in consciousness) (seriousness criteria death and medically significant). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant products were not provided. Patient was a 75-year-old male with a history of heart disease. On 22/12/21 the dependents complained that after receiving the first dose of Moderna vaccine on 08/07/21 from the Health Center. On 13/08/21 the patient developed suddenly discomfort and was admitted to Hospital service diagnosed with cerebral infarction and stroke. Due to poor condition, he was transferred to Hospital for treatment. On 13/08/21 COVID-19 PCR test showed negative. During the hospitalization the patient ever received embolization surgery, 07/09/21 returned home due to stable condition, and completely rested on the bed. On 15/10/21 the patient died at home. The autopsy certificate was issued by Health Center with the cause of death as cerebral infarction. This fatal regulatory case concerns a 75-year-old male patient with medical history of heart disease who experienced the unexpected fatal event of ALTERED STATE OF CONSCIOUSNESS The event occurred 35 days after 1st dose of Moderna Covid 19 vaccine.

Case ID	Narrative (Complete)
	The pacient died 15/10/2021. The autopsy certificate was issued by Health Center with the cause of death as cerebral infarction The rechallenge is not applicable The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event terms, seriousness and onset dates were captured as provided by the regulatory Authority
4.1(b) [redacted]	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 03-Jan-2022 and was forwarded to Moderna on 05-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of ASTHMA (Asthma) in a 72-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 939599-CDC) for an unknown indication. No Medical History information was reported. On 02-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 ml. On 22-Aug-2021, the patient experienced ASTHMA (Asthma) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant products were reported. The patient was a non-institutional resident and was provided with handbook for physical and mental disabilities (category 7 nerves, muscles, bones and movement-related structures and functions), a history of fractures, traumatic small bowel rupture. On 02-Jul-2021, The patient received the first dose of covid-19 vaccine (Moderna). On 14-Aug-2021, Patient developed dizziness, vomiting, foot weakness, fall, loss of appetite, and was admitted to the emergency room of Hospital. On 15-Aug-2021, He visited hospital for treatment due to general weakness, continuous hiccups and other symptoms, and returned home for rest on the same day. On 16-Aug-2021, due to the second onset of asthma the patient was admitted to the emergency department of hospital, and was admitted into intensive care unit. On 16-Aug-2021, He visited hospital for treatment and was hospitalized (intensive care unit) due to shortness of breath, abdominal pain and loss of appetite. COVID-19 PCR test showed negative and the patient received intubation and respirator. During the period, he was diagnosed with intestinal obstruction and intestinal adhesion, but the dependents refused treatment. On 22-Aug-2021, the patient died around 4 am in the hospital, the cause of death was pneumonia combined with respiratory failure. The patient was blind, and his left forearm was amputated. No treatment information was reported by the reporter. Company Comment: This case concerns a 72-year-old male patient, with medical history of physical and mental disabilites, who experienced the unexpected event of Asthma. The event occurred 1 month and 21 days after the first dose of mRNA-1273 vaccine and had a fatal outcome, with death occurring. The reported cause of death was pneumonia combined with respiratory failure. It is unknown if an autopsy was performed. Patient´s medical history remains confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of SEPSIS (Sepsis), ASTHENIA (body weakness), DECREASED APPETITE (loss of appetite), BACK PAIN (back pain), PYREXIA (fever) and DEATH (Death) in a 79-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (batch no. 3004736) for COVID-19 vaccination. The patient's past medical history included Oedema and Folate deficiency anaemia. Concurrent medical conditions included Hypertension, Diabetes (Diabetes tightly controlled.), Chronic back pain (Chronic low back pain with hypercalcemia.), Osteoporosis, Hypercalcaemia (Chronic low back pain with hypercalcemia.) and Hyperlipidaemia (Hyperlipidemia dietary controlled.). On 05-Sep-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) 1 dosage form. On 09-Sep-2021, the patient experienced SEPSIS (Sepsis) (seriousness criterion death). On an unknown date, the patient experienced ASTHENIA (body weakness) (seriousness criterion death), DECREASED APPETITE (loss of appetite) (seriousness criterion death), BACK PAIN (back pain) (seriousness criterion death) and PYREXIA (fever) (seriousness criterion death). The patient died on 14-Sep-2021. The reported cause of death was Sepsis, body weakness, loss of appetite, Fever and Back pain. An autopsy was not performed. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not reported. Treatment medications were not reported. Time of vaccination include 12:59 PM. Company Comment include This case concerns a 79-year-old female patient with a relevant medical history of Hypertension, Hyperlipidemia, and Diabetes, who experienced the serious unexpected events of Sepsis, Asthenia, Decreased Appetite, Back Pain, Pyrexia, and Death. The event of Sepsis occurred 4 days after the first dose of mRNA-1273 vaccine, while the events of Asthenia, Decreased Appetite, Back Pain, Pyrexia occurred on an unspecified date after the first dose of mRNA-1273 vaccine, with death occurring 9 days after the administration of mRNA-1273 vaccine. The patient's medical history of Hypertension, Hyperlipidemia, and Diabetes are confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting as Death and retained for consistency with the RA report.
4.1(b) [redacted]	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Jan-2022 and was forwarded to Moderna on 06-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of HAEMORRHAGIC STROKE (Haemorrhagic stroke) in an 82-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (batch no. 3004736) for an unknown indication. Concurrent medical conditions included Hypertension and Heavy smoker.

Case ID	Narrative (Complete)
	On 11-Sep-2021 at 10:29 AM, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular) 1 dosage form. On 12-Sep-2021 at 3:00 PM, the patient experienced HAEMORRHAGIC STROKE (Haemorrhagic stroke) (seriousness criteria death and medically significant). The reported cause of death was Haemorrhagic stroke. An autopsy was not performed. For mRNA-1273 (Moderna COVID-19 Vaccine (mRNA-1273 Vaccine)) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not reported. No treatment information was provided by the reporter. Company Comment: This case refers to a 82-year-old male patient with a medical history of hypertension and heavy smoker who experienced the unexpected event of Haemorrhagic stroke approximately 1 day after the first dose of mRNA-1273 vaccine. No causality assessment was provided by the reporter. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 07-Jan-2022. The most recent information was received on 31-Jan-2022 and was forwarded to Moderna on 31-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of MUSCULOSKELETAL CHEST PAIN (Pain in ribs), DEATH (Death), PULMONARY OEDEMA (Extended pulmonary edema), RESPIRATORY DISTRESS (Respiratory distress), LOSS OF CONSCIOUSNESS (Lost consciousness), CARDIAC ARREST (Cardiac arrest), PYREXIA (Low grade fever), VOMITING (Vomiting), NECK PAIN (Neck pain), PULMONARY THROMBOSIS (Thrombosis pulmonary), CEREBRAL THROMBOSIS (Thrombosis cerebral), SYNCOPE (Fainting episode), DIARRHOEA (Diarrhea) and BACK PAIN (Pain back) in a 65-year-old patient of an unknown gender who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 26-May-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-May-2021, the patient experienced MUSCULOSKELETAL CHEST PAIN (Pain in ribs) (seriousness criterion medically significant), RESPIRATORY DISTRESS (Respiratory distress) (seriousness criterion medically significant), PYREXIA (Low grade fever) (seriousness criterion medically significant), NECK PAIN (Neck pain) (seriousness criterion medically significant), SYNCOPE (Fainting episode) (seriousness criterion medically significant), DIARRHOEA (Diarrhea) (seriousness criterion medically significant) and BACK PAIN (Pain back) (seriousness criterion medically significant). 27-May-2021, the patient experienced VOMITING (Vomiting) (seriousness criterion medically significant). On 28-May-2021, the patient experienced DEATH (Death) (seriousness criteria death and medically significant), LOSS OF CONSCIOUSNESS (Lost consciousness) (seriousness criterion medically significant), PULMONARY THROMBOSIS (Thrombosis pulmonary) (seriousness criterion death) and CEREBRAL THROMBOSIS (Thrombosis cerebral) (seriousness criterion death). On an unknown date, the patient experienced PULMONARY OEDEMA (Extended pulmonary edema) (seriousness criterion medically significant). an unknown date, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criterion death). The patient died on 28-May-2021. The reported cause of death was extensive thrombosis of small vessels and extensive thrombosis of small vessels. An autopsy was performed, but no results were provided. At the time of death, MUSCULOSKELETAL CHEST PAIN (Pain in ribs), PULMONARY OEDEMA (Extended pulmonary edema), RESPIRATORY DISTRESS (Respiratory distress), LOSS OF CONSCIOUSNESS (Lost consciousness), PYREXIA (Low grade fever), VOMITING (Vomiting), NECK PAIN (Neck pain), SYNCOPE (Fainting episode), DIARRHOEA (Diarrhea) and BACK PAIN (Pain back) outcome was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter considered MUSCULOSKELETAL CHEST PAIN (Pain in ribs), PYREXIA (Low grade fever), VOMITING (Vomiting), NECK PAIN (Neck pain), SYNCOPE (Fainting episode), DIARRHOEA (Diarrhea) and BACK PAIN (Pain back) to be probably related. No further causality assessments were provided for DEATH (Death), PULMONARY OEDEMA (Extended pulmonary edema), RESPIRATORY DISTRESS (Respiratory distress), LOSS OF CONSCIOUSNESS (Lost consciousness), CARDIAC ARREST (Cardiac arrest), PULMONARY THROMBOSIS (Thrombosis pulmonary) and CEREBRAL THROMBOSIS (Thrombosis cerebral). Concomitant product use was not provided by the reporter. No treatment information was provided. Company Comment: This regulatory case concerns a 65-year-old patient, of unknown gender, with no medical history reported, who experienced the unexpected, serious event of death and cardiac arrest; unexpected, serious AESI of pulmonary oedema, pulmonary thrombosis and cerebral thrombosis; and other unexpected, serious events of musculoskeletal chest pain, respiratory distress, loss of consciousness, pyrexia, vomiting, neck pain, syncope, diarrhoea and back pain. The events musculoskeletal chest pain, respiratory distress, loss of consciousness, pyrexia, vomiting, neck pain, syncope, diarrhoea and back pain occurred beginning 1 day and up to 2 days after administration of the second dose of the Moderna mRNA-1273 vaccine. The events death, pulmonary thrombosis and cerebral thrombosis, which resulted in a fatal outcome, occurred 2 days after administration of the second dose of the Moderna mRNA-1273 vaccine. The start dates of the events pulmonary oedema and cardiac arrest were not provided. Treatment information was not provided. The report stated that the patient expired on 28May2021 (2 days after vaccination). Autopsy was done. The reported causes of death were cerebral thrombosis and pulmonary thrombosis (extensive thrombosis of small vessels). The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 31-Jan-2022: Significant follow-up received: Dose detail, additional event of death and reporter causality was updated.
4.1(b) [redacted]	This spontaneous case was reported by a consumer and describes the occurrence of DEATH (later died.) in an 8-decade-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	Company comment: This is a spontaneous case concerning a 8-decade-old female patient with no reported medical history, who experienced the serious unexpected event Death, on an unknown date after receiving the second dose of mRNA-1273. The cause of death was not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Reported that she heard from her friends about their two aunts in their 70s that received the second Moderna COVID-19 dose and they each later died. No additional information known or provided. Consent not given for Safety follow-up. Caller wished to remain anonymous. No concomitant medication provided. No treatment information mentioned. This case was linked to 4.1(b) (Patient Link). Reporter did not allow further contact
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Jan-2022 and was forwarded to Moderna on 07-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Unknown) in a 98-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 018G21A) for COVID-19 vaccination. The patient's past medical history included Asthma and Hypercholesterolemia. Concurrent medical conditions included Hypertension arterial, Dementia of the Alzheimer's type NOS and Type 2 diabetes mellitus. On 16-Dec-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on an unknown date It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. No treatment medications were provided. Company Comment: This case concerns a 98-year-old, female patient with reported relevant medical history of Asthma, Hypertension arterial, Dementia of the Alzheimer's type NOS, Hypercholesterolemia and Type 2 diabetes mellitus, who experienced the fatal serious unexpected event of Death, cause of death not provided, Autopsy was also not done. Death was reported to occur in an unknown date after the administration of the second dose of the mRNA-1273 vaccine. Event seriousness assessed as per Regulatory Authority as Death; limited information was provided at this time. he benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 10-Jan-2022 and was forwarded to Moderna on 10-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death unexplained) in an 86-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004951) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax (Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injection SpykeVax) on 01-Apr-2021 and Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax (Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injection SpykeVax) on 13-May-2021. Past adverse reactions to the above products included No adverse event with Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax and Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax. On 21-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 21-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication details was provided. No treatment medication details was provided.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 10-Jan-2022 and was forwarded to Moderna on 10-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 (SARS-CoV-2 infection) and VACCINATION FAILURE (Vaccination failure) in a 79-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3002188 and 3000493) for COVID-19 vaccination. No Medical History information was reported. On 10-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 18-May-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 09-Oct-2021, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criterion death) and VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Oct-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant products were not provided. Treatment medication were not reported. Company comment: This case concerns a 79-year-old male patient with unknown medical history who experienced fatal unexpected SARS-CoV-2 infection and Vaccination failure approximately five months after the second dose of mRNA-1273. No information regarding death details was disclosed, it is unknown if an autopsy was performed. The patient's advanced age remains major confounder. Based on the current available information, the mRNA-1273 vaccine does not contain a virus capable of causing COVID-19 infection after vaccination, therefore, the causality for COVID-19 is not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 10-Jan-2022 and was forwarded to Moderna on 10-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death unexplained) and BREAST PAIN (Breast pain) in a 67-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Previously administered products included for COVID-19: COVID-19 VACCINE ASTRAZENECA on 21-Apr-2021 and COMIRNATY on 14-Jul-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY and COVID-19 VACCINE ASTRAZENECA. On 01-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Dec-2021, the patient experienced BREAST PAIN (Breast pain) (seriousness criterion death). The patient died on 09-Dec-2021. The cause of death was not reported. An autopsy was performed, but no results were provided. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter considered SUDDEN DEATH (Sudden death unexplained) and BREAST PAIN (Breast pain) to have an unknown relationship. Autopsy result was pending. Concomitant product use was not provided by reporter. Treatment information was not provided.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 10-Jan-2022 and was forwarded to Moderna on 10-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC FAILURE (HEART FAILURE) and ACUTE MYOCARDIAL INFARCTION (MYOCARDIAL INFARCTION/STEMIA) in a 93-year-old male patient who received mRNA-1273 (Spikevax) (batch no. DOS 3: 3005835) for COVID-19 vaccination. The patient's past medical history included COVID-19 immunisation (SPIKEVAX DOS 1) on 10-Feb-2021 and COVID-19 immunisation (SPIKEVAX DOS 2) on 10-Mar-2021. In October 2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In December 2021, the patient experienced CARDIAC FAILURE (HEART FAILURE) (seriousness criterion death) and ACUTE MYOCARDIAL INFARCTION (MYOCARDIAL INFARCTION/STEMIA) (seriousness criterion death). The reported cause of death was Cardiac failure. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication were not reported. No treatment medication were not reported. Company comment: This fatal regulatory authority case concerns a 93-year-old male patient with no reported medical history who experienced serious unexpected AESIs cardiac failure and acute myocardial infarction, that occurred approximately 2 months after 3rd dose of the mRNA-1273 however, the exact time to onset and vaccination dates were not provided. The rechallenge was not applicable due to occurrence after the 3rd dose and fatal outcome of the events. Patient's advanced age is a possible confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness as per regulatory authority.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 10-Jan-2022 and was forwarded to Moderna on 10-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Unknown) in a 74-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Arthritis rheumatoid, Hypertension arterial, Diabetes and TIA. Concomitant products included INSULIN DEGLUDEC (TRESIBA), METFORMIN (METFORMINE [METFORMIN]), AMLODIPINE, ACETYLSALICYLATE LYSINE (KARDEGIC), METHOTREXATE, PERINDOPRIL, ALLOPURINOL, BISOPROLOL FUMARATE, HYDROCHLOROTHIAZIDE, REPAGLINIDE and FOLIC ACID (ACIDE FOLIQUE) for an unknown indication.

Case ID	Narrative (Complete)
	In June 2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 01-Nov-2021, the patient experienced VACCINATION FAILURE (Unknown) (seriousness criterion death). The patient died on 23-Nov-2021. The reported cause of death was acute respiratory distress syndrome - covid. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Nov-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided by the reporter. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 07-Jan-2022.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 10-Jan-2022 and was forwarded to Moderna on 10-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Death) in a 73-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: COVID-19 VACCINE MODERNA and COVID-19 VACCINE MODERNA. Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE MODERNA and COVID-19 VACCINE MODERNA. Concurrent medical conditions included Diabetes mellitus and Hypertension arterial. On 01-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 23-Dec-2021 It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. No treatment information was provided. Company Comment: This is a regulatory case concerning a 73-year-old, male patient with medical history of diabetes mellitus and hypertension, who experienced the unexpected serious event Death. The event occurred approximately 22 days after the third dose of mRNA-1273 vaccine. Cause of death was not reported. It is unknown if an autopsy was performed. The medical history reported and patient´s age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. case was assessed as serious as per Regulatory Authority´s report due to death.
4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of DEPRESSED LEVEL OF CONSCIOUSNESS (Disturbance of consciousness and epileptic seizure with subsequent focal neurological failures), EPILEPSY (Disturbance of consciousness and epileptic seizure with subsequent focal neurological failures), DEATH (Death) and ACUTE DISSEMINATED ENCEPHALOMYELITIS (Acute demyelinating encephalomyelitis (ADEM)) in an 82-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 23-Mar-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 24-Mar-2021, the patient experienced DEPRESSED LEVEL OF CONSCIOUSNESS (Disturbance of consciousness and epileptic seizure with subsequent focal neurological failures) (seriousness criteria death, hospitalization, disability and medically significant), EPILEPSY (Disturbance of consciousness and epileptic seizure with subsequent focal neurological failures) (seriousness criteria death, hospitalization, disability and medically significant) and ACUTE DISSEMINATED ENCEPHALOMYELITIS (Acute demyelinating encephalomyelitis (ADEM)) (seriousness criteria death, hospitalization, disability and medically significant). The patient died in September 2021. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In March 2021, Imaging procedure: inconclusive (Inconclusive) Inconclusive. In March 2021, Lumbar puncture: negative (Negative) Negative. On an unknown date, Bacterial test: negative (Negative) Culture on bacteria & mycobacteria- Negative. On an unknown date, Imaging procedure: abnormal (abnormal) TEST 10068979 (RESUL1) imaging (202103) [In the Imaging shows a space requirement with swelling of the thalamus and hippocampus on the right.]: Imaging shows a space requirement with swelling of the thalamus and hippocampus on the right. and negative (Negative) TEST 10024999 (24.1) LP (202103) [RESULT: no indication of infection]: LP: 1 cell (monocytic), protein and glucose, multiplex PCR, CNS pathogen negative. On an unknown date, Polymerase chain reaction: negative (Negative) Negative. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered DEPRESSED LEVEL OF CONSCIOUSNESS (Disturbance of consciousness and epileptic seizure with subsequent focal neurological failures), EPILEPSY (Disturbance of consciousness and epileptic seizure with subsequent focal neurological failures), DEATH (Death) and ACUTE DISSEMINATED ENCEPHALOMYELITIS (Acute demyelinating encephalomyelitis (ADEM)) to be unlikely related. No concomitant drug therapy and Treatment medications were reported.The patient was in EMERGENCY with impaired consciousness, epi-seizure. The imaging showed a mass with swelling of the thalamus and hippocampus on the right. Only moderate improvement in focal clinic under high-dose steroids. An LP gives no indication of an infection. The pictures were assessed by the Inselspital during the process. In ADEM after vaccination would be the cause and possible DD. No further known course, no further information or diagnostic findings were provided. As a result of the consequences of

Case ID	Narrative (Complete)
	ADEM, the patient died, 6 months after the event. ADEM was caused by an inflammatory reaction in the brain and spinal cord. The onset of encephalopathy and multifocal neurologic deficits was acute and often rapidly progressive. The patient had swelling/edema in the right thalamus and hippocampus, while pathogens were excluded. Not known if a COVID-19 swab was taken. Company comment This case concerns an 82-year-old male patient, with no reported medical history, who experienced the unexpected serious fatal events of DEPRESSED LEVEL OF CONSCIOUSNESS, EPILEPSY, DEATH and ACUTE DISSEMINATED ENCEPHALOMYELITIS (AESI). Events DEPRESSED LEVEL OF CONSCIOUSNESS, EPILEPSY, and ACUTE DISSEMINATED ENCEPHALOMYELITIS occurred on the following day after the administration of the first dose of mRNA-1273 vaccine, on 24-Mar-2021. Patient died in September 2021. It is unknown if an autopsy was performed. The reporter considered the events to be unlikely related to mRNA-1273 vaccine. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of DEATH (later died.) in a 7-decade-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. Caller reported that she heard from her friends about their two aunts in their 70's that received the second Moderna COVID-19 dose and they each later died. No additional information known or provided. No concomitant medication provided. No treatment information mentioned This case was linked to 4.1(b) (Patient Link). Reporter did not allow further contact
4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of DEATH (she took the booster and die) in a 98-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant product was provided. No treatment information was provided. Patient was very healthy, days before vaccination, in TV she said she was very well. Company Comment: This is a spontaneous case concerning a 98-year-old, female patient with no medical history reported, who experienced the unexpected serious event of death. The event occurred at an unknown date after the booster dose of mRNA-1273 vaccine. Cause of death was not reported, it is unknown if an autopsy was performed. Patient´s age remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as serious due to death and important medical event. Reporter did not allow further contact
4.1(b)	This literature-non-study case was reported in a literature article and describes the occurrence of ACUTE RESPIRATORY DISTRESS SYNDROME (Acute respiratory distress syndrome) and COVID-19 PNEUMONIA (COVID-19 pneumonia) in a 70-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. LITERATURE REFERENCE: Adedoyin O, Brijmohan S,Lavine R, Lisung FG. Undetectable SARS-CoV-2 active adaptive immunity post-vaccination or post-COVID-19 severe disease after immunosuppressants use. BMJ Case Rep. 2021;14:e246308 The patient's past medical history included End stage renal failure (renal transplant 6 months ago) and Renal transplant (6 months ago). Concurrent medical conditions included Diastolic heart failure and Insulin-dependent diabetes mellitus. Concomitant products included MYCOPHENOLATE MOFETIL (MYCOPHENOLATE), TACROLIMUS and PREDNISONE for Renal transplant. On 14-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 14-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced ACUTE RESPIRATORY DISTRESS SYNDROME (Acute respiratory distress syndrome) (seriousness criteria death, hospitalization and medically significant), COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death and medically significant) and VACCINE INDUCED ANTIBODY ABSENT (Vaccine induced antibody absent). The patient was treated with CONVALESCENT PLASMA COVID-19 for ARDS and COVID-19 pneumonia, at an unspecified dose and frequency; REMDESIVIR for ARDS and COVID-19 pneumonia, at an unspecified dose and frequency; DEXAMETHASONE for ARDS and COVID-19 pneumonia, at an unspecified dose and frequency; BAMLANIVIMAB on 20-Mar-2021 for COVID-19 pneumonia and ARDS, at an unspecified dose and frequency; APIXABAN for ARDS and COVID-19 pneumonia, at an unspecified dose and frequency and ETESEVIMAB for COVID-19 pneumonia and ARDS, at an unspecified dose and frequency. The patient died on an unknown date. The reported cause of death was ards and COVID-19 pneumonia. It is unknown if an autopsy was performed. At the time of death, VACCINE INDUCED ANTIBODY ABSENT (Vaccine induced antibody absent) outcome was unknown. Related

Case ID	Narrative (Complete)
	DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2020, Chest X-ray: abnormal Chest X-ray showing diffuse bilateral mixed interstitial/ alveolar opacities.. In 2020, SARS-CoV-2 antibody test: negative (Negative) Negative. On 19-Mar-2021, SARS-CoV-2 RNA: positive (Positive) Positive. On 31-Mar-2021, SARS-CoV-2 antibody test: negative (Negative) Negative. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered ACUTE RESPIRATORY DISTRESS SYNDROME (Acute respiratory distress syndrome), COVID-19 PNEUMONIA (COVID-19 pneumonia) and VACCINE INDUCED ANTIBODY ABSENT (Vaccine induced antibody absent) to be related. Patient Treatment also includes broad-spectrum antibiotics. Company comment: This literature-non-study case concerns a 70-year-old male patient with relevant medical history of end stage renal disease leading to renal transplant 6 months prior to this report, diabetes mellitus and diastolic heart failure and concurrent use of prednisone, tacrolimus and mycophenolate, who experienced serious unexpected fatal AESI events of acute respiratory distress syndrome and COVID-19 pneumonia and non-serious unexpected event of vaccine induced antibody absent. The events occurred approximately a month after the 2nd dose of the mRNA-1273. The rechallenge was not applicable due to occurrence after the 2nd dose. Patient's concomitant medications used for renal transplant rejection prevention are possible confounders for the events. The event of ARDS was secondary to COVID-19. Based on the current available information, the mRNA-1273 does not contain a virus capable of causing COVID-19 infection after vaccination. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 13-Jan-2022: Follow up received by safety 13-Jan-2022 included an Email with FTA received from SARA team and contain significant information. Lab Data, Treatment drugs, event outcome were added.
4.1(b) [redacted]	This case was received via Zuellig Pharma (Reference number: 4.1(b) [redacted]) on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (chest pain), CHEST DISCOMFORT (tightness during the day and more symptoms in the evening), SEIZURE (seizure) and LOSS OF CONSCIOUSNESS (unconscious) in an 84-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3005841) for an unknown indication. No Medical History information was reported. On 26-Dec-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced CHEST PAIN (chest pain) (seriousness criterion death), CHEST DISCOMFORT (tightness during the day and more symptoms in the evening) (seriousness criterion death), SEIZURE (seizure) (seriousness criterion death) and LOSS OF CONSCIOUSNESS (unconscious) (seriousness criterion death). The reported cause of death was Chest pain, tightness during the day and more symptoms in the evening, Seizure and Unconscious. It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. It was reported that 6 days after vaccination, the vaccine recipient's relative informed that the vaccine recipient experienced chest pain and tightness during the day and more symptoms in the evening. While being taken to the hospital, he experienced seizure and was unconscious. The vaccine recipient passed away before arriving at the hospital. Patient type was OPD. Serial number was reported as 702300202BX13. Event onset date was 02Dec2021. Patient received unspecified treatment on 02Dec2021. Company Comment: This regulatory case concerns an 84-year-old, male patient with no medical history reported, who experienced the unexpected, serious AESI of seizure and the unexpected, serious events of chest pain, chest discomfort and loss of consciousness. The events, which resulted in a fatal outcome, occurred 6 days after administration of the first dose of the Moderna mRNA-1273 vaccine. The patient experienced chest pain and chest tightness during the day, and more symptoms in the evening. While being brought to the hospital, he experienced seizure and lost consciousness. The patient passed away before arriving at the hospital. No further details were provided, except that the patient received an unspecified treatment on 02Dec2021. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via Zuellig Pharma (Reference number: 4.1(b) [redacted]) on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (UN/Attended death), PYREXIA (Fever/ Had high fever), DYSPNOEA (Dyspnea) and FATIGUE (Fatigue) in an 84-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 021F21A) for an unknown indication. The patient's past medical history included Hip fracture (Had an accident and the fell cause a broken hip bone and he was bedridden about 10 years). Concurrent medical conditions included Osteoporosis (Had an accident and the fell cause a broken hip bone and he was bedridden about 10 years) and Bedridden (Had an accident and the fell cause a broken hip bone and he was bedridden about 10 years). On 13-Dec-2021 at 2:00 PM, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 15-Dec-2021, the patient experienced DEATH (UN/Attended death) (seriousness criterion death), PYREXIA (Fever/ Had high fever) (seriousness criterion death), DYSPNOEA (Dyspnea) (seriousness criterion death) and FATIGUE (Fatigue) (seriousness criterion death). The patient died on 17-Dec-2021. An autopsy was performed, but no results were provided. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Concomitant products were not provided.

Case ID	Narrative (Complete)
	On 17-Dec-2021 at 08:50 am, the hospital was notified and sent the Advance life support (ALS) car to the vaccine recipient with bedridden. The vaccine recipient had fever and dyspnea. At the place, the vaccine recipient had no pulse, not breathing and passed away. The hospital informed to bring the vaccine recipient's body to the hospital for autopsy. The vaccine recipient had fever, fatigue and had high fever last night. The preliminary autopsy results: The corpse of an elderly Thai male, gray hair, white mustache and beard, wearing a white shirt with blue stripes, wearing pampers and no injuries from the physical examination. Found hardening of the joints throughout the body and cloudy white eyes. It was found dark purple blood at back, button and when press it and fade. The relative suspected the cause of death. Send the vaccine recipient's body for an autopsy to the hospital. On 17-Dec-2021, treatment was received. Vaccine serial number was reported as 1080864120700002. Company Comment: This is a regulatory case concerning an 84-year-old, male patient with a history of bedridden (for 10 years, he had osteoporosis, had a fall and a hip fracture), who experienced the unexpected serious event of Death. The event occurred approximately 2 days after the first dose of mRNA-1273 vaccine. It is reported that the patient had dyspnoea, fatigue and high fever before the death outcome occurred. An autopsy was done, no final report was provided. The medical history and patient´s age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via Zuellig Pharma (Reference number: 4.1(b)) on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of MOUTH HAEMORRHAGE (He had red blood out of his mouth) and DYSPNOEA (He had fast breathing) in an 85-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3005841) for an unknown indication. The patient's past medical history included Embolic stroke (Embolic stroke+AF) and Atrial fibrillation (Embolic stroke+AF). On 02-Dec-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 09-Dec-2021 at 10:00 PM, the patient experienced MOUTH HAEMORRHAGE (He had red blood out of his mouth) (seriousness criterion death) and DYSPNOEA (He had fast breathing) (seriousness criterion death). The patient died on 09-Dec-2021. The reported cause of death was he had red blood out of his mouth and he had fast breathing. It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered MOUTH HAEMORRHAGE (He had red blood out of his mouth) and DYSPNOEA (He had fast breathing) to be not related. No concomitant medication information was provided. No treatment medication was provided. After vaccination, he had no fever, no abnormal symptom, could eat and no choking. On 09-Dec-2021, he could eat properly and no choking in the morning and in the afternoon. In the evening, he did not eat and slept. At 10:00 pm, he had fast breathing and before he passed away he had red blood out of his mouth. He passed away at 10:30 pm at home. Company comment: This case concerns an 85-year-old male patient with relevant medical history of Embolic Stroke and Atrial fibrillation, who experienced the unexpected serious events of Mouth Hemorrhage and Dyspnea, the events led to the death of the patient as reported by the regulatory authority. The events occurred in 7 days and 22 hours after receiving the first dose of mRNA-1273 Vaccine. The reported cause of death was he had red blood out of his mouth, and he had fast breathing. It is unknown if an autopsy was performed. No clinical or treatment details were given. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.
4.1(b)	This case was received via Zuellig Pharma (Reference number: 4.1(b)) on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of CEREBROVASCULAR ACCIDENT (stroke) in a 77-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 021F21A) for an unknown indication. No Medical History information was reported. On 09-Dec-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 16-Dec-2021, the patient experienced CEREBROVASCULAR ACCIDENT (stroke) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Relevant concomitant medications were not reported. Patient experienced weakness of right arm and leg, fatigue and weakness. On 16-Dec-2021, Treatment received but the information was not provided. Patient had no underlying disease for relevant medical history and concurrent conditions. Company comment This case concerns a 77-year-old male patient, with no reported medical history, who experienced the unexpected serious fatal event of CEREBROVASCULAR ACCIDENT (AESI). The event occurred approximately 7 days after the administration of the first dose of mRNA-1273 vaccine. It is unknown if an autopsy was performed. Patient experienced weakness of right arm and leg, fatigue and weakness. Patient had no underlying disease or relevant medical history and concurrent conditions. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 11-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (Embolism pulmonary) in a 68-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.

Case ID	Narrative (Complete)
	No Medical History information was reported. On 16-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 26-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced PULMONARY EMBOLISM (Embolism pulmonary) (seriousness criterion death). The patient died on 26-Dec-2021. The reported cause of death was pulmonary embolism. An autopsy was not performed. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 16-Dec-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. No treatment information was provided. Company comment: This is a regulatory authority case concerning a 68-year-old male patient with no medical history reported, who experienced unexpected event of Pulmonary embolism (AESI). The event occurred 10 days after administration of the booster dose of the mRNA-1273 Vaccine and had a fatal outcome on the same day as the onset of event. Clinical course and treatment details were not provided. The patient died on 26-Dec-2021 and the reported cause of death was pulmonary embolism. An autopsy was not performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-Jan-2022: Patient's death date, autopsy information and cause of death is added. On 12-Jan-2022: Translation received on 20-JAN-2022, which contains: Dosage text translated
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 11-Jan-2022. The most recent information was received on 12-Jan-2022 and was forwarded to Moderna on 12-Jan-2022. This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 11-Jan-2022. The most recent information was received on 12-Jan-2022 and was forwarded to Moderna on 12-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of ISCHAEMIC STROKE (Ischemic stroke) in a 70-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 017G21A) for COVID-19 vaccination. The patient's past medical history included Multinodular goitre, Syncope in 2019, Tabaquism, Dyslipidaemia and Smoker. Concurrent medical conditions included Hypertension arterial and Meningioma. Concomitant products included EZETIMIBE, ROSUVASTATIN ZINC (LIPOCOMB) for Dyslipidaemia, PERINDOPRIL ERBUMINE (COVERSYL [PERINDOPRIL ERBUMINE]) for Hypertension arterial, CITICOLINE SODIUM (TRAUSAN), THIAMAZOLE (METIBASOL) and ACETYLSALICYLIC ACID for an unknown indication. On 11-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On an unknown date, the patient experienced ISCHAEMIC STROKE (Ischemic stroke) (seriousness criteria death and hospitalization). The patient died on 14-Dec-2021. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Magnetic resonance imaging: result not provided Sequelar ischemic lesions in distal territory of posterior cerebral arteries, reaching the visual cortex and sequelar ischemic lesion on the posterosuperor strand of the left cerebellous cortex, small bilateral lacunar cerebellous ischemic vascular lesions not recent in the vertebro-basilar territory (had minor hemorrhagic transformations in ischemic lesions in the 1st NMR EC. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered ISCHAEMIC STROKE (Ischemic stroke) to be possibly related. No treatment information provided. Company comment: This Regulatory authority case concerns a 70-year-old, female patient, with medical history of hypertension, dyslipidemia and smoker, who experienced the unexpected, serious (fatal/hospitalization) and AESI of Ischaemic stroke. The event occurred on an unknown date after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the patient's COVID-19 vaccination schedule. The patient died 3 days after vaccination. Autopsy is not available. The medical history of hypertension, dyslipidemia and smoker remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 11-Jan-2022: Follow-up received contains Translation which includes translated event verbatim and causality. On 12-Jan-2022: Follow-up received contains added medical history, current conditions, concomitant drugs.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 11-Jan-2022. The most recent information was received on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of LOSS OF CONSCIOUSNESS (loss of consciousness appearance of hemiparesis and deviation of the buccal rim and aphasia), HEMIPARESIS (loss of consciousness appearance of hemiparesis and deviation of the buccal rim and aphasia), APHASIA (loss of consciousness appearance of hemiparesis and deviation of the buccal rim and aphasia) and FACIAL SPASM (loss of consciousness appearance of hemiparesis and deviation of the buccal rim and aphasia) in a 97-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 94f21a) for COVID-19 vaccination. The patient's past medical history included Ischemic stroke. On 17-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 18-Dec-2021, the patient experienced LOSS OF CONSCIOUSNESS (loss of consciousness appearance of hemiparesis and deviation of the buccal rim and aphasia) (seriousness criterion death), HEMIPARESIS (loss of consciousness appearance of hemiparesis and deviation of the buccal rim and aphasia) (seriousness criterion death), APHASIA (loss of consciousness appearance of hemiparesis and deviation of the buccal rim and aphasia) (seriousness criterion death) and FACIAL SPASM (loss of

Case ID	Narrative (Complete)
	consciousness appearance of hemiparesis and deviation of the buccal rim and aphasia) (seriousness criterion death). The patient died on 20-Dec-2021. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. No treatment information was provided. Company comment: This is a regulatory case that concerns a 97-year-old male patient, with medical history of Ischemic stroke, who experienced the unexpected, fatal events of hemiparesis, loss of consciousness, aphasia and facial spasm 1 day after a dose of the mRNA-1273 vaccine. The patient died three days after the dose of RNA-1273 and two days after events' onset date. The patient received previous vaccination with Tozinameran, which along with medical history of Ischemic stroke, remain a confounding factor. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 14-Feb-2022: Significant follow up received and updated start and stop date of events. On 03-Mar-2022: Non significant follow-up appended- No new information was added to case. On 07-Mar-2022: Follow-up received and contains non significant information. On 16-Mar-2022: Non significant follow-up appended- No new information was added to case.
4.1(b)	This case was received via Zuellig Pharma (Reference number: 4.1(b)) on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC ARREST (Sudden Cardiac arrest) in a 72-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. TRC3005841) for an unknown indication. Concurrent medical conditions included Chronic ischaemic heart disease, unspecified (I259 Chronic ischaemic heart disease - Chronic ischaemic heart disease, unspecified). On 03-Dec-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 15-Dec-2021, the patient experienced CARDIAC ARREST (Sudden Cardiac arrest) (seriousness criterion death). It is unknown if an autopsy was performed. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. Patient took unspecified treatment on 15-DEC-2021. The suspect product serial n was mentioned as TRC3005841. Company Comment - This regulatory authority case concerns a 72 year old male patient with medical history of chronic ischaemic heart disease, who experienced the serious unexpected events of cardiac arrest. The event occurred 12 days after the first dose of mRNA-1273 vaccine. Date and cause of death were undisclosed. Patient's medical history of chronic ischaemic heart disease remains a confounder. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 11-Jan-2022. The most recent information was received on 22-Jan-2022 and was forwarded to Moderna on 22-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN CARDIAC DEATH (death, acute death, possible heart death) in a 73-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 044G21ABS) for COVID-19 immunization. The occurrence of additional non-serious events is detailed below. Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3ML on 26-Apr-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3ML on 31-May-2021. Past adverse reactions to the above products included No adverse event with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3ML, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3ML. Concomitant products included ACETYLSALICYLZUUR for an unknown indication. On 21-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Dec-2021, the patient experienced MYALGIA (Muscle pain). On 25-Dec-2021, the patient experienced MALAISE (Don't feel good). The patient died on 26-Dec-2021. The reported cause of death was acute death, possibly cardiac death. It is unknown if an autopsy was performed. At the time of death, MALAISE (Don't feel good) outcome was unknown and MYALGIA (Muscle pain) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment was reported by the reporter. Company comment: This is an RA case concerning a 73-year-old, male patient with no relevant medical history reported, only use of AAS 80mg as concomitant medication, who experienced the event of sudden cardiac death. Patient received the third dose of mRNA1273 on 21DEC2021 (two previous doses were Covid-19 vaccine Pfizer), two days later started with myalgia, on the 25th reported malaise and passed away on the following day. No further details were provided by the RA, and despite no medical history being reported, it calls attention the fact the patient took AAS 80mg which can suggest a potential cardiovascular comorbidity. The benefit-risk relationship of mRNA-1273 in not affected by this report. Most recent FOLLOW-UP information incorporated above includes:

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	On 20-Jan-2022: Due to incorrect follow-up receipt date, this case is amended to reflect the actual follow-up receipt date/Date FU Rcvd by Safety. This case was submitted on-time based on the actual follow-up receipt date. The actual follow-up receipt date/ Date FU Rcvd by Safety for this case is 20-Jan-2022. On 22-Jan-2022: Significant follow up Received ,Batch/lot number Added.
4.1(b)	This case was received via Zuellig Pharma (Reference number: 4.1(b)) on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of COVID-19 PNEUMONIA (Pyrexia, cough, rhinorrhea, secretion discharge, fatigue and asthenia) and RESPIRATORY FAILURE (Covid pneumonia with respiratory failure) in a 91-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. TRC3005841) for an unknown indication. The patient's past medical history included Insomnia (Insomnia) and Coronary artery disease (CAD). Concurrent medical conditions included Hypertension (HT) and Dyslipidemia (DLP). On 03-Dec-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 04-Dec-2021, the patient experienced COVID-19 PNEUMONIA (Pyrexia, cough, rhinorrhea, secretion discharge, fatigue and asthenia) (seriousness criteria death and medically significant) and RESPIRATORY FAILURE (Covid pneumonia with respiratory failure) (seriousness criteria death and medically significant). The reported cause of death was covid pneumonia, Respiratory failure, high fever, cough with mucus, mild runny nose, mucus in her throat, fatigue/tiredness, Weakness and covid-19. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Dec-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Concomitant medication information was not provided by the reporter. Date of treatment was 09-DEC-2021. The Patient experienced after vaccination on 04-DEC-2021 high fever, cough with mucus, mild runny nose, on 07-DEC-2021 eat slowly, on 08-DEC-2021 could not drink the water and her relative provided the water to her through the spoon, mucus in her throat, fatigue, on 09-DEC-2021 tiredness, weakness then her relative called the hospital. Lab data included COVID-19 test, Rapit test, performed at emergency room on 12-DEC-2021 08:20 am and result of Rapit test was positive and ordered RT-PCR. The result was detected on 09-DEC-2021. The vaccine recipient's relative provided paracetamol, expectorant drug to her and her symptoms were improved. Company Comment : This is a regulatory authority case concerning a 91-year-old, female patient with relevant medical history of hypertension and coronary artery disease, who experienced the unexpected serious events of Covid-19 pneumonia and respiratory failure. The events Covid-19 pneumonia and respiratory failure exact occurrence unknown but stated that the events occurred after the first dose of mRNA-1273 vaccine administration. The events were described as, 1 day after the first dose of mRNA-1273 vaccine the patient experienced high fever, cough with mucus and mild runny nose. The patient was given paracetamol and expectorant by her relative and allegedly her symptoms improved. 4 days after the first dose of mRNA-1273 vaccine administration patient was able to eat slowly from the usual 15 minutes to 30 minutes. 5 days after the first dose of mRNA-1273 vaccine administration patient could not drink water and her relative provided the water to her through the spoon and with mucus in her throat and fatigue. 6 days after the first dose of mRNA-1273 vaccine administration patient's fatigue continued accompanied by weakness and was brought to ER and the patient was tested positive on Covid-19 rapid test. The outcome of the events Covid-19 pneumonia and respiratory failure was fatal. The patient's age and medical history of hypertension and coronary artery disease remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via Zuellig Pharma (Reference number: 4.1(b)) on 10-Jan-2022 and was forwarded to Moderna on 11-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC ARREST (Acute Cardiac arrest) in a 66-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 049F21A) for an unknown indication. No Medical History information was reported. On 28-Dec-2021, the patient received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 28-Dec-2021, the patient experienced CARDIAC ARREST (Acute Cardiac arrest) (seriousness criterion death). The reported cause of death was acute cardiac arrest. It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Concomitant product usage were not provided. Patient was Observed at ER. Treatment was provided on 28 Dec 2021 with unknown medication. Serial Number was reported as KVA000226. Company Comment - This regulatory authority case concerns a 66 year old female patient with no relevant medical,, who experienced the serious unexpected events of cardiac arrest. The event occurred on the same day after the second dose of mRNA-1273 vaccine, the outcome was fatal, with death occurring the same day. The reported cause of death was acute cardiac arrest. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 12-Jan-2022 and was forwarded to Moderna on 12-Jan-2022.

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	This regulatory authority case was reported by a consumer and describes the occurrence of LEUKAEMIA (leukemid), RASH MACULAR (blue-violet spots), PAIN (pantalgia) and DYSPNOEA (respiration labored) in a 72-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Heart disease, unspecified. On 15-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 18-Nov-2021, after starting mRNA-1273 (Spikevax), the patient experienced PAIN IN EXTREMITY (painful arm injection site). On 21-Nov-2021, the patient experienced SPINAL PAIN (rachialgia). On 24-Nov-2021, the patient experienced PAIN IN EXTREMITY (left leg pain). On 02-Dec-2021, the patient experienced DYSPNOEA (respiration labored) (seriousness criterion medically significant). On 10-Dec-2021, the patient experienced LEUKAEMIA (leukemid) (seriousness criteria death, hospitalization, medically significant and life threatening) and RASH MACULAR (blue-violet spots) (seriousness criteria death, hospitalization, medically significant and life threatening). On 16-Dec-2021, the patient experienced PAIN (pantalgia) (seriousness criterion death). The patient died on 17-Dec-2021. The reported cause of death was Leukemia. It is unknown if an autopsy was performed. At the time of death, DYSPNOEA (respiration labored), PAIN IN EXTREMITY (left leg pain), SPINAL PAIN (rachialgia) and PAIN IN EXTREMITY (painful arm injection site) outcome was unknown. Concomitant and treatment medication was not reported. Company comment: This case concerns a 72-year-old female patient with medical history of Chronic Heart disease, who experienced serious unexpected events of Leukaemia, Rash macular, Dyspnoea and Pain, as well as non serious unexpected events of Pain in extremity (reported as painful arm injection site and left leg pain) and Spinal pain. The event of Pain in extremity (painful arm injection site) occurred tree days after vaccination with the mRNA-1273 vaccine (as third dose, booster). The events of spinal pain occurred six days, Pain in leg occurred 9 days and Dyspnoea occurred 17 days after this vaccination. The patient also experienced Leukaemia and Rash macular 25 days after the administration of the mRNA-1273 vaccine, while the event of Pain (pantalgia) occurred one month after the vaccination. The patient subsequently died approximately month after vaccination and the reported cause of death was Leukemia. It remained unknown whether an autopsy was performed. No additional details regarding the clinical course of the events were provided. The re-challenge is not applicable having in mind that the patient died. The underlying history of heart disease remains a confounder for the fatal outcome. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 11-Jan-2022.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 12-Jan-2022 and was forwarded to Moderna on 12-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of SOMNOLENCE (Somnolence), GENERAL PHYSICAL HEALTH DETERIORATION (General physical condition decreased) and HYPOPHAGIA (Oral intake reduced) in a 91-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005291) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: SPIKEVAX (Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax) on 28-Jan-2021 and SPIKEVAX (Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax) on 18-Feb-2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX and SPIKEVAX. On 20-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 20-Dec-2021, the patient experienced SOMNOLENCE (Somnolence) (seriousness criterion death), GENERAL PHYSICAL HEALTH DETERIORATION (General physical condition decreased) (seriousness criterion death) and HYPOPHAGIA (Oral intake reduced) (seriousness criterion death). The patient died on 27-Dec-2021. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by reporter. Treatment information was not provided. Company Comment - This regulatory authority case concerns a 91 year old female patient with no relevant medical history, who experienced the serious unexpected events of somnolence, general physical health deterioration and hypophagia. The events occurred on the same day after a dose of mRNA-1273 vaccine, the outcome was fatal. Patient died 7 days later, the reported cause of death was unknown. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 13-Jan-2022 and was forwarded to Moderna on 13-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and COVID-19 (SARS-CoV-2 infection) in a 73-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3002545 and 3001938) for COVID-19 vaccination. No Medical History information was reported. On 23-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form.

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	On 04-Jun-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 05-Nov-2021, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death) and COVID-19 (SARS-CoV-2 infection) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Nov-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was provided. No treatment medication was provided. Company Comment: This regulatory case concerns a 73-year-old male patient with no relevant medical history reported, who experienced the unexpected serious adverse events of special interest of COVID-19 (sars cov2 test positive) and unexpected serious event of vaccination failure which resulted in a fatal outcome, with death occurring 6 months 14 days after the second dose of mRNA-1273 vaccine. Vaccination failure was coded as an additional event as per RA, and was retained as such, having in mind that the patient developed COVID-19 after vaccination with both doses of vaccine. Based on the current available information, the mRNA-1273 vaccine does not contain a virus capable of causing COVID-19 infection after vaccination, therefore, the causality for COVID-19 is not applicable, while the causality for the event of Vaccination failure is assessed as possible. Patients elderly age and infection with covid-19 remains as confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 12-Jan-2022.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted] on 13-Jan-2022. The most recent information was received on 02-Mar-2022 and was forwarded to Moderna on 02-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of VOMITING (Vomiting), BACK PAIN (Back pain), URINARY TRACT INFECTION (Urinary tract infection), FALL (Fall), ANXIETY (Anxiety), HAEMATOMA (Haematoma), DEMENTIA (Dementia), FEAR (Fear), CONFUSIONAL STATE (Confusion), DEHYDRATION (Dehydration), ERYSIPELAS (Erysipelas), BALANCE DISORDER (Balance disorder), EYELID PTOSIS (Eyelid ptosis), DECREASED APPETITE (Appetite lost) and EMOTIONAL DISTRESS (Emotional distress) in an 88-year-old female patient who received mRNA-1273 (Spikevax) for an unknown indication. No Medical History information was reported. On 02-Jun-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In 2021, the patient experienced VOMITING (Vomiting) (seriousness criterion death), BACK PAIN (Back pain) (seriousness criterion death), URINARY TRACT INFECTION (Urinary tract infection) (seriousness criterion death), FALL (Fall) (seriousness criterion death), ANXIETY (Anxiety) (seriousness criterion death), HAEMATOMA (Haematoma) (seriousness criterion death), DEMENTIA (Dementia) (seriousness criteria death and medically significant), FEAR (Fear) (seriousness criterion death), CONFUSIONAL STATE (Confusion) (seriousness criterion death), DEHYDRATION (Dehydration) (seriousness criterion death), ERYSIPELAS (Erysipelas) (seriousness criterion death), BALANCE DISORDER (Balance disorder) (seriousness criterion death), EYELID PTOSIS (Eyelid ptosis) (seriousness criterion death), DECREASED APPETITE (Appetite lost) (seriousness criterion death) and EMOTIONAL DISTRESS (Emotional distress) (seriousness criterion death). The patient died on 29-Aug-2021. The reported cause of death was Dementia. An autopsy was not performed. No concomitant medications were reported. No treatment information was provided. Company comment: This is a regulatory case concerning an 88 year-old, female patient with no reported medical history, who experienced the serious Fatal unexpected, events of vomiting, balance disorder, anxiety, back pain, emotional distress, eyelid ptosis, confusional state, urinary tract infection, fall, haematoma, erysipelas, death, dehydration, fear and decreased appetite. The events occurred on an unknown date after the second dose of mRNA-1273 vaccine. The patient died approximately 2 months after receiving the second dose of mRNA-1273 vaccine. The reported cause of death was dementia and no autopsy was performed. Patient´s advanced age remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 02-Mar-2022: Significant Follow Up- Autopsy done was updated from unknown to no. Cause of death was added. Death event was deleted. Suspect product dosage text was updated.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 13-Jan-2022 and was forwarded to Moderna on 13-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (sudden death) in an 80-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005242) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Obesity. Concurrent medical conditions included Hypertension arterial. Concomitant products included TOZINAMERAN (COMIRNATY) from 14-Mar-2021 to an unknown date for COVID-19 vaccination. On 05-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 07-Dec-2021, the patient experienced SUDDEN DEATH (sudden death) (seriousness criterion death) and IMMUNISATION REACTION (reactogenicity). The patient died on an unknown date. It is unknown if an autopsy was performed. At the time of death, IMMUNISATION REACTION (reactogenicity) outcome was unknown.

Case ID	Narrative (Complete)
	For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided. Patient was previously administered with Pfizer Comirnaty-30 vaccine for adults on 14-MAR-2021 as dose 1 in left arm as intramuscular injection with the lot No .: ET3620 and Pfizer Comirnaty-30 vaccine for adults on 11-APR-2021 as dose 2 in left arm as injection intramuscular with lot No: EW2246. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 12-Jan-2022.
4.1(b)	This case was initially received via Zuellig Pharma (Reference number: 4.1(b)) on 13-Jan-2022. The most recent information was received on 13-Jan-2022 and was forwarded to Moderna on an unknown date. This spontaneous case was reported by an other health care professional and describes the occurrence of CEREBRAL HAEMORRHAGE (hemorrhage in the brain) and FALL (fall accident) in an 85-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) for an unknown indication. On 02-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) .25 milliliter. On 09-Dec-2021, the patient experienced CEREBRAL HAEMORRHAGE (hemorrhage in the brain) (seriousness criteria death and medically significant) and FALL (fall accident) (seriousness criterion death). The patient died on 04-Jan-2022. The reported cause of death was fall accident and Hemorrhage brain. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Body temperature: 36.2 (normal) 36.2 Degree Celsius, 36.3 (normal) 36.3 Degree Celsius, 36.0 (normal) 36.0 Degree Celsius and 37 (High) 37.0 Degree Celsius. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter considered CEREBRAL HAEMORRHAGE (hemorrhage in the brain) and FALL (fall accident) to be unlikely related. No treatment information were reported. Company comment: This is a spontaneous case concerning an 85 year-old, female patient with no reported medical history and Interchange of vaccine products (vaccination with two doses of COVID-19 vaccine AstraZeneca dates not provided), who experienced the serious Fatal unexpected, AESI of Cerebral haemorrhage; and the serious Fatal unexpected, event of fall. The events occurred approximately 7 days after the booster dose of mRNA-1273 vaccine. The patient died 33 days after the vaccination, it is unknown whether an autopsy was performed. According to the report, the physician diagnosed the cause of death as hemorrhage in the brain and fall accident. The events were considered unrelated to the vaccine per the reporter's assessment. Patient´s advanced age remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 13-Jan-2022: Upon query received from business partner, significant correction was performed on 21-JAN-2022. The dose was updated from 0.25 dosage form to 0.25 milliliter. Reporter causality was updated to unlikely and MAH causality was corrected from unlikely to related.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 13-Jan-2022 and was forwarded to Moderna on 13-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and COVID-19 (SARS-CoV-2 infection) in a 74-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004218) for COVID-19 vaccination. No Medical History information was reported. On 23-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 15-Nov-2021, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death) and COVID-19 (SARS-CoV-2 infection) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Nov-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. Treatment information was not provided. Company Comment: This case refers to a 74-year-old female patient with no known medical history who experienced the unexpected events of Vaccination failure and COVID-19 approximately 3 months and 3 weeks after the first dose of mRNA-1273 vaccine. No causality assessment was provided by the reporter. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Jan-2022 and was forwarded to Moderna on 14-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of HYPERTENSIVE CRISIS (HYPERTENSIVE CRISIS), HAEMORRHAGE INTRACRANIAL (INTRACRANIAL HAEMORRHAGE) and DRUG INEFFECTIVE (THE WOMAN RECEIVED TREATMENT

Case ID	Narrative (Complete)
	WITH CLONIDINE AND FUROSEMIDE FOR HYPERTENSIVE CRISIS. DESPITE THE TREATMENT, AND NINE DAYS FOLLOWING THE INITIAL EVENT, SHE DIED WITHOUT ANY IMPROVEMENT) in a 71-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect products included non-company products FUROSEMIDE for Hypertensive crisis and CLONIDINE HYDROCHLORIDE for Hypertensive crisis. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form, FUROSEMIDE (Intravenous) 20 milligram and CLONIDINE HYDROCHLORIDE (Intravenous) .15 milligram. On an unknown date, the patient experienced HYPERTENSIVE CRISIS (HYPERTENSIVE CRISIS) (seriousness criteria death and hospitalization), HAEMORRHAGE INTRACRANIAL (INTRACRANIAL HAEMORRHAGE) (seriousness criteria death and hospitalization) and DRUG INEFFECTIVE (THE WOMAN RECEIVED TREATMENT WITH CLONIDINE AND FUROSEMIDE FOR HYPERTENSIVE CRISIS. DESPITE THE TREATMENT, AND NINE DAYS FOLLOWING THE INITIAL EVENT, SHE DIED WITHOUT ANY IMPROVEMENT) (seriousness criteria death and hospitalization). The reported cause of death was Hypertensive crisis and Intracranial haemorrhage. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood pressure measurement: 210/110 mmhg 210/110 mmHg, 110/70 mm hg. lifetime values were around 110/70 mm Hg. Not Applicable and 180/100 mmhg 180/100 mmHg. On an unknown date, Blood test: no abnormality no abnormality found Not Applicable. On an unknown date, Computerised tomogram: intracranial haemorrhage CT scan showed an intracranial haemorrhage. For mRNA-1273 (Spikevax) (Unknown), the reporter considered HYPERTENSIVE CRISIS (HYPERTENSIVE CRISIS) and HAEMORRHAGE INTRACRANIAL (INTRACRANIAL HAEMORRHAGE) to be possibly related and DRUG INEFFECTIVE (THE WOMAN RECEIVED TREATMENT WITH CLONIDINE AND FUROSEMIDE FOR HYPERTENSIVE CRISIS. DESPITE THE TREATMENT, AND NINE DAYS FOLLOWING THE INITIAL EVENT, SHE DIED WITHOUT ANY IMPROVEMENT) to be not related. The patient was treated with 4 intravenous doses of 0.15 mg [clonidine] and 2 IV doses of furosemide (20 mg). However, BP remained over 180/100 mm Hg, despite treatment during hospitalization. Company Comment: This is a regulatory case concerning a 71-year-old female patient with no reported medical history, who experienced the serious unexpected fatal AESI event of haemorrhage intracranial and serious unexpected fatal events of hypertensive crisis and drug ineffective. The events occurred 3 days after the unknown dose of mRNA-1273 vaccine administration. The events of haemorrhage intracranial and hypertensive crisis were assessed as related to the product administration and the event of drug ineffective was in response to therapy for hypertensive crisis and assessed as not related to the company product. The rechallenge was not applicable. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 15-Jan-2022 and was forwarded to Moderna on 15-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (fatalities) in an 85-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005242) for COVID-19 vaccination. The patient's past medical history included Cardiac arrhythmia, Hypoacusis, Silicosis, Hepatic mass and Hernia inguinal. Concurrent medical conditions included Decompensation cardiac, Diabetes, Hypertension arterial and Ventricular dysfunction. Concomitant products included TOZINAMERAN (COMIRNATY) for COVID-19 vaccination. On 15-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on 15-Dec-2021 The patient died on 15-Dec-2021. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment details were not provided. Company Comment: This is a regulatory case concerning an 85-year-old, male patient with medical history including Ventricular dysfunction, Cardiac arrhythmia, Decompensation cardiac, Diabetes, Hypertension arterial, Silicosis and Hepatic mass, with an Interchange of vaccine products (TOZINAMERAN (COMIRNATY) for COVID-19 vaccination), who experienced the unexpected serious event of death. The event occurred approximately on the same day after a dose of mRNA-1273 vaccine. It is unknown if an autopsy was performed. No cause of death was reported. The medical history and patient´s age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 14-Jan-2022.
4.1(b) [redacted]	This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Deceased), CEREBRAL THROMBOSIS (Found a clot in her brain after vaccination/The doctor found a clot in her brain), FALL (Fallen ten times) and NEUROLOGICAL SYMPTOM (A major neurological event) in a 77-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 939909) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Blood pressure high (High Blood Pressure), Depression, Disability and Obesity. Concomitant products included GABAPENTIN (NEURONTIN) and INFLUENZA VACCINE from 12-Jan-2022 to an unknown date for an unknown indication. On 13-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form.

Case ID	Narrative (Complete)
	On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 14-Jan-2022, the patient experienced FALL (Fallen ten times) (seriousness criterion medically significant), NEUROLOGICAL SYMPTOM (A major neurological event) (seriousness criterion medically significant), INCOHERENT (Talks her sentences are jumbled and not coherent) and JOINT SWELLING (Joints are swollen). 14-Jan-2022, the patient experienced ARTHRALGIA (Joints are painful). On 15-Jan-2022, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced CEREBRAL THROMBOSIS (Found a clot in her brain after vaccination/The doctor found a clot in her brain) (seriousness criteria hospitalization and medically significant). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, CEREBRAL THROMBOSIS (Found a clot in her brain after vaccination/The doctor found a clot in her brain), FALL (Fallen ten times), NEUROLOGICAL SYMPTOM (A major neurological event), INCOHERENT (Talks her sentences are jumbled and not coherent), JOINT SWELLING (Joints are swollen) and ARTHRALGIA (Joints are painful) outcome was unknown. Treatment medication was not provided. It is reported that the patient had started taking new medications for the rest of life. The names of the medications are not known. Company Comment: This is a spontaneous case concerning a 77-year-old, female patient with a medical history of high blood pressure, depression, disability and obesity, who experienced the fatal event death on an unknown date and unexpected serious AESI of Cerebral thrombosis and unexpected serious events of Fall and Neurological symptom which occurred one day after the third dose of mRNA-1273 vaccine. It's reported the patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. The patient's elderly age, medical history remains as confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Feb-2022: Follow-up received on 4 Feb 2022 contains newevent death was added.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Jan-2022 and was forwarded to Moderna on 14-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death unexplained) in an 86-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 057G21A) for COVID-19 vaccination. The patient's past medical history included Osteoporosis with fracture, Pseudopolyarthritis and Peripheral arterial occlusive disease. Previously administered products included for COVID-19 vaccination: Pfizer vaccine (Dose 1: Adult Comirnaty-30 Pfizer Vaccine, 20/04/2021, Left Arm, Intramuscular Injection, Lot #: EW4815) on 20-Apr-2021, Pfizer vaccine (Dose 2: Adult Pfizer Comirnaty-30 Vaccine, 18/05/2021, Left Arm, Intramuscular Injection and Lot #: FA4598) on 18-May-2021. Past adverse reactions to the above products included No adverse event with Pfizer vaccine and Pfizer vaccine. On 09-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on 21-Dec-2021 The patient died on 21-Dec-2021. The cause of death was not reported. An autopsy was not performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications information was reported. No treatment medications were provided Company Comment: This is a regulatory case concerning an 86-year-old, male patient with a history of Peripheral arterial occlusive disease, with Interchange of vaccine products (2 prior doses of TOZINAMERAN), who experienced the unexpected serious event of death (unknown cause of death). The event occurred approximately 12 days after the first dose of mRNA-1273 vaccine (third dose in the series). An autopsy was not performed. The medical history and patient´s age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authority´s report due to death.
4.1(b)	This case was received via United Kingdom MHRA (Reference number: 4.1(b)) on 14-Jan-2022 and was forwarded to Moderna on 14-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of EMPYEMA (Empyema), DELIRIUM (Delirium), CIRCULATORY COLLAPSE (Circulatory collapse), COUGH (Coughing) and PYREXIA (Fever) in an 83-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. Concurrent medical conditions included Diabetic (type 2 diabetic well managed), COPD (well managed) and Suspected COVID-19 (Unsure when symptoms started). In November 2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. In 2021, the patient experienced COUGH (Coughing) (seriousness criteria death and hospitalization) and PYREXIA (Fever) (seriousness criteria death and hospitalization). On 09-Dec-2021, the patient experienced EMPYEMA (Empyema) (seriousness criteria death and hospitalization). On an unknown date, the patient experienced DELIRIUM (Delirium) (seriousness criteria death and hospitalization). an unknown date, the patient experienced CIRCULATORY COLLAPSE (Circulatory collapse) (seriousness criteria death and hospitalization). The patient died on 28-Dec-2021. The reported cause of death was Empyema and Delirium. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Negative COVID-19 test. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. No concomitant medications were provided. No treatment medications were provided.

Case ID	Narrative (Complete)
	It was reported that, approximately 7 days after the booster vaccine, patient felt very unwell, coughing and fever. About 5 days later he collapsed at home and was taken into hospital. He did not have COVID-19. About 3 days after being admitted into hospital, it was confirmed that he had an empyema. This worsened, causing delirium and he was unable to have a chest drain. He died in hospital about 5 weeks after he had his booster jab. He did not tested positive for COVID-19 after taking the vaccine. He was not enrolled in clinical trial. It was reported that, his reaction was not related to possible inflammation of the heart (myocarditis or pericarditis). Company comment: This case concerns a 83-year-old male patient with medical history of diabetes type 2, COPD and suspected COVID-19, who experienced the serious (fatal and hospitalization) unexpected events of empyema, delirium, circulatory collapse, pyrexia and cough after the third dose of mRNA-1273. It was reported that approximately 7 days after the booster vaccine, the patient felt very unwell, coughing and fever. About 5 days later he collapsed at home and was taken into hospital. It was reported that he did not have COVID. About 3 days after being admitted into hospital, it was confirmed that he had an empyema. This worsened, causing delirium and he was unable to have a chest drain. The patient died on 28-DEC-2021, cause of death was reported as empyema and delirium. Unknown if an autopsy was performed. Patient´s underlying diabetes remains a contributing factor for the event empyema. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number 4.1(b) [redacted]) on 14-Jan-2022. The most recent information was received on 29-Jan-2022 and was forwarded to Moderna on 29-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (Vomiting, Tremor, Fever), TREMOR (Vomiting, Tremor, Fever) and VOMITING (Vomiting, Tremor, Fever) in a 90-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Arthrosis and Arrhythmia (Heart arrhythmias.). On 24-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 24-Dec-2021, the patient experienced PYREXIA (Vomiting, Tremor, Fever) (seriousness criterion death), TREMOR (Vomiting, Tremor, Fever) (seriousness criterion death) and VOMITING (Vomiting, Tremor, Fever) (seriousness criterion death). The patient died on 25-Dec-2021. It is unknown if an autopsy was performed. No concomitant medications were provided.Treatment medications were not provided. Patient received Pfizer as a first dose. Rep comments: Previous vaccinations: Pfizer as a first dose, Moderna as a second dose. Reason for recall: Other or not known. - Flu vaccination was carried out on 2021-11-17. - Concomitant conditions: Knee and hip arthrosis; cardiac arrhythmias - Allergies: Dermatitis - Reaction time: 17:00 - Submitted by VigicoVid19-Card S comments: 30/12/2021 CRFV: requests for follow-up information on clinical documentation. Pending. 30/12/2021 CRFV: the card is updated with the info provided by the signaller and attaches docs clinics. Company Comment: This case concerns a 90-year-old male patient, with reported medical history of Arrhythmia, who experienced the fatal unexpected adverse events of Pyrexia, Tremor and Vomiting. The events occurred the same day of the administration of one dose of the mRNA-1273 vaccine in an unknown schedule of vaccination. The events were assessed by the reporter with the seriousness criteria of Death. No further information on clinical course, treatments performed, or autopsy report was disclosed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Previous vaccinations: Pfizer as a first dose, Moderna as a second dose. Reason for recall: Other or not known. - Flu vaccination was carried out on 2021-11-17. - Concomitant conditions: Knee and hip arthrosis; cardiac arrhythmias - Allergies: Dermatitis - Reaction time: 17:00 - Submitted by VigicoVid19-Card Most recent FOLLOW-UP information incorporated above includes: On 29-Jan-2022: Follow-up received included medical history added, indication updated
4.1(b) [redacted]	This spontaneous case was reported by a consumer and describes the occurrence of LUNG NEOPLASM MALIGNANT (lung cancer) and PNEUMONIA (pneumonia) in a 70-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 038A21A and 026A21A) for COVID-19 vaccination. The patient's past medical history included Ex-smoker (He was a previous smoker, but he hadn't smoked in the last 15-20 years.). On 08-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. In 2021, the patient experienced PNEUMONIA (pneumonia) (seriousness criterion medically significant). In September 2021, the patient experienced LUNG NEOPLASM MALIGNANT (lung cancer) (seriousness criteria death and medically significant). The patient died on 14-Nov-2021. The reported cause of death was Lung cancer. It is unknown if an autopsy was performed. At the time of death, PNEUMONIA (pneumonia) outcome was unknown. No Concomitant medications were provided. Treatment Information was not provided. She wanted to report the speed at which this cancer happened and grew. Patient had no symptoms, then cough in late August. They diagnosed him with pneumonia a week or two later. She hopes that by reporting this, Moderna would be able to find if the vaccine has a correlation with exacerbating the tumor or making it grow quicker. It was very aggressive. Patient was died in the hospital called Atlantic General Hospital.

Case ID	Narrative (Complete)
	Company comment: This case concerns a 70-year-old, male patient with medical history of smoking(previous smoker, but he hadn't smoked in the last 15-20 years), who experienced the unexpected events of lung cancer(which ended fatally) and pneumonia. The event of pneumonia occurred approximately occurred approximately 5 months after the second dose of mRNA-1273, while lung cancer was diagnosed 6 months after second dose. As reported, the tumor was 12 centimeters, which was huge and the patient died of cancer 1 month later. The reporter (patient's daughter) was concerned if the vaccine correlated with exacerbating the tumor or making it grow quicker as it was very aggressive. Considering the size of tumour and advanced progression as well as patient's medical history of smoking causality for this event was assessed as not related per Company. Underlying cancer is also a confounding factor for event of pneumonia. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 23-Mar-2022: Follow-up received 23-MAR-2022. Which contains no new information.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 15-Jan-2022 and was forwarded to Moderna on 15-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), CHEST DISCOMFORT (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), ABDOMINAL DISTENSION (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), INSOMNIA (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), CONFUSIONAL STATE (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), ASTHENIA (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), HEADACHE (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC), VOMITING (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) and NAUSEA (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) in a 72-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3006322) for COVID-19 vaccination. The patient's past medical history included Tabaquism, Obstructive chronic bronchitis, Cachexia, Chronic pain, Anxiety, Eating disorder, Lumbago and Toxic nodular goitre. Concurrent medical conditions included Depression. Concomitant products included FENTANYL (DUROGESIC) from 14-Jul-2021 to 28-Dec-2021 for Ache, FLUOXETINE HYDROCHLORIDE, OLANZAPINE (FOSTERA) from 25-Jan-2019 to 28-Dec-2021 for Bronchitis chronic, SERTRALINE HYDROCHLORIDE (ZOLOFT) from 06-Aug-2021 to 28-Dec-2021 for Depression, THIAMAZOLE (TAPAZOLE) from 07-Jul-2017 to 28-Dec-2021 for Hyperthyroidism, PARACETAMOL (PARACETAMOLO) from 01-Dec-2021 to 28-Dec-2021, MACROGOL, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE (MOVICOLON) from 25-Jul-2017 to 28-Dec-2021, OMEPRAZOLE from 01-Dec-2021 to 28-Dec-2021, COLECALCIFEROL (DIBASE) from 12-Mar-2018 to 28-Dec-2021, ALPRAZOLAM (XANAX) from 16-Apr-2021 to 28-Dec-2021 and TRIAZOLAM (HALCION) from 20-Oct-2021 to 28-Dec-2021 for an unknown indication. On 22-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 23-Dec-2021, the patient experienced CARDIAC ARREST (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criteria death and medically significant), CHEST DISCOMFORT (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death), ABDOMINAL DISTENSION (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death), INSOMNIA (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death), CONFUSIONAL STATE (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death), ASTHENIA (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death), HEADACHE (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death), VOMITING (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death) and NAUSEA (Vaccination on 22.12.2021 with Spikevax (0.25 ml). In the following days marked headache, insomnia, asthenia, confusion states. On 28.12.21 at 10.00 am retrosternal weight, nausea, vomiting at 1pm ACC) (seriousness criterion death). The patient died on 28-Dec-2021. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment medication were not reported. Company Comment - This regulatory authority case concerns a 72 year old female patient with medical history of obstructive chronic bronchitis and cachexia who experienced the serious unexpected events of cardiac arrest, chest discomfort, abdominal distension, insomnia, asthenia, headache, vomiting and nausea. The events occurred between 1 day and 6 days after a dose of mRNA-1273 vaccine. The outcome was fatal, with death occurring 5 days after the onset of the events. Patient's medical history of obstructive chronic bronchitis and cachexia remains a confounder. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Jan-2022: Follow-up received and contains no new information. On 28-Jan-2022: Follow up document received contains no new information On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 14-Jan-2022.

Case ID	Narrative (Complete)
	On 13-Jun-2022: Due to incorrect follow-up receipt date in live follow-up, this case is amended to reflect the actual follow-up receipt date/Date FU Received by Safety in the narrative. This case was submitted on-time based on previous significant follow-up/initial. The actual follow-up receipt date/ Date FU Received by Safety for this case is 14-Jan-2022.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 17-Jan-2022. The most recent information was received on 18-Jan-2022 and was forwarded to Moderna on 18-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of VOMITING (Occurrence of malaise with vomiting, taken to hospital and operating room, not operable due to intestinal infarction. Covid 19 vaccine third dose carried out on 29 november, probable presence of thrombus), INTESTINAL INFARCTION (Occurrence of malaise with vomiting, taken to hospital and operating room, not operable due to intestinal infarction. Covid 19 vaccine third dose carried out on 29 november, probable presence of thrombus) and MALAISE (Occurrence of malaise with vomiting, taken to hospital and operating room, not operable due to intestinal infarction. Covid 19 vaccine third dose carried out on 29 november, probable presence of thrombus) in an 84-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005887) for COVID-19 vaccination. No Medical History information was reported. On 29-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 18-Dec-2021, the patient experienced VOMITING (Occurrence of malaise with vomiting, taken to hospital and operating room, not operable due to intestinal infarction. Covid 19 vaccine third dose carried out on 29 november, probable presence of thrombus) (seriousness criterion death), INTESTINAL INFARCTION (Occurrence of malaise with vomiting, taken to hospital and operating room, not operable due to intestinal infarction. Covid 19 vaccine third dose carried out on 29 november, probable presence of thrombus) (seriousness criteria death and medically significant) and MALAISE (Occurrence of malaise with vomiting, taken to hospital and operating room, not operable due to intestinal infarction. Covid 19 vaccine third dose carried out on 29 november, probable presence of thrombus) (seriousness criterion death). It is unknown if an autopsy was performed. Concomitant medication was not reported. Treatment information was not reported. It was reported that reporter tried to obtain more information for the purposes of the clinical report required in cases of death. Company comment: This case concerns a 84-year-old, male patient with no relevant medical history, who experienced the unexpected fatal events of Intestinal Infarction, Malaise, and Vomiting. The events occurred approximately 19 days after the booster dose of mRNA-1273 (Moderna covid-19 vaccine). It was reported that patient experienced malaise and vomiting, he was taking to the hospital and was inoperable due to intestinal infarction. The rechallenge was not applicable as events occurred after a booster dose of mRNA-1273 with fatal outcomes. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 18-Jan-2022: Significant Follow-up received included: Vaccination date and batch number. On 18-Jan-2022: Upon query received from business partner, non-significant correction was performed on 08-Mar-2022. The company comment was added from previous significant version, since it was removed in NNI version. On 16-Feb-2022: Follow up document received and contains no new information. On 03-Mar-2022: Follow up document received and contains no new information. On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 14-Jan-2022.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 18-Jan-2022 and was forwarded to Moderna on 18-Jan-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of HAEMOLYTIC ANAEMIA (Hemolytic anemia) in a 71-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 300042722) for COVID-19 vaccination. No Medical History information was reported. On 06-Mar-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Apr-2021, after starting mRNA-1273 (Spikevax), the patient experienced HAEMOLYTIC ANAEMIA (Hemolytic anemia) (seriousness criteria death and medically significant). It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not reported. No treatment information was provided by the reporter. Company Comment: This RA case concerns a 71 year old male with no medical history reported , who experienced Serious (Fatal, Medically significant) , unexpected event of hemolytic anemia which occurred 1 month 14 days post vaccination with the 1st dose of mRNA-1273 vaccine (Moderna Covid 19 vaccine) . The outcome of this event was fatal. Details re the cause of death, date of death or if an autopsy was done were not reported. The re-challenge for this case is not applicable . The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b) on 18-Jan-2022. The most recent information was received on 21-Mar-2022 and was forwarded to Moderna on 21-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of BLOOD PRESSURE DECREASED (vomiting strain, intense cold, difficulty breathing, fatigue and shortness of breath, stomach weight and back pain, very low blood pressure), ASTHENIA (vomiting strain, intense cold, difficulty breathing, fatigue and shortness of breath, stomach weight and back pain, very low blood pressure), DYSPNOEA (vomiting strain, intense cold, difficulty breathing, fatigue and shortness of breath, stomach weight and back pain, very low blood pressure) and RETCHING (vomiting

Case ID	Narrative (Complete)
	strain, intense cold, difficulty breathing, fatigue and shortness of breath, stomach weight and back pain, very low blood pressure) in an 81-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002545) for COVID-19 vaccination. No Medical History information was reported. On 04-Jun-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Jun-2021, the patient experienced BLOOD PRESSURE DECREASED (vomiting strain, intense cold, difficulty breathing, fatigue and shortness of breath, stomach weight and back pain, very low blood pressure) (seriousness criterion death), ASTHENIA (vomiting strain, intense cold, difficulty breathing, fatigue and shortness of breath, stomach weight and back pain, very low blood pressure) (seriousness criterion death), DYSPNOEA (vomiting strain, intense cold, difficulty breathing, fatigue and shortness of breath, stomach weight and back pain, very low blood pressure) (seriousness criterion death) and RETCHING (vomiting strain, intense cold, difficulty breathing, fatigue and shortness of breath, stomach weight and back pain, very low blood pressure) (seriousness criterion death). It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. Treatment information was not provided. Sender's comment: On 04/03 Cardiology reports attached. These are the most recent report available, although from 2014, but it confirms the picture of a cardiopathic patient. There was no trace of a recent cardiac examination, nor is the "very low pressure" value available. CRA BWNJB0. Company comment: This is a regulatory authority case concerning a 81-year-old, male patient with relevant concurrent medical condition of heart disease, who experienced the unexpected serious (fatal according to regulatory authority) events of very low blood pressure, dyspnea, asthenia and retching. The events occurred the same day with the unknown dose number of mRNA-1273 vaccine administration and was accompanied by intense cold, weight on the stomach and back pain. It is unknown if an autopsy was performed. The concurrent medical condition of heart disease remain confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Mar-2022: Follow up received included sender's comment was updated. On 22-Apr-2022: Follow-up document received on 22-Apr-2022 with no new information.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 19-Jan-2022. The most recent information was received on 19-Jan-2022 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (Cardiorespiratory arrest) and RESPIRATORY ARREST (Cardiorespiratory arrest) in a 72-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000004A) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: VAXZEVRIA (EX COVID-19 VACCINE ASTRAZENECA) (ASTRAZENECA AB) (J07BX03) on 09-Apr-2021. Past adverse reactions to the above products included No adverse event with VAXZEVRIA (EX COVID-19 VACCINE ASTRAZENECA) (ASTRAZENECA AB) (J07BX03). On 11-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 27-Dec-2021, the patient experienced CARDIAC ARREST (Cardiorespiratory arrest) (seriousness criterion death) and RESPIRATORY ARREST (Cardiorespiratory arrest) (seriousness criterion death). The patient died on 27-Dec-2021. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported by reporter. Patient without significant pathologies, patient was experienced cough 10 days ago for which patient took antibiotics, fatal episode with hypotension, new episode resulted in death. Patient took antibiotics as a treatment medication. Company comment: This regulatory case concerns a 72-year-old female patient with no relevant medical history and with interchange of vaccine (VAXZEVRIA (EX COVID-19 VACCINE ASTRAZENECA) experienced serious unexpected fatal events of Cardiac arrest and Respiratory arrest after receiving a dose of mRNA-1373. The events occurred 17 days after the vaccination. Elderly age of the patient could be a risk factor for the events. It was reported that the Patient had no significant pathologies. Had cough 10 days ago for which she took antibiotics, fatal episode with hypotension, and another new episode next day resulted in death. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 19-Jan-2022: Upon internal Review on 27-JAN-2022, significant correction was made to update the seriousness of arrest respiratory to only death. On 14-Feb-2022: Follow up received included original language updated to Spanish from Italian. On 14-Feb-2022: Follow up received included event verbatim updated. On 28-Feb-2022: Follow up received is NNI.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of STEVENS-JOHNSON SYNDROME (Stevens-Johnson syndrome (SJS)), TOXIC EPIDERMAL NECROLYSIS (Toxic epidermal necrolysis (TEN)) and HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Macrophage activating syndrome) in a 77-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.

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	The patient's past medical history included Oral ulceration (presented with EM like lesion with oral/perineal ulcers, diagnosed at Tungs' Taichung MetroHarbor Hospital) on 04-Oct-2021 and Perineal ulceration (presented with EM like lesion with oral/perineal ulcers, diagnosed at Tungs' Taichung MetroHarbor Hospital) on 04-Oct-2021. On 04-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 23-Sep-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 04-Oct-2021, the patient experienced STEVENS-JOHNSON SYNDROME (Stevens-Johnson syndrome (SJS)) (seriousness criteria death and hospitalization prolonged), TOXIC EPIDERMAL NECROLYSIS (Toxic epidermal necrolysis (TEN)) (seriousness criteria death and hospitalization prolonged) and HAEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (Macrophage activating syndrome) (seriousness criteria death and hospitalization). The patient died on 05-Dec-2021. The reported cause of death was hemophagocytosis syndrome, Acute cholecystitis and suspected vaccine adverse reactions. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medication of the patient was not reported. No treatment information was provided by the reporter. It was reported that on January 7, 2022, Wuqi Health Center assisted in handling the application for relief for harm from of vaccination and an application was made to close the case. Company Comment: This is a RA case concerning a 77-year-old female patient, with no medical history reported, who experienced the unexpected events of Stevens-Johnson syndrome (AESI), Toxic epidermal necrolysis (AESI), and Haemophagocytic lymphohistiocytosis. The patient completed primary vaccination for COVID-19 with mRNA-1273 vaccine, with an interval between doses of 81 days (Inappropriate schedule of vaccine administered). The events occurred 12 days after the second dose of mRNA-1273 vaccine, and had a fatal outcome, with death occurring 13 days after second dose of mRNA-1273 vaccine. It is unknown if an autopsy was performed. Cause of death was reported as hemophagocytic syndrome, acute cholecystitis, and suspected vaccine adverse reaction. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up document received, contains no new information (NNI).
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC DISCOMFORT (Insomnia, cardiac discomfort) and INSOMNIA (Insomnia, cardiac discomfort) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 14-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Oct-2021, the patient experienced CARDIAC DISCOMFORT (Insomnia, cardiac discomfort) (seriousness criterion death) and INSOMNIA (Insomnia, cardiac discomfort) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by reporter. The patient had no chronic diseases or long-term drug use. The patient received the first dose of Moderna vaccine on 11-Jul, and then developed insomnia; the patient visited the clinic for medical treatment, and the doctor thought that the psychological pressure of the patient was too high. On 14-Oct, patient received the second dose of Moderna vaccine at Far Eastern Memorial Hospital, and insomnia worsened, and heart discomfort was found after that. During that period, the patient went to a clinic for medical treatment. The doctor prescribed sleeping pills. On about 30-Nov, the patient went to Tucheng Hospital for medical treatment. The doctor said that the patient used excessive sleeping pills and should reduce the medication. On 03-Jan, the patient died at home. The doctor diagnosed that the cause of death was cardiogenic shock. Company Comment: This case concerns a 68-year-old female patient, with no medical history reported, who experienced the unexpected serious events of Cardiac discomfort and Insomnia. The events occurred approximately 1 day after receiving the second dose of mRNA-1273 Vaccine. Around 47 days after the last dose, the patient had a medical treatment and was advised to reduce the sleeping pill medication. Patient died at home 81 days after the last dose. Cause of death was reported as psychogenic shock. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up document received contains non significant information
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Unknown cause of death) in an 89-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 045921A) for COVID-19 vaccination. The patient's past medical history included COVID-19 in December 2020 and Lung embolism. Concurrent medical conditions included Bronchial carcinoma, COPD, Diabetes mellitus and Partial lung resection. On 21-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 22-Dec-2021 The patient died on 22-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not provided. Treatment information was not provided. Company Comment: This regulatory case concerns an 89-year-old, female patient with medical history of Bronchial carcinoma, Chronic Obstructive Pulmonary Disease (COPD), Diabetes Mellitus (DM), and status post Partial Lung resection (indication not specified), who experienced the unexpected, serious event of death. The event occurred 1 day after administration of an unspecified dose of the Moderna mRNA-1273 vaccine. No further details were provided and the cause of death was unknown. The medical history of Bronchial carcinoma, COPD, DM and Partial Lung resection remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Unknown cause of death) in a 72-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 26-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 29-Dec-2021 The patient died on 29-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant medications were mentioned. No treatment details were reported. COMPANY COMMENT : This regulatory case concerning a 72 years old male patient with no medical history reported, who experienced unexpected serious event of death (reported as unknown cause of death).The event occurred 3 days after the third dose of mRNA-1273 vaccine. The outcome of the event is fatal. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authority´s report due to death.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of RECTAL CANCER (Rectal cancer) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Prostatic disorder. Concurrent medical conditions included Colorectal cancer. On 06-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-Nov-2021, the patient experienced RECTAL CANCER (Rectal cancer) (seriousness criterion death). The patient died on 03-Nov-2021. The reported cause of death was Rectal cancer. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient worked and rested normally from July 6 to November 2 and died at home on November 3. Upon follow-up on Jan-03-2022, it was reported that the family members did not apply for drug injury relief, so the case was closed. The patient's wife stated that the patient's death was not related to the vaccine and no VICP was required. Concomitant medication was not provided. Treatment information was not reported. Company Comment: This case concerns a 75-year-old male patient, with relevant medical history of prostate disease and colorectal cancer, who experienced the unexpected serious event of Rectal cancer. The event occurred approximately 3 months and 29 days after receiving the first dose of mRNA-1273 Vaccine which resulted in a fatal outcome. According to the physician's diagnosis the cause of death was rectal cancer. The patient's medical history of prostate disease and colorectal cancer remain as confounders for the occurrence of the event. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received and had no new information.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) and MYOCARDIAL INFARCTION (Myocardial infarct) in an 83-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included AFib, Ischaemic heart disease, Hypertension arterial and Dyslipidaemia. On 21-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 22-Dec-2021, the patient experienced CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) (seriousness criteria death and medically significant) and MYOCARDIAL INFARCTION (Myocardial infarct) (seriousness criterion death). The patient died on 24-Dec-2021. The reported cause of death was Cardio-respiratory arrest and Myocardial infarction. An autopsy was not performed.

Case ID	Narrative (Complete)
	For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment details were reported. Company comment: This case concerns an 83-year-old female patient with relevant medical history of Atrial Fibrillation, Ischaemic heart disease, Hypertension arterial and Dyslipidaemia, who experienced serious unexpected events of Cardio-respiratory arrest and Myocardial infarction. The events occurred one day after the patient had received the mRNA-1273 vaccine. The patient died two days after the occurrence of the events and both events were reported with fatal outcome. No further information was provided. An autopsy was not performed. The patient's underlying medical history of Atrial Fibrillation, Ischaemic heart disease, Hypertension arterial and Dyslipidaemia remains a major confounding factor for the reported events. The rechallenge was not applicable having in mind that the patient died. The patient's elderly age remains additional confounding factor. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDIAL INFARCTION (Infarct myocardial) in a 65-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004951) for COVID-19 vaccination. Concurrent medical conditions included Hyperuricaemia, Hypercholesteremia and Smoker. On 08-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Dec-2021, the patient experienced MYOCARDIAL INFARCTION (Infarct myocardial) (seriousness criterion death). The patient died on 11-Dec-2021. An autopsy was not performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided.No treatment medications were reported. Company Comment: This case concerns an 65-year-old male patient with concurrent medical condition of Hyperuricaemia, Hypercholesteremia and Smoking, who experienced the serious unexpected fatal event of Myocardial infarction. Patient died on 11-Dec-2021, 3 days after a dose of COVID-19 Vaccine Moderna (mRNA-1273). Very limited information regarding this event has been provided at this time, It was reported that an autopsy was not performed. Hyperuricaemia, Hypercholesteremia and Smoking as concurrent conditions and could remain as confounders risk factors. The benefit-risk relationship of COVID-19 Vaccine Moderna (mRNA-1273) is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (stroke) in an 82-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 13-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Dec-2021, the patient experienced CEREBROVASCULAR ACCIDENT (stroke) (seriousness criterion death). The patient died on 27-Dec-2021. The reported cause of death was Apoplectic fit. It is unknown if an autopsy was performed. Concomitant medications details were not reported by the reporter. Treatment details was not reported by the reporter. On Jan-2021, Patient received moderna first dose and experienced sometimes slurred language and and on Jun-2021, received second dose of moderna vaccination after one hour patient experienced hypertonic crisis, hemorragic sinus vein, paralysis on the right. Reha.Care level three. After booster on 23-DEC-2021 experienced flabby paralysis bds and on 27-DEC-2021 experienced exitus. Company comment: This case concerns an 82-year-old female patient with no medical history provided, who experienced serious unexpected event of Cerebrovascular accident which occurred 10 days after the patient had received the third dose of the mRNA-1273 vaccine. The patient died due to this apoplectic fit four days later. It was unknown whether an autopsy was performed. The rechallenge is not applicable since the patient died. The patient's elderly age remains a significant confounding factor for the reported event. It should be noted that, according to the case narrative the patient had received the first dose of the vaccine in Jan-2022, and the second dose was administered in Jun-2021, therefore, this is considered to be Inappropriate schedule of product administration. In addition, after the administration of the first dose the patient had slurred speech, and after the administration of the second dose, the patient had hypertonic crisis, hemorrhagic sinus vein, paralysis on the right. No additional details were provided. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (decease) in a 66-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Single bypass since an unknown date. Concurrent medical conditions included Coronary heart disease.

Case ID	Narrative (Complete)
	On 18-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 20-Dec-2021 The patient died on 20-Dec-2021. The reported cause of death was Sudden cardiac death. It is unknown if an autopsy was performed. No concomitant medication was provided. No treatment medication was provided. It was reported that -Are you or the person concerned aware of allergies? If yes, which one? no information on risk factors or pre-existing illnesses CHD; bypass/sudden cardiac death. Company comment: This is a fatal case from Regulatory Authority that concerns a 66-year-old male patient, with a medical history of Coronary heart disease and a single bypass, who experienced the unexpected fatal event of DEATH. He died two days after the third dose of the mRNA-1273. The cause of death was Sudden cardiac death. The history of Coronary heart disease and a single bypass remain as confounders. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (My mother collapsed 6 hours after the 3rd vaccination (Moderna) and verstorben on 26.12.2021 after 12 days in hospital.) and LOSS OF CONSCIOUSNESS (My mother collapsed 6 hours after the 3rd vaccination (Moderna) and verstorben on 26.12.2021 after 12 days in hospital.) in an 89-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 14-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Dec-2021, the patient experienced LOSS OF CONSCIOUSNESS (My mother collapsed 6 hours after the 3rd vaccination (Moderna) and verstorben on 26.12.2021 after 12 days in hospital.) (seriousness criterion medically significant). The patient died on 26-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, LOSS OF CONSCIOUSNESS (My mother collapsed 6 hours after the 3rd vaccination (Moderna) and verstorben on 26.12.2021 after 12 days in hospital.) had not resolved. Concomitant product use was not provided by the reporter. Treatment medication was not provided by the reporter. Patient had no allergies. Reporter reported arm was swollen after 4 hours, collapsed after 6 hours, full consciousness no longer returned. Company Comment: This is a regulatory case concerning a 89-year-old, female patient with no relevant medical history, who experienced the unexpected Fatal event of Unknown cause of death and the unexpected, serious (medically significant) event of Loss of consciousness. The event Loss of consciousness occurred on the same day after the third dose of mRNA-1273 vaccine administered on 14-Dec-21 for the indication of COVID-19 vaccination. After 12 days, on 26-Dec-21, Loss of consciousness was not resolved and patient died. Cause of death was unknown and it was unknown if autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as Serious as per Regulatory Authority report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC ARREST (Heart condition) in a 90-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000117A) for COVID-19 vaccination. Concurrent medical conditions included Cardiac insufficiency. On 21-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Dec-2021, the patient experienced CARDIAC ARREST (Heart condition) (seriousness criterion death). The patient died on 21-Dec-2021. The reported cause of death was Arrest cardiac. It is unknown if an autopsy was performed. No concomitant medication was reported. No treatment medications were reported. It was reported that information on risk factors or diseases included silicosis, heart failure / date of birth: 07.08.1931. Administration of the booster by the GP. After approx. 6 hours of sudden collapse with cardiac arrest. Attempted resuscitation attempts by emergency physician. Company Comment: This case concerns a 90-year-old male patient, with relevant medical history of Cardiac insufficiency, who experienced the unexpected serious event of Cardiac arrest. The event occurred on the same day after receiving the third dose of mRNA-1273 Vaccine which resulted in a fatal outcome. The patient's medical history of Cardiac insufficiency remain as a confounder for the occurrence of the event. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.

Case ID	Narrative (Complete)
	Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 20-Jan-2022 and was forwarded to Moderna on 20-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (Cardiac arrest) in a 67-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004959) for COVID-19 vaccination. Previously administered products included for COVID-19 immunisation: SPIKEVAX on 04-May-2021 and SPIKEVAX on 01-Jun-2021. Past adverse reactions to the above products included No adverse reaction with SPIKEVAX and SPIKEVAX. Concomitant products included VENLAFAXINE HYDROCHLORIDE (EFASTAD) from 26-Mar-2021 to an unknown date and VENLAFAXINE HYDROCHLORIDE (VENLAFAXIN KRKA) from 03-Dec-2015 to an unknown date for Depression, AMLODIPINE BESILATE, ATORVASTATIN CALCIUM (ZARATOR MAX) from 17-Mar-2016 to an unknown date for Hypercholesterolaemia, HYDROCHLOROTHIAZIDE, NEBIVOLOL HYDROCHLORIDE (CARDIOSTAD PLUS) from 04-Nov-2015 to an unknown date for Hypertension, CHLORZOXAZONE (KLORZOXAZON) from 29-Mar-2016 to an unknown date for Muscle pain, IBUPROFEN (IBUPROFEN DH) from 30-Jun-2014 to an unknown date for Pain, LANSOPRAZOLE (LANSOPRAZOL CF) from 04-Feb-2014 to an unknown date for Peptic ulcer, METFORMIN HYDROCHLORIDE (METFORMIN BOIE) from 17-Feb-2016 to an unknown date for Type 2 diabetes mellitus, PARACETAMOL (PANODIL) from 28-Oct-2013 to an unknown date for an unknown indication. On 13-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 23-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criterion death). The patient died on 23-Dec-2021. The reported cause of death was Cardiac arrest. An autopsy was not performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided by the reporter. Company comment: This fatal regulatory authority case concerns a 67-year-old female patient with relevant medical history of hypercholesterolemia, diabetes mellitus type 2 and hypertension (based on concomitant medications), who experienced serious unexpected event of cardiac arrest, that occurred approximately 10 days after the 3rd dose of the mRNA-1273. The rechallenge was not applicable due to occurrence after the 3rd dose and fatal outcome of the event. The patient's relevant medical history is a possible confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. The seriousness assessment as per regulatory authority.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (Deadly stroke) in a 96-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 10-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Dec-2021, the patient experienced CEREBROVASCULAR ACCIDENT (Deadly stroke) (seriousness criterion death). The patient died on 17-Dec-2021. The reported cause of death was Apoplectic fit. It is unknown if an autopsy was performed. No concomitant and treatment medications were reported. A few days after vaccination, the previously completely healthy and completely independent and fit 96 year old suddenly collapsed from weakness, could no longer speak properly and died within 24 hours as a result of stroke. Company comment: This is a regulatory authority case concerning a 96-year-old, male patient with no reported medical history, who experienced the unexpected, serious, AESI event of apoplectic fit. The event apoplectic fit occurred 7 days after the third dose of mRNA-1273 vaccine administration which resulted to death. The event was described as, a few days after vaccination, the previously completely healthy and completely independent and fit 96 year old suddenly collapsed from weakness, could no longer speak properly and died within 24 hours as a result of stroke. The reported cause of death was apoplectic fit. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of RESPIRATORY DISTRESS (Reaction overlapping the 2nd dose chills followed by difficulty breathing) and CHILLS (Reaction overlapping the 2nd dose chills followed by difficulty breathe) in an 85-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005885) for COVID-19 vaccination. Concomitant Elements: Well Despite Cardiovascular Comorbidities. The patient's past medical history included Renal failure chronic and Cardiovascular disease, unspecified (Concomitant Elements: Well Despite Cardiovascular Comorbidities).

Case ID	Narrative (Complete)
	On 27-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1.5 milliliter. On 28-Nov-2021, the patient experienced RESPIRATORY DISTRESS (Reaction overlapping the 2nd dose chills followed by difficulty breathing) (seriousness criterion death). On an unknown date, the patient experienced CHILLS (Reaction overlapping the 2nd dose chills followed by difficulty breathe) (seriousness criterion death). The patient died on 28-Nov-2021. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Company comment:This case concerns a 85-year-old, male patient with medical history of renal failure chronic and cardiovascular disease, who experienced the unexpected fatal events of respiratory distress and chills, which met seriousness criterion of death as per Regulatory authority information. The events occurred approximately 1 day after the third dose of mRNA-1273. As reported, the patient experienced reaction overlapping the 2nd dose chills followed by difficulty breathing. Above mentioned patient's medical history remains a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 21-Jan-2022: Translation contains non significant information, reporter's causality translated. On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (stroke, one week after vaccination) in a 92-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Artificial cardiac pacemaker wearer. On 20-Feb-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Mar-2021, after starting mRNA-1273 (Spikevax), the patient experienced CEREBROVASCULAR ACCIDENT (stroke, one week after vaccination) (seriousness criterion death). The patient died on 01-Mar-2021. The reported cause of death was Apoplectic fit. It is unknown if an autopsy was performed. No treatment was reported by the reporter. Company comment: This is a regulatory case concerning a 92-year-old male patient with medical history of artificial cardiac pacemaker, breathing discomfort and use of blood-thinning drugs, who experienced the unexpected serious fatal AESI of Cerebrovascular accident nine days after the unspecified dose of mRNA-1273 vaccine. Cerebrovascular accident was reported as cause of death, however autopsy results were not provided. The medical history and patient's advanced age remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (cause of death unknown) in a 90-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 25-Nov-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2. Concurrent medical conditions included Dementia. On 30-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 4 dosage form. Death occurred on 01-Dec-2021 The patient died on 01-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant drugs were not reported. Treatment medications were not provided. It was reported that on 25-Nov-2021 patient had third booster with biontech and on 30-Nov-2021 patient had fourth boosting with Moderna vaccine. Company comment: This Regulatory authority case concerns a 90-year-old, female patient, with medical history of dementia, who experienced the unexpected, serious (fatal) event of death. The event occurred 1 day after receiving a dose of mRNA-1273 vaccine, considered as the fourth dose of her COVID-19 vaccination schedule. It was reported that the patient received a third boosting dose in a hospital 5 days prior vaccination with mRNA-1273 vaccine at the same hospital. Due to underlying condition, it was reported that she could not say she had already been vaccinated with the booster dose. The patient died 1 day after vaccination and the cause of death was reported as unknown. Autopsy report is not available. The medical history of dementia remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Case ID	Narrative (Complete)
	Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (After 3 doses of Covid-19 vaccine in conjunction with the 1st dose of influenza vaccine, the patient immediately presents fever (3.6 C max, on average 37.3 / 37.4) for about a month and chronic bronchitis) and BRONCHITIS CHRONIC (After 3 doses of Covid-19 vaccine in conjunction with the 1st dose of influenza vaccine, the patient immediately presents fever (3.6 C max, on average 37.3 / 37.4) for about a month and chronic bronchitis) in a 92-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect product included non-company product INFLUENZA VACCINE for Vaccination. No Medical History information was reported. On 25-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form and dose of INFLUENZA VACCINE (Intramuscular) 1 dosage form. On 25-Nov-2021, the patient experienced PYREXIA (After 3 doses of Covid-19 vaccine in conjunction with the 1st dose of influenza vaccine, the patient immediately presents fever (3.6 C max, on average 37.3 / 37.4) for about a month and chronic bronchitis) (seriousness criterion death) and BRONCHITIS CHRONIC (After 3 doses of Covid-19 vaccine in conjunction with the 1st dose of influenza vaccine, the patient immediately presents fever (3.6 C max, on average 37.3 / 37.4) for about a month and chronic bronchitis) (seriousness criterion death). It is unknown if an autopsy was performed. No concomitant medication reported. No Treatment Medication reported. Sender's comment: the report was without important information that will be found and entered as soon as possible. Given the reported outcome, the clinical documentation available to support the case will be requested Company comment: This is a regulatory case concerning a 92 year-old, female patient with no reported medical history and concomitant administration of the influenza vaccine the same day as the mRNA-1273 vaccine, who experienced the serious Fatal unexpected, events of pyrexia and bronchitis chronic. The events occurred the same day after the third dose of mRNA-1273 vaccine. It was reported that the patient immediately had a fever for about a month and chronic bronchitis. The patient died on an unknown, date, no further details were provided, it is unknown whether an autopsy was performed. Patient´s advanced age and concomitant administration of the influenza vaccine remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Mar-2022: Follow-up received wherein non-Significant information updated. On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of ARRHYTHMIA (Arrhythmia cardiac (NOS)) in an 85-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000128A) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 21-Jul-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2. On 05-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced ARRHYTHMIA (Arrhythmia cardiac (NOS)) (seriousness criterion death). The cause of death was not reported. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided. Treatment information was not provided. It was reported that Date of death was not communicated. Reported cause of death was Unknown cause of Death. Company comment: This regulatory authority case concerns a 85-year-old female patient with no medical history reported, who experienced the unexpected fatal event of Arrythmia (AESI) in association with mRNA- 1273 vaccine, dose number unknown. The patient had received prior dose of Comirnaty vaccine. Temporal association of the event with mRNA- 1273 vaccine is not assessable since the onset date of the event was not disclosed. The fatal outcome occurred on an unknown date. Very limited information is available regarding clinical course, medical assessment and circumstances leading to death. Cause of death was reported as Unknown. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (heart attack with death) in a 66-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216044) for COVID-19 vaccination.

Case ID	Narrative (Complete)
	No Medical History information was reported. On 21-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Dec-2021, the patient experienced MYOCARDIAL INFARCTION (heart attack with death) (seriousness criterion death). The patient died on 25-Dec-2021. The reported cause of death was Infarct myocardial. It is unknown if an autopsy was performed. Concomitant product use was not provided by reporter. Sudden heart attack at home, the ambulance service was called, who reanimated another half an hour, but this remained unsuccessful Company comment: This regulatory authority case concerns a 66-year-old male patient with no medical history reported, who experienced the unexpected fatal event of Myocardial infarction (AESI) after mRNA- 1273 vaccine. The onset of the event occurred approximately 5 days after the third dose mRNA- 1273 vaccine (unknown dosage) and had a fatal outcome on the same day. Very limited information is available regarding circumstances leading to death other than the patient was reanimated at his home, without success. Cause of death was reported as Myocardial infarction. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of SUDDEN DEATH (Unexpected death) in an 81-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 03-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 12-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant medication were reported. No information on risk factors or pre-existing diseases PAvK, hypertonus, coronary sclerosis without hemodyn. relev. stenosis, Z.n. isthma ablation in atrial flutter Fever attacks up to 39 with body aches without further signs of infection since booster vaccination, found dead in apartment on Saturday 11.12. No treatment information were reported. Company comment: This regulatory authority case concerns a 81-year-old male patient with a medical history of Arteriosclerosis coronary artery, Atrial flutter and Cardiac ablation, who experienced the unexpected fatal event of Sudden death after mRNA- 1273 vaccine. The fatal outcome occurred approximately 9 days after the booster dose of mRNA- 1273 vaccine, patient was found dead in his department. Additionally, it was reported that the patient had experienced pyrexia and myalgia since the vaccination. Very limited information is available regarding baseline health condition before vaccination and circumstances leading to death. Cause of death was reported as unknown. It is unknown if an autopsy was performed. Patient´s age and history of Arteriosclerosis coronary artery, Atrial flutter and Cardiac ablation remain as confounders. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 21-Jan-2022. The most recent information was received on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC ARREST (cardiovascular arrest), PYREXIA (39.2 Fever) and CHILLS (chills) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005897) for COVID-19 vaccination. The patient's past medical history included Myocardial infarction (Patient had a heart attack 7 years ago) in 2015, Medical device site joint infection (bedridden due to missing hip joint), Hip surgery (bedridden due to missing hip joint) in 2020, Hip surgery (bedridden due to missing hip joint. Patient had a hip surgery 3 years ago and unfortunately got a germ there, which was why hip was removed and was bedridden since then. Patient mother cared for it and a care aid came by every day.) and Cardiac pacemaker insertion (pacemakers). Concurrent medical conditions included Bedridden (bedridden due to missing hip joint) and Decreased immune responsiveness (Weakened immune system). Concomitant products included APIXABAN (ELIQUIS), RETINOL PALMITATE (OLEOVIT A), OXAZEPAM (ANXIOLIT), FUROSEMIDE (LASIX P), SERTRALINE HYDROCHLORIDE (SERTRALINE A), DOXYCYCLINE HYDROCHLORIDE (DOXYCYCLINE RIA), TRAZODONE HYDROCHLORIDE (TRITTICO), RISPERIDONE (RISPERIDONA), PANTOPRAZOLE, MACROGOL 3350, POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE (MOLAXOLE), HYDROMORPHONE HYDROCHLORIDE (HYDAL), HYDROMORPHONE HYDROCHLORIDE (HYDAL) and BISOPROLOL FUMARATE (BISOPROLOL EG) for an unknown indication. On 20-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Dec-2021, the patient experienced PYREXIA (39.2 Fever) (seriousness criterion medically significant) and CHILLS (chills) (seriousness criterion medically significant). On 22-Dec-2021, the patient experienced CARDIAC ARREST (cardiovascular arrest) (seriousness criterion death). The patient died on 22-Dec-2021. An autopsy was not performed. At the time of death, PYREXIA (39.2 Fever) and CHILLS (chills) had not resolved.

Case ID	Narrative (Complete)
	DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Nov-2021, Bacterial test: 201 Bacteria urine. On 10-Nov-2021, Blood creatinine: 1.52 (High) 1.52 mg/dl (0.72-1.25). On 10-Nov-2021, Blood uric acid: 9.1 (High) 9.1 mg/dl (3.5-7.2). On 10-Nov-2021, C-reactive protein: 1.20 (High) 1.20 mg/dl (0-0.50). On 10-Nov-2021, Glomerular filtration rate: 44 (Low) 44 ml/min (>60). On 10-Nov-2021, Haematocrit: 38.4 38.4%. On 10-Nov-2021, Platelet count: 182 182. On 10-Nov-2021, White blood cells urine: 206 206. On 12-Nov-2021, Alanine aminotransferase: <6 u/l (normal) <6 U/l (0-50). On 12-Nov-2021, Blood calcium: 2.29 (normal) 2.29 mmol/l (2.05-2.60). On 12-Nov-2021, Blood iron: 72 (normal) 72µg/dl (65-175). On 12-Nov-2021, Blood sodium: 129 (Low) 129 mmol/l (136-145). On 12-Nov-2021, Glycosylated haemoglobin: 5.1% , 33mmol/mol 5.1% , 33mmol/mol. On 12-Nov-2021, Low density lipoprotein: 107 107 mg/dl. On 12-Nov-2021, Prostatic specific antigen: 0.57 (normal) 0.57 µg/l (0-6.5). On 12-Nov-2021, Rheumatoid factor: <10 ku/l <10 kU/l (0-30). On 12-Nov-2021, SARS-CoV-2 antibody test: 121.08 121.08 construction/ml (normal value from 7.1 positive). On 12-Nov-2021, Serum ferritin: 472.9 (abnormal) 472.9 µg/l (21.8-27.5). On 12-Nov-2021, Transferrin: 1.44 (Low) 1.44 g/l (1.74-3.64). On 12-Nov-2021, Transferrin saturation: 35.50 (normal) 35.50% (16-45) and 35.50 (normal) 35.50% (16-45). The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. The patient died on 22-Dec-2021 at 03:00. Treatment medication was not provided by the reporter. Company Comment: This Fatal Regulatory Authority case concerns a 80-year-old, male patient, with medical history of decreased immune responsiveness, medical device joint infection, myocardial infarction, pace maker user and bedridden, who experienced the unexpected, serious (death) event of cardiac arrest, among others. The patient developed pyrexia and chills 1 day after receiving a the first dose of mRNA-1273 vaccine, complicated with cardiac arrest and died 2 days after vaccination. Complementary tests with date of approximately 1 months and 8 days prior vaccination evidenced sodium of 129 mmol, white blood cell urine 206 (no units), C-reactive protein 1.20 mg/dl, creatinine 1.52 mg/dl, ferritin 472.9 mcg/l. Cause of death was not reported. Autopsy report is not available. Patient's age, gender, medical history of decreased immune responsiveness, medical device joint infection, myocardial infarction, pace maker user, bedridden and polypharmacy remain as confounders. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 09-Feb-2022: Significant follow-up received included added lab tests and updated concomitant medication details. On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of SYNCOPE (attack of weakness) and DEATH (decease) in an 89-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for Prophylactic vaccination. No Medical History information was reported. On 14-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 16-Dec-2021, the patient experienced SYNCOPE (attack of weakness) (seriousness criterion hospitalization). The patient died on 26-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, SYNCOPE (attack of weakness) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. No concomitant medication was provided by reporter. No treatment drug was provided by reporter. Sender's Comment : six hours after vaccination weakness, 2 days after vaccination hospitalization deceased 12 days after vaccination. Company comment: This is a fatal case from Regulatory Authority that concerns an 89-year-old female patient, with no medical history reported, who experienced the unexpected fatal event of DEATH and the serious unexpected events of SYNCOPE. The event SYNCOPE occurred on two days after the dose of the mRNA-1273 vaccine. She died twelve days after the dose of the mRNA-1273. The cause of death was not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022.

Case ID	Narrative (Complete)
	This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (Malaise) in an 86-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 018G21A) for COVID-19 vaccination. Co-suspect product included non-company product CIPROFLOXACIN (CIFLOXA) for Urinary infection. The patient's past medical history included Anxiety depression. Concurrent medical conditions included Cardiac valve disease and Hypertension arterial. On 04-Jan-2022, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In January 2022, the patient started CIPROFLOXACIN (CIFLOXA) (unknown route) at an unspecified dose. On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced CARDIAC ARREST (Malaise) (seriousness criterion death). The patient died on 05-Jan-2022. The reported cause of death was Arrest cardiac. An autopsy was not performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant Medication use information was not provided by reporter. Treatment Medication use information was not provided by reporter. Company comment This is a regulatory case concerning a 86-year-old female patient with medical history of Cardiac valve disease and Hypertension arterial, who experienced death with the Fatal unexpected, according to CCDS, event of cardiac arrest. The event occurred on an unknown date after the first dose of mRNA-1273 vaccine. The patient died on 05-Jan-2022. The reported cause of death was Arrest cardiac. An autopsy was not performed. The medical history of Cardiac valve disease and Hypertension arterial remains a confounder. The rechallenge was not applicable due to the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 21-Jan-2022 and was forwarded to Moderna on 21-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (blood clots in the brain, followed by cerebral hemorrhage.) and THROMBOSIS (blood clots in the brain following cerebral hemorrhage) in an 81-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 22-Mar-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 2 dosage form. On 20-Apr-2021, the patient experienced THROMBOSIS (blood clots in the brain following cerebral hemorrhage) (seriousness criteria hospitalization and life threatening). On 21-Apr-2021, the patient experienced CEREBRAL HAEMORRHAGE (blood clots in the brain, followed by cerebral hemorrhage.) (seriousness criterion death). The patient died on 21-Apr-2021. The reported cause of death was Hemorrhage brain. It is unknown if an autopsy was performed. At the time of death, THROMBOSIS (blood clots in the brain following cerebral hemorrhage) had not resolved. No concomitant medications were reported. The treatment information was unknown. The patient was hospitalized, intensive care unit, died within 5 days. Company Comment - This regulatory authority case concerns a 81 year old male patient with no relevant medical history, who experienced the serious unexpected events of.cerebral haemorrhage and thrombosis. The events occurred approximately one month after a dose of the vaccine. The outcome was fatal with death occurring 1 day after the onset of the event cerebral hemorrhage. Patient was hospitalized, in the intensive care unit. The reported cause of death was brain hemorrhage. The rechallenge was not .applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 22-Jan-2022 and was forwarded to Moderna on 22-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 (SARS-CoV-2 infection) and VACCINATION FAILURE (Vaccination failure) in a 90-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 28-Feb-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 28-Mar-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 13-Oct-2021, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criterion death) and VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Oct-2021, SARS-CoV-2 test: positive (Positive) Positive.

Case ID	Narrative (Complete)
	For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was provided by reporter. No treatment drug was provided by reporter. The report was for a patient/patient. None mail was sent to reporters. Company comment: This case concerns a 90-year-old male patient with no relevant medical history, who experienced the unexpected fatal event of COVID-19 (SARS-COV-2 Infection), vaccination failure was considered as an additional event. The fatal events occurred approximately 6 months 15 days after the second dose of mRNA-1273 (Moderna covid-19 vaccine). The rechallenge was not applicable as events occurred after second dose with a fatal outcome. This patient's advanced age remains a contributory factor to the fatal outcomes. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 22-Jan-2022. The most recent information was received on 11-Mar-2022 and was forwarded to Moderna on 11-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of RESUSCITATION (19/12/2021 19 hr: collapsed, CPR), RECTAL HAEMORRHAGE (19/12/2021, 6.38 am: a lot of rectal blood loss), CIRCULATORY COLLAPSE (19/12/2021 19 hr: collabed, resuscitation) and ABDOMINAL PAIN (19/12/2021 06.38 hr: Abdominal pain; seen on SEH, suspected GE/food poisoning of spoiled fish.) in a 77-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Pancreatitis in 2001, Morbid obesity (BMI 36.8, lost 5 kg compared to the year before) in 2021, Fracture of head of radius, open (Distal radius fracture left) in 1989, Dyspnoea (Been ill with dyspnea and fever in early and mid-2020. At the time, testing was not available usual. Restored without AB usage. May have been Covid, but can no longer be traced) in 2020, Type 1 diabetes mellitus in 1991, Trigger finger in 2009, Cholangitis in 2006, Tibia fracture (lower leg fracture right) in 1986, Trigger finger release (there was no family history) in 2009, Agoraphobia (supervised by POH GGZ), Gallstones (ERCP with papillotomy, cholecystectomy) in 1996 and Neurolysis (Release N medianus right, April 2014: neurolysis without operating microscope or loupe magnification) in 2014. Previously administered products included for Drug use for unknown indication: COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 14-Apr-2021, COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 20-May-2021. Past adverse reactions to the above products included No adverse event with COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST, COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST. Concurrent medical conditions included Hypertension. Concomitant products included AZITHROMYCIN (AZITROMYCINE) from 17-Dec-2021 to an unknown date for Sinusitis, INSULIN and HYDROCHLOORTHIAZIDE for an unknown indication. On 13-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Dec-2021, the patient experienced BLOOD GLUCOSE FLUCTUATION (17/12 GP consulted for sinus complaints, glucose fluctuations and headache), HEADACHE (17/12 GP consulted for sinus symptoms, glucose fluctuations and headaches) and SINUSITIS (17/12 GP consulted for sinus symptoms, glucose fluctuations and headaches). On 18-Dec-2021, the patient experienced VOMITING (18/12/21, 21 hr: abdominal pain, diarrhea and vomiting), DIARRHOEA (18/12/21, 9:00 pm: abdominal pain, diarrhea and vomiting), GASTROINTESTINAL PAIN (18/12/21, 9:00 pm: abdominal pain, diarrhea and vomiting) and ABDOMINAL PAIN (19/12/2021 06.38 hr: Abdominal pain; seen on SEH, suspected GE/food poisoning of spoiled fish.) (seriousness criterion death). On 19-Dec-2021, the patient experienced RESUSCITATION (19/12/2021 19 hr: collapsed, CPR) (seriousness criterion death), RECTAL HAEMORRHAGE (19/12/2021, 6.38 am: a lot of rectal blood loss) (seriousness criterion death), HAEMATOCHEZIA (19/12/2021 06.38 hr: stomach ache; seen at ED, suspected GE/food poisoning from spoiled fish. Some blood in faeces) and CIRCULATORY COLLAPSE (19/12/2021 19 hr: collabed, resuscitation) (seriousness criterion death). The patient died on 19-Dec-2021. The reported cause of death was a lot of rectal bleeding. An autopsy was not performed. At the time of death, HAEMATOCHEZIA (19/12/2021 06.38 hr: stomach ache; seen at ED, suspected GE/food poisoning from spoiled fish. Some blood in faeces), BLOOD GLUCOSE FLUCTUATION (17/12 GP consulted for sinus complaints, glucose fluctuations and headache), VOMITING (18/12/21, 21 hr: abdominal pain, diarrhea and vomiting), DIARRHOEA (18/12/21, 9:00 pm: abdominal pain, diarrhea and vomiting), HEADACHE (17/12 GP consulted for sinus symptoms, glucose fluctuations and headaches), SINUSITIS (17/12 GP consulted for sinus symptoms, glucose fluctuations and headaches) and GASTROINTESTINAL PAIN (18/12/21, 9:00 pm: abdominal pain, diarrhea and vomiting) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Oct-2020, Physical examination: abnormal (abnormal) RR 134/55, MAP: 81.3, height 1.59 cm, weight 98 kg and normal (normal) BP 134/55, MAP: 81.3, height 1.59 cm, weight 98 kg. On 20-Apr-2021, Ophthalmological examination: normal (normal) left eye: no abnormalities, right eye: no abnormalities and normal (normal) left eye: no abnormalities, right eye: no abnormalities. On 13-Oct-2021, Glycosylated haemoglobin: 52 (normal) 52= high for non-diabetics, but well-set diabetic should have < 53, so ok.. On 13-Oct-2021, Laboratory test: abnormal (abnormal) Hb 7.4 (net te laag), HT 0.36 (LLN), MCV 88 fl, trombo's 252 (normal), leuko's 4.5 (normal), Natrium 141 (normal) , Kalium 4.3 (normal), and normal (normal) Hb 7.4 (net te laag), HT 0.36 (LLN), MCV 88 fl, trombo's 252 (normal), leuko's 4.5 (normal), Natrium 141 (normal) , Kalium 4.3 (normal). On 13-Oct-2021, Liver function test: abnormal (abnormal) ALAT 16, Cholesterol 3.5, HDL cholesterol 1.3, non-HDL cholesterol: 2.2 (= low) and low (Low) ALT 16, Cholesterol 3.5, HDL cholesterol 1.3, non- HDL cholesterol: 2.2 (= low). On 13-Oct-2021, Renal impairment: abnormal (abnormal) Kreatinine 105 (high, ULN: 100), EGFR (CKD-EPI): 44 = moderate renal impairment. On 20-Oct-2021, Physical examination: abnormal (abnormal) RR 138/70, MAP: 92.7, height 1.59 cm, weight 93 kg, BMI 36.8 BSA 1.94 and normal (normal) BP 138/70, MAP: 92.7, height 1.59 cm, weight 93 kg, BMI 36.8 BSA 1.94. On 19-Dec-2021, Blood glucose: 16.7 (High) On SEH: 16.7. On 19-Dec-2021, Liver function test: abnormal (abnormal) on SEH: alk phosph 103 other liver enzymes not abnormal and 103 (normal) on emergency room: alk fosf 103 other liver enzymes not abnormal.

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	On 19-Dec-2021, Physical examination: abnormal (abnormal) 0.38 hr on 19/12/2021: T 35.9, vivid intestinal peristalsis, pressure pain epigastrio upper left., abnormal (abnormal) 06.38 hr: RR 130/70, pols 77, sat 97%., normal (normal) 06.38 hr: RR 130/70, pols 77, sat 97%. and abnormal (abnormal) 00:38 am on 19/12/2021: T 35.9, vivid intestinal peristalsis,pressure pain epigastrio upper left.. On 19-Dec-2021, Renal impairment: abnormal (abnormal) SEH : eGFR 41 (was 44 2 months ago) , creatinine 111 (was 105 2 months ago). For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Additional information on azithromycin drug was as follow:Patient had sinus symptoms from +/- 1 dec for which she was using Otrivin. On 17/12 tel. consult informed "TC: persistent sinus symptoms, headaches and rising sugars. Patient had no fever, no rhinitis. Nasal spray does not help, Patient seen weekend and rising sugars yet blind cure: Patient took Azithromycin 500mg 1d1t, 3 dgn. No treatment medications were provided. Company comment: This regulatory authority case concerns a 77-year-old female patient, with medical history of Morbid obesity, hypertension, Type 1 diabetes Mellitus, and interchange of vaccine products (PFIZER COVID-19 vaccine), who experienced the serious (fatal), unexpected events of rectal hemorrhage, abdominal pain, circulatory collapse and resuscitation. The patient consulted a physician 4 days after receiving the dose of mRNA-1273 COVID-19 vaccine (3rd dose in the series) due to sinus complaints, glucose fluctuation and headaches. Five days after the vaccine, patient diarrhea, and gastrointestinal pain. Six days after the vaccine, patient had abdominal pain and was seen on SEH, she was suspected to have gastroenteritis/food poisoning due to spoiled fish. At SEH, blood glucose was 16.7 (no measurement unit) liver function test was abnormal, eGFR was decreased 41, on physical examination she had te
4.1(b) [redacted]	This case was received via United Kingdom MHRA (Reference number: 4.1(b) [redacted]) on 23-Jan-2022 and was forwarded to Moderna on 23-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (SARS-CoV-2 infection) and RUPTURED CEREBRAL ANEURYSM (Intracranial hemorrhage ruptured aneurysm) in a 76-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000014A) for an unknown indication. No Medical History information was reported. On 08-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 23-Dec-2021, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criteria death and life threatening) and RUPTURED CEREBRAL ANEURYSM (Intracranial hemorrhage ruptured aneurysm) (seriousness criteria death and life threatening). The patient died on 25-Dec-2021. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Dec-2021, SARS-CoV-2 test: positive (Positive) Positive. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. No concomitant products were reported. No treatment information was reported by the reporter. N/a no underlying illnesses Unsure if patient had symptoms associated with COVID-19. It was reported that her mother tested positive for COVID on the 23-Dec-2021, when she was tested in the hospital as she was brought in with a ruptured aneurysm. However, test results sent to her phone said she was negative. Patient was not enrolled in clinical trial. Patient report did not relate to possible inflammation of the heart (myocarditis or pericarditis). COMPANY COMMENT : This is a regulatory case concerning a 76 years old female patient with no medical history reported. who experienced the unexpected serious AESI event of Covid-19 and unexpected serious event of ruptured cerebral aneurysm. The events occurred 15 days after the third dose of mRNA-1273 vaccine. The outcome of the events are fatal. SARS -COV-2 test was positive. The patient died on 25-Dec-2021. It is unknown if an autopsy was performed. It was reported that her mother tested positive for COVID on the 23-Dec-2021, when she was tested in the hospital as she was brought in with a ruptured aneurysm. However, test results sent to her phone said she was negative. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as serious as per Regulatory Authority´s report due to death and life threating.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 22-Jan-2022. The most recent information was received on 11-Feb-2022 and was forwarded to Moderna on 11-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDIAL INFARCTION (myocardial infarction) in an 80-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Myocardial infarction in 2015. Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 18-Mar-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 26-Apr-2021. Past adverse reactions to the above products included No adverse reaction with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST.

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	Concurrent medical conditions included Atrial fibrillation, Diabetes mellitus, Obesity (BMI >32), Benign paroxysmal positional vertigo (Complaining of dizziness matching orthostasis and BPPD for a long time), Hypertension and Orthostatic dizziness (Complaining of dizziness matching orthostasis and BPPD for a long time). Concomitant products included METFORMIN (METFORMINE [METFORMIN]), FUROSEMIDE (FRUSEMIDE [FUROSEMIDE]), ACENOCOUMAROL, INSULIN ISOPHANE PORCINE (INSULINE NPH), OMEPRAZOLE (OMEPRAZOL A), ATORVASTATIN (ATORVASTATINE [ATORVASTATIN]), GLIMEPIRIDE, VALSARTAN, PAROXETINE (PAROXETIN [PAROXETINE]), METOPROLOL, MORPHINE (METOPROLOL;MORPHINE) and BARNIDIPINE for an unknown indication. On 02-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced MYOCARDIAL INFARCTION (myocardial infarction) (seriousness criterion death). The patient died on 05-Jan-2022. The reported cause of death was myocardinfarct. An autopsy was not performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided. Company comment: This is a regulatory authority case concerning a 80-year-old, female patient with relevant medical history of myocardial infarction and concurrent medical conditions of atrial fibrillation, diabetes mellitus, hypertension and obesity (BMI >32) and vaccine history of receiving 2 doses of another brand of Covid-19 vaccine (Covid-19 vaccine Comirnaty) as previous doses, who experienced the unexpected, serious, AESI event of myocardial infarction. The event myocardial infarction occurred approximately 3 days after the unknown dose number of mRNA-1273 vaccine administration. The outcome of the event myocardial infarction was fatal. The reported cause of death was myocardial infarction. Autopsy was not performed. The medical history of myocardial infarction and concurrent medical conditions of atrial fibrillation, diabetes mellitus, hypertension and obesity remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 11-Feb-2022: Patient medical history added, autopsy details and concomitant drug details updated. On 11-Feb-2022: Translation document received on 17 FEB 2022 with event verbatim updated. On 12-May-2022: Due to case creation with incorrect initial receipt date, this case is amended to reflect the actual initial receipt date within the narrative. This case was submitted on-time based on the actual initial receipt date. The actual initial receipt date for this case is 20-Jan-2022.
4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (Myocardial infarction), DEATH (Death), CORONARY ARTERY OCCLUSION (Coronary occlusion), DYSPNOEA (Dyspnea) and the first episode of CHILLS (Shivers) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Hypertension and Diabetes. On 22-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 22-Dec-2021, the patient experienced DYSPNOEA (Dyspnea) (seriousness criterion death) and the first episode of CHILLS (Shivers) (seriousness criterion death). On 23-Dec-2021, the patient experienced MYOCARDIAL INFARCTION (Myocardial infarction) (seriousness criterion death), DEATH (Death) (seriousness criterion death) and CORONARY ARTERY OCCLUSION (Coronary occlusion) (seriousness criteria death and medically significant). On an unknown date, the patient experienced FEELING COLD (Sensation of cold), PYREXIA (Fever), FATIGUE (Fatigue aggravated), FATIGUE (Fatigue) and the second episode of CHILLS (Shivers). The patient died on 23-Dec-2021. The reported cause of death was Coronary occlusion and Myocardial infarction. It is unknown if an autopsy was performed. At the time of death, FEELING COLD (Sensation of cold), PYREXIA (Fever), FATIGUE (Fatigue aggravated), FATIGUE (Fatigue) and the last episode of CHILLS (Shivers) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, COVID-19: infection covid-19 (Inconclusive) INFECTION COVID-19. Concomitant product was not provided by the reporter. No treatment information was provided. Patient had third dose of the vaccine (booster dose). This is a regulatory authority case concerning a 73-year-old, male patient with medical history of Hypertension and Diabetes, who experienced the unexpected fatal events of Myocardial infact, Death, Coronary artery occlusion, Dyspnea and Chills and unexpected non-serious event of feeling cold, and expected non-serious events of Pyrexia, fatigue, fatigue and chills. The events dyspnea, chills occurred the same day after the third dose of mRNA-1273 COVID 19 Vaccine. The events myocardial infarct, death and Coronary Artery Occlusion occurred 1 day after the third dose of mRNA-1273 COVID 19 Vaccine. The reported cause of death was Coronary occlusion and myocardial infarction. It is unknown if an autopsy was performed. The medical history of Hypertension and Diabetes remains a confounder. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 24-Jan-2022 and was forwarded to Moderna on 26-Jan-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). The patient had COPD and was being placed on home oxygen therapy (HOT). On an unknown date, the patient received the 1st dose of a vaccine. On an unknown date, the patient received the 2nd dose of a vaccine. On an unknown date, body temperature before vaccination: 36.6 degrees Celsius. On 22-Jan-2022, at 15:00, the patient received the 3rd dose of this vaccine. On 23-Jan-2022, a decrease in SAT was observed at dawn, and the flow rate of HOT was increased. At 13:25, there was a poor improvement in symptoms and the patient died. Because the patient had COPD and heart failure, it is considered that aspiration pneumonia and deterioration of respiratory failure occurred. The outcome of aspiration pneumonia and

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	deterioration of respiratory failure was reported as fatal. Follow-up investigation will be made. Company Comment: Although respiratory failure developed after the administration of ELASOMERAN, factors such as concurrent conditions may have also had an influence.
4.1(b) [redacted]	This spontaneous case was reported by a nurse and describes the occurrence of SUDDEN DEATH (Sudden death) in a 66-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 31-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. The patient died on 01-Jan-2022. The reported cause of death was sudden death. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered SUDDEN DEATH (Sudden death) to be related. No concomitant medications were reported. Treatment drug information was not provided. The reporter, who was the patient's son-in-law reported that the patient was healthly enough to go to the gym every day. The patient has been routinley excercising since 2015, after retirement to take care of his health. On 01-JAN-2022, 1 day after the vaccination, the patient died in a public bath while taking a bath. No further details regarding the event was reported. The patient's son-in-law (reporter) is a nurse and suspected that this event event was related to the vaccine. Company comment: This case concerns a 66-year-old male patient, with no medical history reported, who experienced the serious unexpected fatal event of sudden death the next day after the third dose of mRNA-1273. It is unknown if an autopsy was performed. Very limited information provided at this time. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 27-Jan-2022. The most recent information was received on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death) and AGONAL RESPIRATION (agonal breathing) in a 93-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004952) for COVID-19 vaccination. The patient's past medical history included Unspecified neurotic disorder (F48 - other neurotic disorders) and Cholecystectomy (State following cholecystectomy). Previously administered products included for Product used for unknown indication: Vaxzevria 2nd dose (Vaxzevria 2nd dose (ABW4801)), Oxygen therapy and Vaxzevria 1st dose (Vaxzevria 1st dose (ABV4678)). Past adverse reactions to the above products included No adverse event with Oxygen therapy, Vaxzevria 1st dose and Vaxzevria 2nd dose. Concurrent medical conditions included Cor pulmonale chronic (Cor pulmonale chr. (I27.8)), Chronic respiratory failure (St post pneumonia I.dex. am II [State after right lung pneumonia 2 months ago] Insufficientio respiratoria globalis [Global respiratory failure] (J96.1)), Struma nodosa (Nodular goitre of the thyroid gland), Scoliosis (Scoliosis vertebrae thoracalis), Hypertension arterial (Arterial hypertension) and Organic delusional syndrome (Organic delusional disorder (F06.2)). Concomitant products included POTASSIUM CHLORIDE (KALINORM) for Chronic cor pulmonale, IPRATROPIUM BROMIDE (ATROVENT N) for Chronic respiratory failure, NEBIVOLOL HYDROCHLORIDE (NEBILET) and FUROSEMIDE (FUROSEMIDA MK [FUROSEMIDE]) for Cor pulmonale chronic, RISPERIDONE (RISSET) for Organic delusional syndrome, BROMAZEPAM (LEXILLIUM) for Unspecified neurotic disorder. On 27-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter once a day. On 28-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced DEATH (Death) (seriousness criterion death) and AGONAL RESPIRATION (agonal breathing) (seriousness criterion death). The patient died on 28-Dec-2021. An autopsy was not performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered DEATH (Death) and AGONAL RESPIRATION (agonal breathing) to be unlikely related. No concomitant medications were reported No treatment information was provided. Sender's comment: It was reported that patient's medical record and death certificate were provided. The patient's underlying disease led to death and oxygen complications were also presented before 3rd dose of vaccine has been administered. COMPANY COMMENT : This regulatory authority case concerns a 93-year-old, female patient with relevant medical history of Cor pulmonale chronic, Chronic respiratory failure , Oxygen therapy ,who had a fatal outcome with unexpected serious event of death (seriousness criterion Death) and agonal respiration (seriousness criterion Death) which occurred one day after third dose of mRNA-1273. The patient was noted to have received two doses with Vaxzevria unknown day prior to current vaccination with mRNA-1273 (Interchange of vaccine products). Medical history of relevant medical history of Cor pulmonale chronic, Chronic respiratory failure , Oxygen therapy remains as confounding. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting., Most recent FOLLOW-UP information incorporated above includes: On 17-Feb-2022: Follow-up included relevant past drug history, relevant past historical condition, concomitant medication, added autopsy details, sender's comments and reporter causality updated.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 27-Jan-2022. The most recent information was received on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of ISCHAEMIC STROKE (Ischemic stroke from common and internal left carotid artery occlusion and intracranial occlusion of left and middle and anterior artery.), CAROTID ARTERY OCCLUSION (Ischemic stroke from common and internal left carotid artery occlusion and intracranial occlusion of left and middle and anterior artery.) and CEREBRAL

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	ARTERY OCCLUSION (Ischemic stroke from common and internal left carotid artery occlusion and intracranial occlusion of left and middle and anterior artery.) in a 71-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 017G21A) for COVID-19 vaccination. The patient's past medical history included Tabaquism. Concurrent medical conditions included Hypertension arterial. On 14-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 29-Dec-2021, the patient experienced ISCHAEMIC STROKE (Ischemic stroke from common and internal left carotid artery occlusion and intracranial occlusion of left and middle and anterior artery.) (seriousness criterion death), CAROTID ARTERY OCCLUSION (Ischemic stroke from common and internal left carotid artery occlusion and intracranial occlusion of left and middle and anterior artery.) (seriousness criterion death) and CEREBRAL ARTERY OCCLUSION (Ischemic stroke from common and internal left carotid artery occlusion and intracranial occlusion of left and middle and anterior artery.) (seriousness criterion death). The patient died on 05-Jan-2022. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Dec-2021, Computerised tomogram thorax: inconclusive (Inconclusive) Inconclusive. On 30-Dec-2021, Encephalopathy: inconclusive (Inconclusive) Inconclusive. On 30-Dec-2021, Laboratory test: inconclusive (Inconclusive) Inconclusive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication details was reported. No treatment medication details was reported. The patient's age and medical history of hypertension and Tabaquism, remain as confounders. The benefit-risk relationship of mRNA19 VACCINE is not affected by this report. Company comment: This regulatory authority case concerns a 71-year-old, male patient with a medical history of Hypertension and Tabaquism, who experienced the serious unexpected fatal events of Carotid artery occlusion, Cerebral artery occlusion, and Ischaemic stroke (AESI) (seriousness criterion death) which occurred 15 days after a dose of mRNA-1273 VACCINE, dose number not specified. The patient underwent endovascular treatment with stent placement. It was specified that carotid occlusion with extensive severe ischemic stroke has evolved into brain death. The patient died 22 days after vaccination, 8 days from onset of adverse events. It is unknown if an autopsy was performed. Laboratory reports of Computerized tomogram thorax was Inconclusive, and Encephalopathy was Inconclusive. The patient's age and medical history of hypertension and Tabaquism, remain as confounders. The benefit-risk relationship of mRNA19 VACCINE is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 10-Feb-2022: follow-up received on 10Feb2022 , it contains significant information lab test results updated.
4.1(b) [redacted]	This spontaneous case was reported by a consumer and describes the occurrence of PULMONARY THROMBOSIS (Patient died due to a massive blood clot on her lungs) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History was provided by reporter. Previously administered products included for Drug use for unknown indication: Pfizer covid-19 vaccine (1st dose, Batch number: EN6207) on 15-Mar-2021, Pfizer covid-19 vaccine (2nd dose and Batch number: EW0150) on 05-Apr-2021. Past adverse reactions to the above products included No adverse event with Pfizer covid-19 vaccine and Pfizer covid-19 vaccine. Concomitant products included CLOPIDOGREL BISULFATE (PLAVIX) for Anticoagulant therapy. On 17-Nov-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 18-Nov-2021, the patient experienced FEELING OF BODY TEMPERATURE CHANGE (Hot and cold), DISCOMFORT (Patient had an uncomfortable day) and DIZZINESS (Dizziness). On 06-Dec-2021, the patient experienced PULMONARY THROMBOSIS (Patient died due to a massive blood clot on her lungs) (seriousness criteria death and medically significant). On 19-Nov-2021, FEELING OF BODY TEMPERATURE CHANGE (Hot and cold), DISCOMFORT (Patient had an uncomfortable day) and DIZZINESS (Dizziness) had resolved. The patient died on 06-Dec-2021. The reported cause of death was patient died due to a massive blood clot on her lungs. It is unknown if an autopsy was performed. No treatment information was provided. Husband mentioned that previous to the administration of the booster to his wife, there where warning signs to not to get the Moderna vaccine, and to get a stronger blood thinner first. The reporter stated he would consult the case with a lawyer. Company Comment- This is a fatal case that concerns a 66-year-old female patient with no medical history, who experienced the unexpected serious adverse event of special interest, Pulmonary Thrombosis. The event was medically significant and caused the sudden demise of the patient. The event occurred in 20 days after receiving the third dose of mRNA-1273 Vaccine. The patient died on 06-Dec-2021. The reported cause of death was patient died due to a massive blood clot on her lungs. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Reporter did not allow further contact
4.1(b) [redacted]	This case was received via United Kingdom MHRA (Reference number: 4.1(b) [redacted]) on 27-Jan-2022 and was forwarded to Moderna on 27-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Death), FATIGUE (Fatigue/unusual tiredness) and SYNCOPE (Fainting) in a 78-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 3005287) for an unknown indication.

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	No Medical History information was reported. On 13-Dec-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEATH (Death) (seriousness criteria death and medically significant), FATIGUE (Fatigue/unusual tiredness) (seriousness criterion death) and SYNCOPE (Fainting) (seriousness criteria death and medically significant). The patient died on 30-Dec-2021. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. It was reported that patient was fit and healthy, he felt unwell and died within two weeks of that of a heart attack. Patient was not enrolled in clinical trial Patient has not had symptoms associated with COVID-19 and not had a COVID-19 test The report was related to possible inflammation of the heart (myocarditis or pericarditis) and symptoms didn't lead hospital stay Diagnosis was made by a medical professional Patient took Resuscitation and he didn't went through blood tests, such as for certain proteins (called troponin) that signal heart muscle damage Company Comment: This case concerns a 78-year-old, male patient with no relevant medical history, who experienced the unexpected serious events of Death, Fatigue and Syncope. The event occurred approximately 17 days after the dose 3b of Covid-19 Vaccine Moderna. The rechallenge was unknown since there's no information about the first two doses. The event was considered related to the product per the reporter's assessment. The benefit-risk relationship of Spikevax is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-Jan-2022 and was forwarded to Moderna on 27-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of NAUSEA (Nausea), ASTHENIA (General debility), DEATH (Found dead (cause undetermined)), DIZZINESS (Light headedness), DIARRHOEA (Diarrhoea), DEHYDRATION (Exsiccosis) and MALAISE (Malaise) in a 78-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Adrenal insufficiency, Hashimoto's thyroiditis and Vitamin B12 deficiency. Previously administered products included for COVID-19 vaccination: Comirnaty and VAXZEVRIA. Past adverse reactions to the above products included No adverse event with Comirnaty and VAXZEVRIA. On 04-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Dec-2021, the patient experienced ASTHENIA (General debility) (seriousness criterion death) and MALAISE (Malaise) (seriousness criterion death). On 08-Dec-2021, the patient experienced NAUSEA (Nausea) (seriousness criterion death), DIZZINESS (Light headedness) (seriousness criterion death), DIARRHOEA (Diarrhoea) (seriousness criterion death) and DEHYDRATION (Exsiccosis) (seriousness criterion death). The patient died on 09-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant Medication use information was not provided by reporter. Treatment Medication use information was not provided by reporter. Company comment: This case concerns a 78-year-old female patient, with medical history of adrenal insufficiency, who experienced the serious (fatal), unexpected events of nausea, asthenia, dizziness, diarrhea, dehydration, and malaise. The patient experienced asthenia and malaise 1 day after the third dose of mRNA 1273 COVID-19 vaccine. Four days after vaccine, patient had nausea, dizziness, diarrhea and dehydration. The patient died 5 days after the vaccine. The cause of death was undetermined. It is unknown if an autopsy was done. The patient received COVID-19 vaccines: COMIRNATY AND VAXZEVRIA on unknown date prior to the mRNA 1273 vaccine. The patient's age and medical history of adrenal insufficiency remain as confounder to the events. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 28-Jan-2022. The most recent information was received on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC ARREST (Decease) in a 79-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005291) for COVID-19 vaccination. Concurrent medical conditions included Arterial hypertension, Axial hiatal hernia, B-Lymphocytic, CLL (Kiel Classification), Hyperlipoproteinemia and Thoracic spine degeneration. On 29-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Jan-2022, the patient experienced CARDIAC ARREST (Decease) (seriousness criterion death). The patient died on 01-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. The patient had hypertension, hyperlipoproteinemia, axial hiatal hernia, degenerative BWS changes, B-CLL (small cell lymphocytic lymphoma).

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	Vaccine according to vaccination certificate. On 01.01.2022, the patient had dizziness, dropped in the arms, alerting RTW, upon arrival, pale, cold, hypotonic, hypotonic, but responsible, after 2 min. seizure generalized, short recovery of 2 min, then somnolent, increasingly bradykard, deceased a short time later. Company Comment: This is a fatal regulatory authority case concerning a 79-year-old female patient, with medical history of hypertension and small cell lymphocytic lymphoma. This patient died 4 days after receiving a third dose of mRNA-1273. According to source document narrative, patient was pale, cold and hypotonic when arriving to the ward. He experienced a generalized seizure that recovered and deceased a short time later. No further information, including lab data or treatment, was provided for medical reviewing. The cause of the death of this patient was reported as unknown and also it is also unknown if an autopsy was done. Patient's history of hypertension , lymphoma and age remains as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. This case also reported that patient received 3 dosage forms as dose for the vaccine. Event term was captured as provided by the Regulatory Authority. Most recent FOLLOW-UP information incorporated above includes: On 02-Feb-2022: Follow up contains event coding updated.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of HYPERHIDROSIS (Acute dyspnoea, orthopnea, sweating, followed by loss of consciousness and cardio-circulatory arrest), DYSPNOEA (Acute dyspnoea, orthopnea, sweating, followed by loss of consciousness and cardio-circulatory arrest), CARDIAC ARREST (Acute dyspnoea, orthopnea, sweating, followed by loss of consciousness and cardio-circulatory arrest), LOSS OF CONSCIOUSNESS (Acute dyspnoea, orthopnea, sweating, followed by loss of consciousness and cardio-circulatory arrest) and ORTHOPNOEA (Acute dyspnoea, orthopnea, sweating, followed by loss of consciousness and cardio-circulatory arrest) in an 86-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 044G21A) for COVID-19 vaccination. Co-suspect product included non-company product INFLUENZA VACCINE INACT SAG 4V (FLUAD TETRA) for Influenza immunization. The patient's past medical history included Hypertensive heart disease. Concomitant products included SERTRALINE for Depression, HYDROCHLOROTHIAZIDE, VALSARTAN (COTAREG) for Hypertension arterial. On 19-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter and dose of INFLUENZA VACCINE INACT SAG 4V (FLUAD TETRA) (Intramuscular) 1 dosage form. On 08-Jan-2022, the patient experienced HYPERHIDROSIS (Acute dyspnoea, orthopnea, sweating, followed by loss of consciousness and cardio-circulatory arrest) (seriousness criterion death), DYSPNOEA (Acute dyspnoea, orthopnea, sweating, followed by loss of consciousness and cardio-circulatory arrest) (seriousness criterion death), CARDIAC ARREST (Acute dyspnoea, orthopnea, sweating, followed by loss of consciousness and cardio-circulatory arrest) (seriousness criterion death), LOSS OF CONSCIOUSNESS (Acute dyspnoea, orthopnea, sweating, followed by loss of consciousness and cardio-circulatory arrest) (seriousness criterion death) and ORTHOPNOEA (Acute dyspnoea, orthopnea, sweating, followed by loss of consciousness and cardio-circulatory arrest) (seriousness criterion death). The patient died on 08-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided. This is a regulatory case concerning a 86-year-old fmale patient with medical history of hypertensive heart disease, who experienced the serious unexpected events of loss of consciousness, cardiac arrest, dyspnea, orthopnea and hyperhidrosis (seriousness criterion death). These events occurred approximately 19 days after the patient received a dose of mRNA-1273 (Spikevax) and a dose of Influenza Vaccine FLUAD TETRA. The rechallenge was unknown since there's only information about a non-specific dose. The benefit-risk relationship of Spikevax Vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 31-Jan-2022: Follow up received that contains Non significant information, sender comment updated. On 09-Feb-2022: Follow-up received on 09-FEB-2022: contains No new information. On 07-Mar-2022: No new information.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 28-Jan-2022. The most recent information was received on 08-Feb-2022 and was forwarded to Moderna on 08-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of VENTRICULAR FIBRILLATION (Ventricular fibrillation), MYOCARDIAL ISCHAEMIA (Ischaemic heart disease) and BRAIN INJURY (Anoxic brain damage) in an 86-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006274) for an unknown indication. No Medical History information was reported. On 15-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Dec-2021, the patient experienced VENTRICULAR FIBRILLATION (Ventricular fibrillation) (seriousness criterion death), MYOCARDIAL ISCHAEMIA (Ischaemic heart disease) (seriousness criterion death) and BRAIN INJURY (Anoxic brain damage) (seriousness criterion death). The patient died on 23-Dec-2021. The reported cause of death was Ischaemic heart disease. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication provided. No treatment information mentioned. Company comment: This is a regulatory case concerning an 86-year-old male patient with no medical history reported who experienced the unexpected and serious events of ventricular fibrillation, myocardial ischaemia and brain injury the same day a third dose of mRNA-1273 vaccine. The patient died 8

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	days after vaccination. The reported cause of death was Ischaemic heart disease. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 08-Feb-2022: Significant follow up received on 08-Feb-2022 and contains cause of death and new events updated.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of CEREBROVASCULAR ACCIDENT (Right carotid dissection with stroke in middle right brain territory) in an 81-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Hypertension NOS and Diabetes. On 18-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) .5 milliliter. On 19-Dec-2021, the patient experienced CEREBROVASCULAR ACCIDENT (Right carotid dissection with stroke in middle right brain territory) (seriousness criterion death). The patient died on 19-Dec-2021. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications reported No treatment medications provided Company Comment: This case concerns a 81-year-old female patient with medical history of hypertension and diabetes reported, who experienced the serious unexpected event of Cerebrovascular accident with fatal outcome. The event occurred on the day after a dose of mRNA-1273 received for COVID-19 Vaccination. It was reported that the patient experienced a right carotid dissection with stroke in middle right brain territory however very limited information regarding this event has been provided at this time and it is unknown if an autopsy was performed. The medical history of hypertension and diabetes as well as patient's advanced age remain as confounding risk factor. No concomitant medication or treatment information was reported. The benefit-risk relationship of COVID-19 Vaccine Moderna (mRNA-1273) is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY OEDEMA (Lung oedema) and CARDIAC ARREST (Cardiac arrest) in a 72-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000120A) for COVID-19 vaccination. The patient's past medical history included Cardiac arrhythmia, Renal insufficiency and COPD. Previously administered products included for COVID-19 vaccination: SPIKEVAX on 06-Dec-2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX. On 04-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 2 dosage form. On 06-Jan-2022, the patient experienced PULMONARY OEDEMA (Lung oedema) (seriousness criterion death) and CARDIAC ARREST (Cardiac arrest) (seriousness criterion death). The patient died on 06-Jan-2022. The reported cause of death was Heart arrest. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant drug has been provided. No treatment drug has been provided. Company comment: This is a regulatory case concerning a 72-year-old, female patient with a history of Arrhythmia, Chronic obstructive pulmonary disease and Renal failure, who experienced the serious (fatal) unexpected, according CCDS, AESI of Pulmonary oedema and, the serious (fatal) unexpected, according CCDS, event of Cardiac arrest. The events occurred approximately 2 days after the mRNA-1273 vaccine, dose number not provided. It is unknown whether an autopsy was performed. The patient had a fatal outcome 2 days after vaccination. The rechallenge was not applicable due to the fatal outcome. The medical history of Arrhythmia, Chronic obstructive pulmonary disease and Renal failure remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of SUDDEN DEATH (Death sudden) in a 69-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 28-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .25 dosage form. The patient died on 30-Dec-2021. The reported cause of death was sudden death (10052810). It is unknown if an autopsy was performed. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 28-Dec-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication was not provided. Treatment information was not provided.

Case ID	Narrative (Complete)
	Company comment: This case concerns a 69-year-old female patient with no medical history provided who experienced serious unexpected event of Sudden death. Very limited information provided precluding comprehensive assessment. The event occurerd two days after the third, booster dose of mRNA-1273. The cause of death was not provided. Furthermore, it is unknown if an autopsy was performed. The rechallenge was not applicable as the patient died. Causality is confounded with patient's advanced age. The benefit-risk relationship of mRNA-1273 is not affected by this report. Dose was reported as 0.25 dosage form and was retained as such.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Jan-2022 and was forwarded to Moderna on 28-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (Fever), MUSCLE SPASMS (lung edema, temperature increase, AZ reduced, spasm), PULMONARY OEDEMA (lung edema, temperature increase, AZ reduced, spasm), DEATH (cause of death unknown) and GENERAL PHYSICAL HEALTH DETERIORATION (lung edema, temperature increase, AZ reduced, spasm) in an 81-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 08-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Jan-2022, the patient experienced PYREXIA (Fever) (seriousness criterion hospitalization), MUSCLE SPASMS (lung edema, temperature increase, AZ reduced, spasm) (seriousness criterion hospitalization), PULMONARY OEDEMA (lung edema, temperature increase, AZ reduced, spasm) (seriousness criterion hospitalization) and GENERAL PHYSICAL HEALTH DETERIORATION (lung edema, temperature increase, AZ reduced, spasm) (seriousness criterion hospitalization). The patient died on 06-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, PYREXIA (Fever), MUSCLE SPASMS (lung edema, temperature increase, AZ reduced, spasm), PULMONARY OEDEMA (lung edema, temperature increase, AZ reduced, spasm) and GENERAL PHYSICAL HEALTH DETERIORATION (lung edema, temperature increase, AZ reduced, spasm) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company Comment: This is a RA case concerning an 81-year-old female patient, with medical history of diabetes mellitus and renal insufficiency, who experienced the unexpected and serious events of Pyrexia, Muscle spasms, Pulmonary oedema (AESI), and General physical health deterioration. Seriousness assessed due to hospitalization. The events occurred 24 days after an unknown dose of mRNA-1273 vaccine. The event of Death occurred 29 days after vaccination. It is unknown if an autopsy was performed. The cause of death was not reported. The medical history remains confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 27-Jan-2022. The most recent information was received on 21-Feb-2022 and was forwarded to Moderna on 01-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref. 4.1(b) On 21-Feb-2022, follow-up information was received from a physician. The patient was taking lansoprazole 15 mg for gastritis and also continuing to take zonisamide 100 mg as prescribed by a previous physician. On 26-Jul-2011, the patient started to take memantine hydrochloride 5 mg for dementia. On 29-Jul-2019, the patient started to take enteral nutrition 250 mL. On 27-Sep-2021, the patient started to take memantine hydrochloride 10 mg for dementia. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (unknown product name). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (unknown product name). On an unknown date, body temperature before the vaccination: 36.1 degrees Celsius. On 26-Jan-2022, around 10:00, as the patients condition was normal, the 3rd vaccination with this vaccine was performed. On 27-Jan-2022, around 06:10, the patient did not have any significant changes and was in a sitting position in the living room. Around 06:15, a facility care staff found the patient in respiratory arrest. Cardiac massage was performed, but the patient did not recover. At 07:37, the patient was in cardio-respiratory arrest. The reporting hospital, which performed visiting medical examination, visited the patient's home and confirmed death. The symptoms were sudden onset and considered to be arrhythmia due to myocardial infarction. The cause of death was myocardial infarction. There were no abnormal findings in medical examination, and the relationship was unknown. Since the patient was old, the above measures were taken without the family members request for life-prolonging treatment. The outcome of respiratory arrest, cardio-respiratory arrest, arrhythmia, and myocardial infarction was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The occurrence of adverse events is not related to concomitant drug because the patient was taking drugs for a long time and had no previous problems before. The patient was at an old age, and death is very likely to have been caused by sudden pain. Follow-up received on 21-FEB-2022 Updated: Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. Company comment: The case concerns a 96-year-old female patient with medical history of cerebral infarction, who experienced unexpected fatal events of Myocardial infarction (AESI), cardio respiratory arrest, arrhythmia and Respiratory arrest. The events were considered serious per death and medically significant criteria. The events occurred approximately 1 day after the third dose of mRNA 1273 vaccine. As reported, a facility care staff found the patient in respiratory arrest. Cardiac massage was performed, but the patient did not recover and was in cardio-respiratory arrest. The reporting hospital, which performed visiting medical examination, visited the patient's home and confirmed death. The symptoms were with sudden onset and considered to be arrhythmia due to myocardial infarction. The cause of death was myocardial infarction, as reported. There were no abnormal findings in medical examination. The outcome of the events was reported as fatal. Patient's advanced age and prior history of cerebral infarction remain as confounders. The benefit risk relationship of vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 29-Jan-2022 and was forwarded to Moderna on 29-Jan-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (cause of death unknown) in an 81-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000114AM) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Heart valve calcification.

Case ID	Narrative (Complete)
	On 30-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Jan-2022, the patient experienced FATIGUE (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden), PARAESTHESIA (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden), VOMITING (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden) and INFLUENZA (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden). The patient died on 07-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, FATIGUE (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden), PARAESTHESIA (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden), VOMITING (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden) and INFLUENZA (hot flashes, body aches, vomiting and a feeling as if electricity is being chased through the body. So exhausted that bedridden) had not resolved. Treatment medication was not provided. No Information about risk factors or pre-existing conditions. A slightly calcified heart valve has been treated with medication. At the end of November 2021, a follow-up examination took place by cardiologists impression were nothing was noticeable. Patient was doing well before vaccination. After the booster she felt very bad after 2 days and after a week she died in bed at night. Company comment: This regulatory authority case concerns an 81-year-old female patient with no relevant medical history who experienced serious unexpected event of death, that occurred approximately 8 days after the booster dose of the mRNA-1273 . The rechallenge was not applicable due to occurrence after the booster dose and fatal outcome of the event. The cause of death was not reported. The patient had concurrent condition of calcification of heart valve however the most recent cardiologist consultation did not show anything significant. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b)) on 27-Jan-2022. The most recent information was received on 04-Feb-2022 and was forwarded to Moderna on 08-Feb-2022. This case was reported by a physician via the Drug Information Center. On 04-Feb-2022, follow-up information, reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref. 4.1(b)). On 19-Jun-2021, the patient received the 1st dose of SARS-CoV-2 (coronavirus modified uridine RNA vaccine). On 10-Jul-2021, the patient received the 2nd dose of SARS-CoV-2 (coronavirus modified uridine RNA vaccine). On an unknown date, body temperature before the vaccination: 36.7 degrees Celsius. On 23-Jan-2022, at 17:00, the patient received the 3rd vaccination with this vaccine. On 24-Jan-2022, at 10:45, the patient noticed shortness of breath and visited another hospital. After returning home, the patient was transported to the reporting hospital by ambulance in cardio-respiratory arrest. Although resuscitation was performed, no return of spontaneous circulation was noted. At 12:03, the patient was confirmed dead. CT scan showed suspected acute aortic dissection. The cause of death was acute aortic dissection. The outcome of shortness of breath, cardio-respiratory arrest, and acute aortic dissection was reported as fatal. Follow-up investigation will be made. Reporter comments continuation: It is unknown whether shortness of breath was due to an adverse reaction after the vaccination with this vaccine or a symptom of acute aortic dissection. In addition, the association between vaccination with the vaccine and acute aortic dissection cannot be ruled out. As another factor, shortness of breath may have been caused by acute aortic dissection. Follow-up received on 04-FEB-2022 Updated: Reporter Information, Patient Information, Lab Data, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b)) on 28-Jan-2022. The most recent information was received on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (high temperature), TACHYCARDIA (Tachycardia), HYPERTENSION (Hypertension) and OXYGEN SATURATION DECREASED (Oxygen saturation decreased) in a 79-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Pulmonary fibrosis, Chest infection, Breathlessness, Oxygen saturation low, Arthritis and COVID-19 in November 2021. Previously administered products included for Product used for unknown indication: Steroid therapy (Taking regular steroid treatment (e.g. orally or rectally)). Past adverse reactions to the above products included No adverse reaction with Steroid therapy. Concurrent medical conditions included Hypertension. Concomitant products included SALBUTAMOL for Breathing difficult, DOXYCYCLINE from 11-Jan-2022 to 17-Jan-2022 for Chest infection, ATORVASTATIN for Cholesterol, MORPHINE for Pain, TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) from 30-Jan-2021 to an unknown date for Vaccination. On 13-Jan-2022, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 13-Jan-2022, the patient experienced TACHYCARDIA (Tachycardia) (seriousness criteria death and hospitalization). On an unknown date, the patient experienced PYREXIA (high temperature) (seriousness criterion hospitalization), HYPERTENSION (Hypertension) (seriousness criterion hospitalization) and OXYGEN SATURATION DECREASED (Oxygen saturation decreased) (seriousness criterion hospitalization). The patient died on 26-Jan-2022. An autopsy was not performed. At the time of death, PYREXIA (high temperature), HYPERTENSION (Hypertension) and OXYGEN SATURATION DECREASED (Oxygen saturation decreased) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) No - Negative COVID-19 test. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. The concomitant medication included DEXAMETASONE used for an unknown indication. Patient has not tested positive for COVID-19 since having the vaccine. He was not enrolled in clinical trial. Previous COVID infection in Nov 2021 which had reduced lung functioning, hypertension, arthritis. Admitted to hospital 10/1/22 for low oxygen saturation, SOB, chest infection. Palliative care review for breathlessness on admission. He was tachycardic, low BP increased HR and low oxygen levels. High temperature within an hour of covid vaccination. His poor condition due to comorbidities prior to vaccine, but onset of symptoms post

Case ID	Narrative (Complete)
	vaccination. He had severe pulmonary fibrosis and on long term oxygen. Unsure if he has had symptoms associated with COVID-19. He died on 26-Jan-2022. Company Comment: This is a RA case concerning a 79-year-old male patient, with medical history of COVID-19 infection which had reduced lung functioning, pulmonary fibrosis, chest infection, breathlessness, hypertension, oxygen saturation low, and arthritis, who experienced the unexpected and serious events of Pyrexia, Hypertension, and Tachycardia. Patient received Pfizer vaccine against COVID-19, and 1 year later received a third dose with mRNA-1273 (Moderna covid-19 vaccine). The events occurred the same day after the third dose with mRNA-1273 vaccine. Patient died 13 days after vaccination. This patient poor medical conditions prior to vaccination remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 02-Feb-2022: Follow up received wherein, events and lab data was added, outcome of events high temperature and Tachycardia were updated. On 02-Feb-2022: Upon query received from business partner, Non-Significant correction was performed on 15-FEB-2022. Updated Concomitant medication Dexametasone.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 31-Jan-2022 and was forwarded to Moderna on 31-Jan-2022. This regulatory authority case was reported by a physician and describes the occurrence of PYREXIA (Pyrexia), SUDDEN DEATH (Sudden death unexplained), DROP ATTACKS (Drop attacks) and ATONIC SEIZURES (Drop seizures) in an 83-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3001651) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: COVID-19 mRNA Vaccine COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax (Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax) on 23-Mar-2021 and COVID-19 VACCINE (Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax) on 21-Apr-2021. Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE and COVID-19 mRNA Vaccine COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax. On 21-Apr-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 08-Dec-2021, the patient experienced PYREXIA (Pyrexia) (seriousness criterion death), DROP ATTACKS (Drop attacks) (seriousness criterion death) and ATONIC SEIZURES (Drop seizures) (seriousness criterion death). The patient died on 08-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Treatment information not provided. Concomitant medication not provided. Company comment: This case concerns a 83-year-old male patient, with no reported medical history, who experienced the serious, fatal, unexpected events of pyrexia, sudden death, drop attacks, and atonic seizures. The events occurred 7 months after the first dose of mRNA 1273 COVID-19 vaccine. Previously administered products to the patient includes 2 doses of mRNA 1273 COVID-19 vaccine. The patient died 8 months after the vaccine, cause of death was not reported. It is unknown if an autopsy was performed. The patient's age and long onset latency of events remain as confounders to the events. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (Myocardial infarction) in an 80-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Arthrosis. On 05-Nov-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDIAL INFARCTION (Myocardial infarction) (seriousness criterion death). The patient died on 10-Nov-2021. The reported cause of death was cardiac arrest. It is unknown if an autopsy was performed. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on an unknown date. No concomitant medication was reported. No treatment information was provided. Company comment: This case concerns 80-years-old, female patient with past medical history of Arthrosis , who experienced the unexpected Fatal AESI event of Myocardial infarction (seriousness criteria death). The event occurred on unknown date after to the second dose of mRNA-1273 vaccine. At the time of report, very limited information has been provided about the patient and about the event leading to the fatal outcome. The reported cause of death was cardiac arrest. It is also unknown if an autopsy was performed. Patient's elderly age and past medical history remains a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death unexplained) in a 65-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000105A) for COVID-19 vaccination. The patient's past medical history included Coronary disease, Atrial fibrillation and Arterial hypertension.

Case ID	Narrative (Complete)
	On 05-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 06-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. No treatment information was provided. Company comment: This is a regulatory authority case concerning a 65-year-old male patient with a relevant medical history of coronary disease, atrial fibrillation and arterial hypertension, who experienced the serious unexpected event of sudden death. The event of sudden death occurred approximately 2 days after the booster dose of mRNA-1273 (Spikevax). The cause of death, clinical details, labs/diagnostic results and concomitant medications not reported. The medical history of coronary disease, atrial fibrillation complicated by arterial hypertension could be confounders. The benefit-risk relationship of mRNA-1273 (Spikevax) is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 01-Feb-2022 and was forwarded to Moderna on 01-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of SHOCK HAEMORRHAGIC (Hemorrhagic shock), COAGULOPATHY (Clotting disorder), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure), HEPATIC FAILURE (Hepatic failure), COVID-19 (SARS-CoV-2 infection) and THROMBOCYTOPENIA (Thrombopenia) in a 69-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000105A) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 10-May-2021 and Comirnaty BNT162b2 on 02-Aug-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca. Concurrent medical conditions included SARS-CoV-2 infection. On 07-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced SHOCK HAEMORRHAGIC (Hemorrhagic shock) (seriousness criteria death, hospitalization and life threatening), COAGULOPATHY (Clotting disorder) (seriousness criteria death, hospitalization and life threatening), MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure) (seriousness criteria death, hospitalization and life threatening), HEPATIC FAILURE (Hepatic failure) (seriousness criteria death, hospitalization and life threatening) and THROMBOCYTOPENIA (Thrombopenia) (seriousness criteria death, hospitalization and life threatening). On an unknown date, the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criteria death, hospitalization and life threatening). The patient died on 09-Jan-2022. The reported cause of death was Multiorgan failure. An autopsy was not performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not provided. Treatment information was not provided. Company Comment: This case concerns a 69-year-old female patient, with relevant medical history of previous vaccination with Vaxzevria COVID-19 Vaccine and Comirnaty BNT162b2, who experienced the unexpected serious events of Shock Hemorrhagic, Coagulopathy, Multiple organ dysfunction syndrome, Hepatic failure and Thrombocytopenia. The events occurred approximately 2 days after receiving a dose of mRNA-1273 Vaccine and resulted in a fatal outcome. The unexpected serious AESI event of COVID-19 occurred on an unknown date. The reported cause of death was Multiorgan failure. An autopsy was not performed. The patient's medical history of previous vaccination with Vaxzevria COVID-19 Vaccine and Comirnaty BNT162b2, remain as confounders for the occurrence of the events. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 01-Feb-2022. The most recent information was received on 03-Mar-2022 and was forwarded to Moderna on 03-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Strong fatigue and head turns, on 5 January she died due to cardiac intercameral thrombus.), VERTIGO (Strong fatigue and head turns, on 5 January she died due to cardiac intercameral thrombus.) and THROMBOSIS (Strong fatigue and head turns, on 5 January she died due to cardiac intercameral thrombus.) in a 65-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Decompensation cardiac (DECOMPENSATION WITH SEVERE BIVENTRICULAR DYSFUNCTION. IN TP WITH ENTRESTO), Atrial fibrillation (DOES PERSISTENT PERMANENT WITH BIATRILE EXPANSION AND VALVE INSUFFICIENCIES THAT FROM MILD (4 YEARS AGO)) and Tricuspid insufficiency (SEVERE TRICUSPID INSUFFICIENCY). On 28-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 dosage form. On 29-Dec-2021, the patient experienced FATIGUE (Strong fatigue and head turns, on 5 January she died due to cardiac intercameral thrombus.) (seriousness criterion death), VERTIGO (Strong fatigue and head turns, on 5 January she died due to cardiac intercameral thrombus.) (seriousness criterion death) and THROMBOSIS (Strong fatigue and head turns, on 5 January she died due to cardiac intercameral thrombus.) (seriousness criterion death). It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. No concomitant medications were reported. No treatment drugs were reported.

Case ID	Narrative (Complete)
	Company comment: This is a regulatory case concerning a 65-year-old female patient with a medical history of tricuspid insufficiency, atrial fibrillation and decompensation cardiac, who experienced the unexpected serious fatal events of Fatigue, Thrombosis and Vertigo one day after the unspecified dose of mRNA-1273 vaccine. It was reported that the patient experienced strong fatigue and head turns, and she died due to cardiac intercameral thrombus. Biatrial dilation and moderate valve insufficiencies, decompensation with severe bi ventricular dysfunction and atrial fibrillation (ECG) were also reported, which may suggest underlying medical condition. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 03-Mar-2022: medical history were added and action taken updated to unknown. On 28-Mar-2022: Non Significant follow up received:Event verbatim updated On 22-Apr-2022: Follow-up received included updated events verbatim.
4.1(b) [redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of RESPIRATORY FAILURE (Respiratory failure) and COVID-19 (COVID-19) in an 80-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: John BV, Deng Y, Khakoo NS, Taddei TH, Kaplan DE, Dahman B. Coronavirus disease 2019 vaccination is associated with reduced severe acute respiratory syndrome coronavirus 2 infection and death in liver transplant recipients. Gastroenterology. 2022;162(2):645-7 The patient's past medical history included Liver transplant. Concurrent medical conditions included Cirrhosis liver (compensated graft cirrhosis), Cardiomyopathy (non ischemic cardiomyopathy), Atrial fibrillation and Chronic kidney disease. Concomitant products included TACROLIMUS for Liver transplant. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced RESPIRATORY FAILURE (Respiratory failure) (seriousness criteria death and medically significant) and COVID-19 (COVID-19) (seriousness criterion death). The reported cause of death was Respiratory failure and covid-19. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Of the 2 postvaccination COVID-19 deaths, the first was an 80-year-old man who was 9 years post-transplant on tacrolimus, with compensated graft cirrhosis, nonischemic cardiomyopathy, atrial fibrillation, and chronic kidney disease. Patient developed COVID-19 18 days after the second dose of mRNA-1273 vaccine. This patient required mechanical ventilation, pressors, and dialysis and died from respiratory failure. Company Comment: This is a literature case concerning a death of an 80-year-old male patient with medical history of liver transplant, Cirrhosis liver (compensated graft cirrhosis), Cardiomyopathy (non ischemic cardiomyopathy), Atrial fibrillation and Chronic kidney disease, on tacrolimus therapy, who experienced the fatal unexpected AESI of COVID-19 and fatal serious unexpected event of respiratory failure. The events occurred 18 days after the second dose of the mRNA-1273 vaccine. As reported, the patient developed COVID-19 18 days after the second dose of mRNA-1273 vaccine. The administration date of first dose was not provided. Patient required mechanical ventilation, pressors, and dialysis and died from respiratory failure. Based on the current available information, the mRNA-1273 does not contain a virus capable of causing COVID-19 infection after vaccination. Hence, considering that respiratory failure was likely caused by COVID 19 causality for event is assessed as not related per Company. Above mentioned patient's medical history and advanced age might have contributed to fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 03-Feb-2022: Follow up received by safety 03-Feb-2022 has Email with FTA received from SARA team and contains significant information: Medical history, reporter information, Authors, concomitant medication and non drug treatment for COVID-19.
4.1(b) [redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of RESPIRATORY FAILURE (respiratory failure) and COVID-19 PNEUMONIA (COVID-19 pneumonia) in an 82-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: JOHN BV, DENG Y, KHAKOO NS, TADDEI TH, KAPLAN DE, DAHMAN B. Coronavirus disease 2019 vaccination Is associated with reduced severe acute respiratory syndrome coronavirus 2 infection and death in liver transplant recipients. Gastroenterol. 2022;162(2):645-7 The patient's past medical history included Liver transplant (Patient was 8 years post-transplant on single-agent tacrolimus). Concurrent medical conditions included Coronary artery disease, Diabetes mellitus and Chronic kidney disease. Concomitant products included TACROLIMUS for Immunosuppression. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced RESPIRATORY FAILURE (respiratory failure) (seriousness criteria death and medically significant) and COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death and medically significant). The reported cause of death was Respiratory failure and COVID-19 pneumonia. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered RESPIRATORY FAILURE (respiratory failure) and COVID-19 PNEUMONIA (COVID-19 pneumonia) to be related. Company comment: This is a literature case concerning an 82-year-old male patient with medical history of liver transplant, coronary artery disease, diabetes mellitus and chronic kidney disease, who experienced the serious unexpected AESI of COVID-19 pneumonia and serious unexpected fatal event of respiratory failure.

Case ID	Narrative (Complete)
	The events occurred 10 days after the second dose of the mRNA-1273 vaccine. Based on the current available information, the mRNA-1273 vaccine does not contain a virus capable of causing COVID-19 infection after vaccination, therefore, the causality for COVID-19 pneumonia is not applicable, while the causality for the event respiratory failure was assessed as related. The rechallenge was not applicable due to the events outcome. The patient's advanced age, underlying medical history and immunosuppressive therapy remain a confounder for the development of COVID-19 pneumonia and subsequent respiratory failure. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 03-Feb-2022: Follow-up received by safety on 03-Feb-2022 included an Email with FTA received from SARA team includes significant information. Literature Information, Relevant history, Concomitant medication were updated.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: P 4.1(b)) on 01-Feb-2022. The most recent information was received on 24-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) in a 76-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 300042722 & UNK and 300042722 & UNK) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Revaccination with different COVID-19 vaccine. The patient's past medical history included Renal transplant on 21-Apr-2021 and Aortocoronary bypass. Concurrent medical conditions included Sleep apnoea syndromes, Gout, Deafness bilateral, Venous thrombosis deep limb, Ischaemic heart disease, Dyslipidaemia, Hypertension arterial, Anterior ischaemic optic neuropathy in November 2021 and Atrioventricular block third degree. On 12-Feb-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 3 dosage form. On 21-May-2021, received dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 3 dosage form. On 16-Dec-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 28-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). The patient died on 22-Jan-2022. The reported cause of death was pneumopathie covid-19. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Dosage text was reported as 1 DF x3 total D1+D2+D3. No treatment information was provided. Company Comment: This regulatory authority case concerns a 76-year-old male patient with no relevant medical history reported, who experienced the fatal unexpected serious event of Vaccination failure which occurred 221 days after the administration of a dose of the mRNA-1273 vaccine and 12 days after the administration of Co-suspect product (non-company product) TOZINAMERAN (COMIRNATY). The patient died approximately 8 months after vaccination with mRNA-1273 and 37 days after the administration of Co-suspect product (non-company product) TOZINAMERAN (COMIRNATY). The reported cause of death was COVID-19 pneumonia. It is unknown if an autopsy was performed. The patient received the second dose 98 days after the first dose, which is not in accordance with the recommended vaccine interval. The patient was noted to have received a different brand of covid-19 vaccine from TOZINAMERAN (COMIRNATY) 6 months 25 days after vaccination with mRNA1273 (Interchange of vaccine products). Patients elderly age could be confounding. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events were assessed as serious as per Regulatory Authority´s report. Most recent FOLLOW-UP information incorporated above includes: On 24-Mar-2022: Follow-up information received included added death date (22-JAN-2022) and cause of death (COVID-19 pneumonitis), event start date corrected from 21-Dec-2021 to 28-Dec-2021, event outcome updated from NOT RECOVERED/NOT RESOLVED to FATAL and seriousness criterion updated from HOSPITALIZATION to DEATH.
4.1(b)	This literature-non-study case was reported in a literature article and describes the occurrence of HEAD INJURY (head injury) in a 65-year-old male patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. LITERATURE REFERENCE: YEO A, KUEK B, LAU M, TAN SR, CHAN S. Post COVID-19 vaccine deaths - Singapore's early experience. Forensic Sci Int. 2022;332:111199 No Medical History information was reported. In 2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. In 2021, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced HEAD INJURY (head injury) (seriousness criteria death, hospitalization and medically significant). The patient died in 2021. The reported cause of death was Head injury. An autopsy was performed, but no results were provided. Related DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood immunoglobulin E: 173 iu/ml 173 IU/mL. On an unknown date, C-reactive protein: 28.1 mg/l 28.1 mg/L. On an unknown date, Tryptase: 39.2 ug/l 39.2 ug/l. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered HEAD INJURY (head injury) to be related. Author stated that our study has shown no definite causative relationship between the mRNA vaccination and deaths of individuals who died within 72 hours (h) after receiving the vaccination, in particular with regards to anaphylactic reactions, myocarditis and pericarditis, and thrombotic complications. Further studies may consider increasing the incident time frame from 72 h to seven days post-vaccination or longer to include any potential delayed presentation of adverse effects. Concomitant and treatment medications were not reported.

Case ID	Narrative (Complete)
	Company Comment: This is a literature case that concerns a 65-year-old male patient with no medical history, who experienced the unexpected serious event of Head Injury. The event was medically significant, led to the hospitalization, and eventual demise of the patient. The event occurred on an unknown interval after receiving the second dose of mRNA-1273 Vaccine. The patient died on an unknown date. The reported cause of death was Head injury. An autopsy was performed, but no results were provided. No clinical or treatment details were given. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. This case was linked to 4.1(b) [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 03-Feb-2022: Follow-up received by safety on 03-Feb-2022 included an Email with FTA received from SARA team includes significant information lab data, autopsy details, hospitalization were added.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of VOMITING (Vomiting), NAUSEA (Nausea), PYREXIA (Fever), DIARRHOEA (Diarrhoea) and MALAISE (Malaise) in an 89-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 13-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 13-Jan-2022, the patient experienced VOMITING (Vomiting) (seriousness criterion death), NAUSEA (Nausea) (seriousness criterion death), PYREXIA (Fever) (seriousness criterion death), DIARRHOEA (Diarrhoea) (seriousness criterion death) and MALAISE (Malaise) (seriousness criterion death). The patient died on 17-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not reported . Treatment information was not provided. Company comment: This regulatory authority case concerns a 89-year-old male patient with no reported relevant medical history, who experienced the serious unexpected events of vomiting, nausea, pyrexia, diarrhea and malaise one day after the unspecified dose number of mRNA-1273 (Spikevax). The events are unexpected as they are retained as serious and fatal events per the source document authority reporting. Cause of death, complete medical history, labs/diagnostic results, clinical course, concomitant medications and the treatment was not reported. The benefit-risk relationship of mRNA-1273 (Spikevax) is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of HAEMORRHAGIC STROKE (Hemorrhagic stroke of cerebral barter) in a 79-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 006G21A) for COVID-19 vaccination. The patient's past medical history included Myalgia since 29-Oct-2021, CVA (ischemic), Hypertension arterial (balanced according to the attending physician but noted as no followed by the patient) since an unknown date, Ex-smoker (weaned in 2020), Dyslipidaemia since an unknown date and Arrhythmia (with MP laying) since 2020. Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) from 30-Mar-2021 to 22-Jun-2021 for COVID-19 immunisation, RAMIPRIL for Hypertension arterial, ACETYLSALICYLIC ACID (ASPIRINETAS) for Implantable cardiac monitor insertion. On 13-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced HAEMORRHAGIC STROKE (Hemorrhagic stroke of cerebral barter) (seriousness criterion death). The patient died on 04-Jan-2022. The reported cause of death was hemorrhagic stroke of cerebral barter. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Jan-2022, Computerised tomogram: massive hemorrhagic stroke Massive hemorrhagic stroke. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Coronary heredity was reported. Treatment information was not provided. Company comment: This case concerns a 79-year-old male patient with medical history of CVA, Hypertension, Dyslipidaemia and Arrhythmia, who died due to Hemorrhagic stroke 22 days after the third dose of mRNA-1273. Computerised tomogram one day before death confirmed massive hemorrhagic stroke. An autopsy was not performed. and the reported cause of death was hemorrhagic stroke of cerebral barter. The patient's medical history of CVA, Hypertension, Dyslipidaemia and Arrhythmia in addition to the patient's advanced age, remains a strong confounder. The reporter did not provide causality assessment. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Having in mind that this patient received the COVID-19 VACCINE ASTRAZENECA prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of SUDDEN DEATH (Death on 18.12.21) in a 70-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Patient had high blood pressure on 05.08.1951.

Case ID	Narrative (Complete)
	Previously administered products included for Prophylactic vaccination: Comirnaty and COVID-19 Vaccine AstraZeneca. Past adverse reactions to the above products included No adverse event with COVID-19 Vaccine AstraZeneca and Comirnaty. On 29-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. The patient died on 18-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant medications were reported. No treatment medications were reported. Company comment: This Regulatory authority case concerns a 70-year-old, female patient, with medical history of hypertension, who experienced the unexpected, serious (fatal) event of sudden death. The event occurred 19 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the patient COVID-19 vaccination schedule as she previously received a dose of AstraZeneca's COVID-19 vaccine and another of Cominarty's COVID-19 vaccine. The cause of death was reported as unknown. Autopsy report is not available. No further clinical information was provided for medical reviewing. The medical history of hypertension remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of SUDDEN DEATH (just dropped and dead. Suddenly and unexpectedly.) in a 67-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004951) for COVID-19 vaccination. Previously administered products included for Prophylactic vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 21-Apr-2021 and Comirnaty BNT162b2 on 14-Jul-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca. On 13-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 16-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. Reporter reported pre-existing illnesses on 2013, bypass at Herzen. Blood thinner, last analysis at cardiologist inconspicuous. After the first two vaccinations, a few days of rest and then it went back. Treatment medication was not provided by the reporter. Company comment: This Regulatory authority case concerns a 67-year-old, male patient, with medical history of Obesity (Body mass index 39.63) and unspecified bypass, who experienced the unexpected, serious (fatal) event of sudden death. The event occurred 3 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the patient COVID-19 vaccination schedule as he previously received as first dose an AstraZeneca's COVID-19 vaccine and as second a Cominarty's COVID-19 vaccine. The cause of death was reported as unknown. Autopsy report is not available. No further clinical information was provided for medical reviewing. The medical history of Obesity (Body mass index 39.63) and unspecified bypass remains as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 01-Feb-2022. The most recent information was received on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PNEUMONIA (Then his lungs were full and had pneumonia.) in an 84-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Pulmonary embolism (Family history: False), Arrhythmia (Family history: False), Pneumonia (Family history: False) and Pulmonary edema (Family history: False). Previously administered products included for Product used for unknown indication: COMIRNATY (BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST) on 12-Feb-2021, COMIRNATY (BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST) on 26-Mar-2021. Past adverse reactions to the above products included No adverse reaction with COMIRNATY and COMIRNATY. Concurrent medical conditions included Esophageal cancer metastatic (Family history: False). Concomitant products included BROTIZOLAM (LENDORMIN), OXYCODONE HYDROCHLORIDE (OXYCODON), ASCORBIC ACID, FOLIC ACID, IRON PIDOLATE (B IJZER NUTRIDOSES), ANTICOAGULANT CITRATE DEXTROSE and CODEINE SULFATE (CODEINE SULPHATE) for an unknown indication. On 29-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 01-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced PNEUMONIA (Then his lungs were full and had pneumonia.) (seriousness criterion death). The patient died on 08-Dec-2021. The reported cause of death was longontsteking. An autopsy was not performed. No treatment information was provided.

Case ID	Narrative (Complete)
	Company Comment: This regulatory case concerns an 84-year-old, male patient with the concurrent condition of metastatic esophageal cancer and past medical history of pulmonary embolism, pulmonary edema and arrhythmia, who experienced the unexpected, fatal event of Pneumonia. The event occurred 2 days after a dose of mRNA-1273 vaccine. It should also be noted that the patient received 2 doses of Tozinameran COVID-19 vaccine approximately 8 months prior to the mRNA-1273 (Interchange of vaccine products). Clinical course leading to demise and treatment details were not provided. The patient died 10 days post-vaccination. Autopsy was not performed in this case. The elderly age of the patient and concurrent metastatic malignancy remain as confounders for the event. Additionally, the elderly age and malignant condition along with history of pulmonary embolism, pulmonary edema and arrhythmia could have contributed to the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 14-Feb-2022: Significant follow-up included suspect batch number removed. Concomitant drugs updated.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of ACUTE PULMONARY OEDEMA (Acute lung edema) in a 69-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Patient had no known drug allergies. medicaly history included former smoker for 20 years (60 UMA (sic: pack/years), permanent auricular (sic: atrial) fibrillation, pulmonary hypertension and minor thalasemia (sic: thalassemia). Patient had Covid illness in Oct/Nov-2020, later (unknown date) received first Astrazeneca vaccine, without relevant reactions. Concomitant products included GLYCOPYRRONIUM BROMIDE, INDACATEROL MALEATE (ULTIBRO BREEZHALER), RIVAROXABAN (XARELTO), OMEPRAZOLE, MONTELUKAST and BISOPROLOL FUMARATE (CONCOR) for an unknown indication. On 12-Jan-2022, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 12-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced ACUTE PULMONARY OEDEMA (Acute lung edema) (seriousness criterion death). The patient died on 16-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered ACUTE PULMONARY OEDEMA (Acute lung edema) to be probably related. The patient was in a study of basic lung illness with Pulmonology, still with no established diagnosis but requiring oxygen therapy 16 h, 3 L/min. The booster dose was made prior to coming to SU (emergency room) (with symptomatology starting less than six hours after administration), with Moderna vaccine. Clinical circumstances of death: "Diagnoses determined in US (ultrasound]: Severe type 1 respiratory failure- Multifactorial probably (CT angiography Chest, excluded PTE and Pneumonia, only slight bilateral pleural effusion; there are bilateral apical residual fibrotic alterations. There is slight mediastinum ganglion prominence; 2021 CT with suggestion of HTP (PAH) by enlarged pulmonary arteries; right HF) and Cardiorenal Syndrome (Acute edema of the lung at admission, due to decompensated right HF; Improving acute kidney injury). Patient stayed for 4 days in emergency room. NIV was placed on 15-Jan due to respiratory failure with type 1 respiratory failure, with clinical improvement. Presented CRP (sic: went into cardiac arrest) witnessed by a nurse in a patient under well-adapted NIV. Always stop in asystole, effective AVS maneuvers for greater than 20 min, without reversal, with the support of intensive care medicine. Unknown direct cause of death, only certainty of an irreversible serious situation due to ALS maneuvers. Death certificate 03:05 p.m. on 16, 2022 with BIC [sic: Medical Information Report] No. 100490015. No treatment information was provided. PCR witnessed by a nurse in a well adapted NIV patient. Always stop in asystole, AVS maneuvers for greater than 20 min, without reversal. Death certificate 03:05 p.m. on 16, 2022 with BIC No. 100490015. Not able to copy the Company Comment due to limited characters of the iNarrative Supplement box. DJG Most recent FOLLOW-UP information incorporated above includes: On 02-Feb-2022: Translation document received on 04-Feb-2022, patient medical history and causality was added.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 02-Feb-2022 and was forwarded to Moderna on 02-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of CORONARY ARTERIAL STENT INSERTION (Coronary arterial stent insertion), CHEST PAIN (Thorax pain) and ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) in a 67-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Hyperlipoproteinemia. Concurrent medical conditions included Tachyarrhythmia absoluta, Coronary disease and Arterial hypertension. On 29-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced CORONARY ARTERIAL STENT INSERTION (Coronary arterial stent insertion) (seriousness criteria death, hospitalization and life threatening), CHEST PAIN (Thorax pain) (seriousness criteria death, hospitalization and life threatening) and ELECTROCARDIOGRAM ABNORMAL (Electrocardiogram abnormal) (seriousness criteria death, hospitalization and life threatening). The patient died on 29-Dec-2021. The reported cause of death was tu: possible in case of anamnesis and the course of 2nd heart attack. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant Medication use information was not provided by reporter. Treatment Medication use information was not provided by reporter. Company comment:

Case ID	Narrative (Complete)
	This is a regulatory authority case concerning a 67-year-old, male patient with relevant medical history of hyperlipoproteinemia, tachyarrhythmia absoluta, coronary disease and arterial hypertension, who experienced the unexpected serious events of thorax pain, electrocardiogram abnormal and coronary arterial stent insertion. The events thorax pain and electrocardiogram abnormal occurred 11 days before the booster dose of mRNA-1273 vaccine administration while the event coronary arterial stent insertion occurred 6 days before the booster dose of mRNA-1273 vaccine administration which resulted to hospitalization. The outcome of the events thorax pain, electrocardiogram abnormal and coronary arterial stent insertion were fatal. The reported cause of death was possible in case of anamnesis and the course of second heart attack. It is unknown if autopsy was done. The medical history of hyperlipoproteinemia, tachyarrhythmia absoluta, coronary disease and arterial hypertension remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 01-Feb-2022. The most recent information was received on 24-Jun-2022 and was forwarded to Moderna on 24-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DYSARTHRIA (could no longer talk and swallow due to infarction), CEREBRAL INFARCTION (Next day cerebral stroke), DYSPHAGIA (could no longer talk and swallow due to infarction), PNEUMONIA (could no longer talk and swallow due to the infarction, developed pneumonia) and CEREBRAL INFARCTION (Another cerebral stroke) in an 84-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 093F21A) for COVID-19 immunisation. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Fall (Fell on her hip, hospitalised for that. Years ago), Urinary bladder polyp (hospitalisation), Breast cancer (hospitalised for breastcancer when she was 50 years old) in 1987, Claudication (treatment: advice to walk, which she did, until she died, targetting 10000 steps per day. In addition acetylsalicylic acid. In 2016 stent placement in her legs) in 2004, Cataract in 2013, Urogenital prolapse (Prolapse uterus and bladder wv, manchesterplastic and back wall plastic) in 2002, Hypertension, Cognitive impairment (mild cognitive impairment) and Stent placement (placing stents in her\ legs (2016)) in 2016. Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 26-Feb-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 02-Apr-2021. Past adverse reactions to the above products included Confusion with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; and No adverse event with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST. Concurrent medical conditions included Allergy (Rest). Concomitant products included ACETYLSALICYLZUUR for Claudication, METOPROLOL SUCCINATE (METOPROLOL SUCCINAT BETA) and CHLOORTALIDON for Hypertension, PAROXETINE (PAROXETIN [PAROXETINE]) for Seasonal depression. On 12-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Dec-2021, the patient experienced LOSS OF CONSCIOUSNESS (Has had a walk away the same day in the evening). On 13-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced CEREBRAL INFARCTION (Next day cerebral stroke) (seriousness criteria death and hospitalization). On 14-Dec-2021, the patient experienced DYSARTHRIA (could no longer talk and swallow due to infarction) (seriousness criteria death and hospitalization), DYSPHAGIA (could no longer talk and swallow due to infarction) (seriousness criteria death and hospitalization), PNEUMONIA (could no longer talk and swallow due to the infarction, developed pneumonia) (seriousness criteria death and hospitalization) and CEREBRAL INFARCTION (Another cerebral stroke) (seriousness criteria death and hospitalization). The patient died on 17-Dec-2021. The reported cause of death was cerebral infarction (primary cause of death) and Pneumonia. An autopsy was not performed. At the time of death, LOSS OF CONSCIOUSNESS (Has had a walk away the same day in the evening) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Blood cholesterol: last measurement of 2021 was 3.6 Annual measurements since 2010 show that total cholesterol was always slightly elevated: between 5.4 and 6.4 (normal =<5), last value in 2021 was 5.9. HDL cholesterol was always tidy: between 1.7 and 2.2. LDL cholesterol, however, usually above the norm (<3= normal) between 2.9-4. Last measurement of 2021 was 3.6. Ratio always neatly below 5. Triglycerides also normal. In 2021, Blood pressure measurement: 140/80 Her blood pressure according to the general practitioner's file 2015:156/81 2016:154/91 2017:163/83 2018:147/81 2019:128/82 2020:130/72 2021:140/80. very adherence to both means to lower blood pressure.. In 2021, Mini mental status examination: 27/30 27/30 test_result_lowest_range : 25 test_result_highest_range : 30. In 2021, Montreal cognitive assessment: 23/30 23/30 test_result_lowest_range : 26 test_result_highest_range : 30. On 13-Dec-2021, Scan: occlusion of the a. vertebralis on the one hand occlusion of the a. vertebralis on the one hand, without evidence of atrial fibrillation. Company Comment: This regulatory case concerns an 84-year-old female patient, with relevant medical history of hypertension, breast cancer, cognitive impairment, claudication of legs s /p stent placement, who experienced the unexpected serious and fatal events of Cerebral infarction (AESI) (reported 2 episodes), Dysarthria, Dysphagia, and Pneumonia. The event Cerebral infarction (next day cerebral stroke) occurred 1 day, and events Cerebral infarction (another cerebral stroke), Dysarthria, Dysphagia, and Pneumonia occurred 2 days, respectively, after receiving the dose of mRNA-1273 vaccine. The events were reported along with the non-serious loss of consciousness that happened same day post vaccination. Scan showed occlusion of the a. vertebralis on the one hand, without evidence of atrial fibrillation. The following tests were done on an unspecified date (units not reported): total cholesterol 5.9, HDL cholesterol between 1.7 and 2.2, LDL cholesterol 3.6, and triglycerides normal, blood pressure 140/80, mini mental status examination 27/30, and montreal cognitive assessment 23/30. Clinical course of hospitalization and treatment details were not reported. The patient died 5 days post vaccination. The causes of death were reported as Cerebral infarction as the primary cause and Pneumonia. Autopsy was not performed. Patient received 2 doses of Tozinameran vaccine at an interval of 35 days with reported adverse event of confusion with the 2nd dose, and the 2nd dose was given 8 months and 10 days prior to the mRNA-1273 vaccine (Interchange of vaccine products noted). The medical history of hypertension, breast cancer, and claudication could be considered as risk factors for the event cerebral infarction. Cognitive impairment as contributory factor for the event dysarthria. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 24-Jun-2022: Medical history added, Lab tests added, event verbatim updated.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022.

Case ID	Narrative (Complete)
	This regulatory authority case was reported by a physician and describes the occurrence of CHEST PAIN (Chest pain) in a 69-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3006276, ABY1328 and ABW7197) for COVID-19 vaccination. The patient's past medical history included Ischaemic cardiomyopathy in 2005, Renal failure chronic, Alcohol use and Tobacco abuse. Concurrent medical conditions included Hypertension, Type 2 diabetes mellitus and Hyperlipidaemia. On 28-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 02-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On 13-Dec-2021, received third dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .25 milliliter. On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced CHEST PAIN (Chest pain) (seriousness criterion death). The patient died on 14-Dec-2021. The reported cause of death was cardiorespiratory arrest (10007617). It is unknown if an autopsy was performed. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 28-Apr-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Company Comment: This regulatory case concerns a 69-year-old, male patient with medical history of medical history of cardiomyopathy in 2005, Renal failure chronic, Alcohol use and Tobacco abuse and Concurrent medical conditions of Hypertension, Type 2 diabetes mellitus and Hyperlipidaemia arterial, who experienced the unexpected serious event of Chest pain, which resulted in a fatal outcome, with death occurring 1 day after the third dose of mRNA-1273 vaccine. The reported cause of death is cardio-respiratory arrest, It is unknown if an autopsy was performed. Inappropriate schedule of product administration was also noted in the case (interval between dose 1 and dose 2 are longer than 35 days), Dose interval is 65 days. Patients medical history of cardiomyopathy in 2005, Renal failure chronic, Alcohol use and Tobacco abuse and Concurrent medical conditions of Hypertension, Type 2 diabetes mellitus and Hyperlipidaemia remains as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. The event was assessed as serious as per Regulatory Authority´s report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death) in an 88-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 007G21A) for COVID-19 vaccination. The patient's past medical history included Coronary disease. Concurrent medical conditions included Diabetes. On 12-Jan-2022, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. The patient died on 12-Jan-2022. The reported cause of death was Sudden death. It is unknown if an autopsy was performed. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 12-Jan-2022. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication was not reported. Treatment medication was not reported. Company comment: This case concerns a 88-year-old male patient, with medical history of Coronary disease and diabetes, who experienced the serious, fatal, unexpected event of sudden death. The event happened 3 hours after the first dose of mRNA 1273 COVID-19 Vaccine. No further details were provided. It is unknown if an autopsy was performed. The patient's age and history of coronary disease and diabetes remain as confounders to the event. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 03-Feb-2022: Follow-up information received included added medical history and concomitant drugs.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PLASMA CELL MYELOMA RECURRENT (To this is added a good week after, a resumption of myeloma, but without severity according to the doctor), PYREXIA (Fever), INJECTION SITE REACTION (Reaction at the injection site), TINNITUS (tinnitus), INJECTION SITE INDURATION (With hardening at the point of the sting), DEATH (She died in May september 2021), FATIGUE (Fatigue), INJECTION SITE PAIN (left arm (side of the sting) completely immobilized and very painful), CHILLS (Frissons), LIMB IMMOBILISATION (left arm (side of the sting) completely immobilized and very painful), MALAISE (Malaise), LYMPHOMA (lymphoma in the same arm), FEELING COLD (Violent cold sensations), SKIN FISSURES (the skin was cracking), ARTHRALGIA (Joint pain), MYALGIA (Muscle pain), INJECTION SITE MOVEMENT IMPAIRMENT (left arm (side of the sting) completely immobilized and very painful) and EXTENSIVE SWELLING OF VACCINATED LIMB (Extensive swelling of the arm) in a 74-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3000494 and 3000494) for COVID-19 vaccination. The patient's past medical history included Myeloma (Affected with well-monitored and treated myeloma that allowed her to live normally). On 30-Mar-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Apr-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced PLASMA CELL MYELOMA RECURRENT (To this is added a good week after, a resumption of myeloma, but without severity according to the doctor) (seriousness criteria death, disability and medically significant), PYREXIA (Fever) (seriousness criteria death and disability), INJECTION SITE REACTION (Reaction at the injection site) (seriousness criteria death and disability), TINNITUS (tinnitus) (seriousness criteria death and disability), INJECTION SITE INDURATION (With hardening at the point of the sting) (seriousness criteria death and disability), DEATH (She died in May september 2021) (seriousness criteria death and medically significant), FATIGUE (Fatigue) (seriousness criteria death and disability),

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	INJECTION SITE PAIN (left arm (side of the sting) completely immobilized and very painful) (seriousness criteria death and disability), CHILLS (Frissons) (seriousness criteria death and disability), LIMB IMMOBILISATION (left arm (side of the sting) completely immobilized and very painful) (seriousness criteria death and disability), MALAISE (Malaise) (seriousness criteria death and disability), LYMPHOMA (lymphoma in the same arm) (seriousness criteria death, disability and medically significant), FEELING COLD (Violent cold sensations) (seriousness criteria death and disability), SKIN FISSURES (the skin was cracking) (seriousness criteria death and disability), ARTHRALGIA (Joint pain) (seriousness criteria death and disability), MYALGIA (Muscle pain) (seriousness criteria death and disability), INJECTION SITE MOVEMENT IMPAIRMENT (left arm (side of the sting) completely immobilized and very painful) (seriousness criteria death and disability) and EXTENSIVE SWELLING OF VACCINATED LIMB (Extensive swelling of the arm) (seriousness criteria death and disability). The patient died on 16-Sep-2021. It is unknown if an autopsy was performed. Patient had Treatment but without little or no effect. Pain treated with morphine and other medicines she doesn't know. Radiation therapy sessions to try to deflate this arm, which gave no effect. The arm continued to grow fat and the skin cracked. JAB ended her days in a palliative care center, the painkillers were different, but it remained unbearable for her and for us. Evolution of the ADR - Death Situations - Incorrect Vaccine Choice Examination - JAB was seen by a virologist or infectiologist (she no longer know), who acknowledged that the effects of JAB were well related to the vaccine and that at that time, about 20 cases were already known. In parallel, blood tests, ultrasound, MRI, biopsy, where nothing was visible until +/- end of June. A doctor even believed in a bursitis he tried to operate. It was even worse afterwards. ADR time relationship - It all started during the month of March at its first dose ADR description - At the first dose, could not get up for two days as the effects were violent: pyrexia, muscle and joint pain, left arm (side of the sting) totally immobilized and very painful. With hardening at the point of the sting. Violent cold sensations. Didn't know how to eat or drink. And finally, tinnitus. To this is added a good week after, a resumption of myeloma, but without severity according to the doctor. At the second dose she did not want to do; no pyrexia, but again joint and muscle pain. No discomfort, no chills. On the other hand, from this date, the arm already affected by hardening of the skin and muscle at the place of the sting, did not stop swelling, to the point of no longer being able to pass a garment, with appalling pains (morphine treatments had to be administered). When to myeloma, it became unmanageable. to top it all, it was found a start of lymphoma in that same arm. JAB lived 6 months in extreme suffering. She died in May septembre 202. No concomitant medication was provided by reporter. Company comment: This regulatory authority case concerns a 74-year-old female patient, with medical history of well-monitored and treated myeloma, who experienced the unexpected fatal events of plasma cell myeloma recurrent, pyrexia, injection site reaction, tinnitus, injection site induration, fatigue, injection site pain, chills, limb immobilisation, malaise, lymphoma, feeling cold, skin fissures, arthralgia, myalgia, injection site movement impairment and extensive swelling of vaccinated limb, which all met seriousness criteria of death and disability per information provided by Regulatory authority and serious event of death. The events of occurred on an unknown date following the first and the second dose of mRNA-1273. As reported, after first dose the patient could not get up for two days as the effects were violent: pyrexia, muscle and joint pain, left arm (side of the sting) totally immobilized and very painful, with hardening at the point of the sting, violent cold sensations, didn't know how to eat or drink and tinnitus. A resumption of myeloma also occurred. At the second dose the patient had joint and muscle pain and from this date, the arm already affected by hardening of the skin and muscle at the place of the sting, did not stop swelling, with appalling pains (morphine treatments had to be administered), myeloma became unmanageable and start of lymphoma in that same arm was found. Radiation therapy sessions to try to deflate this arm, which gave no effect. The arm continued to grow fat and the skin cracked. A doctor even believed in a bursitis he tried to operate but it was even worse afterwards, as reported. The patient died 6 months after first dose. Above mentioned medical history of myeloma remains a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per Regulatory Authority reporting.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 03-Feb-2022 and was forwarded to Moderna on 03-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 PNEUMONIA (COVID-19 pneumonia) and VACCINATION FAILURE (Vaccination failure) in a 65-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216001) for COVID-19 vaccination. Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) from 26-Mar-2021 to an unknown date for COVID-19 immunisation. On 16-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 17-Dec-2021, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death and medically significant) and VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). It is unknown if an autopsy was performed. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 16-Dec-2021. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment information was provided. Company Comment - This regulatory authority case concerns a 65 year old male patient with no relevant medical history, who experienced the serious unexpected events of COVID-19 pneumonia and vaccination failure. The events occurred 1 day after the third dose of mRNA-1273 vaccine, and resulted in death. The cause of death was not reported and it is unknown if an autopsy was performed. Based on the current available information, the mRNA-1273 vaccine does not contain a virus capable of causing infection. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of EMERGENCY CARE (Lack of strength in arms and hands, a sense of confusion. Until you can talk or swallow. Emergency room access and later hospitalization in the ICU in a state of coma), ASTHENIA (Lack of strength in arms and hands, a sense of confusion. Until you can talk or swallow. Emergency room access and later hospitalization in the ICU in a state of coma), CONFUSIONAL STATE (Lack of strength in arms and hands, a sense of confusion. Until you can talk or swallow. Emergency room access and later hospitalization in the ICU in a state of coma), COMA (Lack of strength in arms and hands, a sense of confusion. Until you can talk or swallow. Emergency room access and later hospitalization in the ICU in a state of coma), DYSPHAGIA (Lack of strength in arms and hands, a sense of confusion. Until you can talk or swallow. Emergency room access and later hospitalization in the ICU in a state of coma) and DYSPHONIA (Lack of strength in arms and hands, a sense of confusion. Until you can talk or swallow. Emergency room access and later hospitalization in the ICU in a state of coma) in a 69-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005884) for COVID-19 vaccination.

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	Concomitant products included NIFEDIPINE (ADALAT), OMEGA-3 TRIGLYCERIDES (ESKIM), VALPROATE SODIUM (DEPAKIN), ATORVASTATIN CALCIUM (TOTALIP), CLONAZEPAM (RIVOTRIL) and HYDROCHLOROTHIAZIDE, TELMISARTAN (PRITORPLUS) for an unknown indication. On 06-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 07-Jan-2022, the patient experienced EMERGENCY CARE (Lack of strength in arms and hands, a sense of confusion. Until you can talk or swallow. Emergency room access and later hospitalization in the ICU in a state of coma) (seriousness criterion death), ASTHENIA (Lack of strength in arms and hands, a sense of confusion. Until you can talk or swallow. Emergency room access and later hospitalization in the ICU in a state of coma) (seriousness criterion death), CONFUSIONAL STATE (Lack of strength in arms and hands, a sense of confusion. Until you can talk or swallow. Emergency room access and later hospitalization in the ICU in a state of coma) (seriousness criterion death), COMA (Lack of strength in arms and hands, a sense of confusion. Until you can talk or swallow. Emergency room access and later hospitalization in the ICU in a state of coma) (seriousness criterion death), DYSPHAGIA (Lack of strength in arms and hands, a sense of confusion. Until you can talk or swallow. Emergency room access and later hospitalization in the ICU in a state of coma) (seriousness criterion death) and DYSPHONIA (Lack of strength in arms and hands, a sense of confusion. Until you can talk or swallow. Emergency room access and later hospitalization in the ICU in a state of coma) (seriousness criterion death). The patient died on 18-Mar-2022. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. Treatment information was not provided. This is a regulatory case concerning a 69-year-old, male patient with no relevant medical history, who experienced the unexpected, serious (fatal) events of Emergency care, Asthenia, Confusional state, Coma, Dyspohagia, Dysphonia. The events occurred 1 day after the unspecified dose of mRNA-1273 vaccine. Patient died 72 days after the unknown dose of mRNA-1273 COVID 19 Vaccine. It is unknown if Autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as Serious as per Regulatory Authority report. Most recent FOLLOW-UP information incorporated above includes: On 24-Feb-2022: Follow-up received and does not contain any new information On 04-Apr-2022: Non-Significant Followup On 04-Apr-2022: Follow-up document received on 04-Apr-2022 contains Date of death, updated seriousness criteria, events end date and updated events outcome added.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Feb-2022 and was forwarded to Moderna on 04-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Found dead (cause undetermined)) in an 85-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 042G21A) for COVID-19 vaccination. No Medical History information was reported. On 16-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 21-Dec-2021 The patient died on 21-Dec-2021. The reported cause of death was Sudden death unexplained. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not reported. Treatment information was not reported. Company Comment: This regulatory case concerns an 85-year-old, male patient with no medical history reported, who experienced the unexpected event of Death of fatal outcome which occurred 5 days after a dose of mRNA-1273 vaccine (dose number not specified). Its reported as sudden death unexplained and its also unknown if an autopsy was performed. At the time of the report, very limited information has been provided about the patient and about the event leading to the fatal outcome. The patient's elderly age remains a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 07-Feb-2022 and was forwarded to Moderna on 07-Feb-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of COUGH (Cough) in a 79-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. PCA0030) for an unknown indication. No Medical History information was reported. On 06-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 14-Jan-2022, the patient experienced COUGH (Cough) (seriousness criteria death and hospitalization prolonged). It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication were reported. No treatment medication were reported. Company Comment: This is a Regulatory Authority case concerning a 79-year-old male patient, with no medical history reported in this case, who experienced the serious fatal unexpected adverse event of Cough. The event was reported to occur approximately 2 days after the administration of a

Case ID	Narrative (Complete)
	dose of the mRNA-1273 vaccine of an unknown schedule of vaccination. No further information regarding clinical course and autopsy report (if performed) was disclosed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Case was assessed with limited information. The case was assessed as serious as per Regulatory Authority's report due to results in Death and Hospitalized.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Feb-2022 and was forwarded to Moderna on 07-Feb-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of CEREBROVASCULAR ACCIDENT (Stroke), HEMIPARESIS (Hemiparesis) and CEREBRAL INFARCTION (Cerebral infarction) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 28-Apr-2021 and Comirnaty BNT162b2 on 09-Jun-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2. Concurrent medical conditions included Atrial fibrillation. On 17-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 03-Jan-2022, the patient experienced CEREBROVASCULAR ACCIDENT (Stroke) (seriousness criteria death, hospitalization and life threatening), HEMIPARESIS (Hemiparesis) (seriousness criteria death, hospitalization and life threatening) and CEREBRAL INFARCTION (Cerebral infarction) (seriousness criteria death, hospitalization and life threatening). The patient died on 04-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant Medication use information was not provided by reporter. Treatment Medication use information was not provided by reporter. Company comment: This Fatal Regulatory Authority case concerns a 80-year-old, male patient, with medical history of atrial fibrillation, who experienced the unexpected, serious (death/ life threatening/ hospitalization) and AESI of Cerebrovascular accident and cerebral infarction, among others. The events occurred approximately 27 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the patient's COVID-19 vaccination schedule, as he received previously two doses of Cominarty's COVID-19 vaccine as first and second doses. The patient died the day after the events developed. Cause of death was reported as unknown. Autopsy report is not available. The medical history of atrial fibrillation remains as a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b)) on 04-Feb-2022 and was forwarded to Moderna on 08-Feb-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by an anatomist, was received via the PMDA (Ref, 4.1(b)). The patient had a history of uterine cancer, rectal cancer, and metastases to lymph nodes and was taking tegafur/uracil. On 25-Apr-2021, the patient received the 1st dose of SARS-CoV-2 vaccine (coronavirus modified uridine RNA vaccine made by Pfizer). On 16-May-2021, the patient received the 2nd dose of SARS-CoV-2 vaccine (coronavirus modified uridine RNA vaccine made by Pfizer). On 31-Jan-2022, at 11:15, the patient received the 3rd dose of the vaccine. After the vaccination, the patient less energetic than usual and looked sleepy. On 02-Feb-2022, at 00:00, the patient was confirmed dead. In the morning, the patient was found dead in the bathtub of her bathroom. The cause of death was considered as drowning. The outcome of lack of energy and sleepy looking was unknown. Follow-up investigation will be made. LP Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. Company comment: This case concerns a 77-year-old female patient with relevant medical history of uterine cancer, rectal cancer, and metastases to lymph nodes who experienced serious unexpected event of Drowning and non-serious unexpected events of Listless and Somnolence. The events Listless and Somnolence occurred on the same day after the third dose of mRNA-1273. Furthermore, two days following the vaccination the patient was confirmed dead. It was reported that in the morning, the patient was found dead in the bathtub of her bathroom. The cause of death was considered as drowning. It is unknown if an autopsy was performed. The outcome of the remaining events was unknown. No further information was provided. Causality is confounded with patient's advanced age and reported medical history. The Reporter considered the events as possibly related to the Company product. The benefit-risk relationship of mRNA-1273 is not affected by this report. Interchange of vaccine products should have been considered in this particular case as the patient received Pfizer vaccine prior to company product.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 04-Feb-2022. The most recent information was received on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of CEREBRAL HAEMORRHAGE (died found [found deceased], doctor detects natural death as a result of cerebral haemorrhage) in a 72-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 24-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced BRADYKINESIA (Extremely slow cycling away from a friend where he had lunch does not suit him. The lunch itself was the same as otherwise/usual). On 06-Jan-2022, the patient experienced INCOHERENT (It strikes a friend that he sends a somewhat tangled mail to her, does not fit in the image, always communicates well. She asks a friend to keep an eye on it.). On 08-Jan-2022, the patient experienced CEREBRAL HAEMORRHAGE (died found [found deceased], doctor detects natural death as a result of cerebral haemorrhage) (seriousness criterion death). The patient died on 08-Jan-2022. The reported cause of death was Cerebral haemorrhage. It is unknown if an autopsy was performed. At the time of death, BRADYKINESIA (Extremely slow cycling away from a friend where he had lunch does not suit him. The lunch itself was the same as otherwise/usual) and INCOHERENT (It strikes a friend that he sends a somewhat tangled mail to her, does not fit in the image, always communicates well. She asks a friend to keep an eye on it.) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2015, Blood pressure measurement: slightly elevated but still normal for his age Blood pressure measurement 2015, slightly elevated but still normal for his age..

Case ID	Narrative (Complete)
	For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not provided by the reporter. Treatment information was not provided. Company comment: This Regulatory Authority case concerns a 72-year-old, male patient with medical history of Blood pressure measurement slightly elevated in 2015, who experienced the unexpected fatal AESI of Cerebral Hemorrhage, which occurred approximately 15 days after an unknown dose of mRNA-1273 vaccine. The reported cause of death was Cerebral haemorrhage. It is unknown if an autopsy was performed. The mentioned medical history remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-Feb-2022: Follow-up received wherein new events and lab data added. Start date and seriousness criteria of the event cerebral haemorrhage updated. On 17-Feb-2022: Translation received on 22-Feb-2022 contains non significant information.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 07-Feb-2022. The most recent information was received on 09-Mar-2022 and was forwarded to Moderna on 17-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 09-Mar-2022, follow-up information was received from a physician. The vaccine recipient underwent cervical spine surgery in 2007 and had been receiving treatments twice a month continuously after the surgery. On an unspecified date in 2009, the patient had a history of traumatic subarachnoid hemorrhage. On an unspecified date in 2014, the patient had a chronic pulmonary murmur, and CT examination was performed for productive cough, and the patient was diagnosed as chronic bronchitis on imaging examination. As for the underlying heart failure, there was no acute heart failure episode and edema of the lower extremities was being controlled with diuretics. On 09-Jun-2021, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). There were no subjective symptoms. On 30-Jun-2021, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 07-Jul-2021, the patient had a medical examination. It was reported that the patient was less talkative and less energetic. In addition, increased edema of the lower extremities was observed. Blood pressure and SpO2 were not different from usual values. On 21-Jul-2021, the patient had the second medical examination. The patient was fine and looked normal. On an unspecified date in Aug-2021, the patient experienced coxalgia in the standing position. The patient took acetaminophen 600 mg/day. From an unspecified date in Dec-2021 to an unspecified date in Jan-2022, the only change in the prescription was reduction in the dosage of acetaminophen to 400 mg/day. On an unknown date, body temperature before vaccination: 36.2 degrees Celsius. On 07-Jan-2022, at 10:00, the patient received the 3rd dose of this vaccine. At the time of the vaccination, the patient did not have physical deconditioning immediately after the vaccination. On 09-Jan-2022, there were no other objective symptoms. On 10-Jan-2022, at 02:30, pericarditis developed. The patient complained of queasy feeling, headache, and heaviness and pain-like symptom in the chest. At 04:00, the patient was complaining of queasy feeling and chest discomfort, without feeling dyspnea. Thereafter, the patient fell asleep. At 10:00, the patient complained of tingling in the chest without queasy feeling. Blood pressure was 122/79 mmHg with pulse of 68 beats/min. The patient had little appetite and only drank fluids. At 13:10, after drinking water, the patient complained of headache and heavy chest and rested in the afternoon. The patient drank water along the way. At 17:45, the patient ate a small amount of dinner. The patient took regular medications after meal. At 18:10, there was no queasy feeling. At 20:10, the patient went to bed. At 22:00, the patient continued to have hiccups and complained of neck pain. Blood pressure was 136/77 mmHg with pulse of 91/min, body temperature of 36.4 degrees Celsius, and SpO2 of 80-84%. At 22:40, the patient vomited a small amount of saliva. At 23:00, the patient complained of body pain. On 11-Jan-2022, until 01:30, the patient repeated supine and sitting positions in bed. There was no vomiting. At 02:30, the facial expression improved a bit. At 05:00, the patient said that there was no body pain, but mild rumbling wheezing was noted in the laryngeal region. Blood pressure was 121/74 mmHg with pulse of 111/min, SpO2 of 80%, and body temperature of 35.6 degrees Celsius. At 07:45, the patient had difficulty eating breakfast on the bed by herself and was assisted in a wheelchair. At 08:10, immediately after the patient was transferred to bed, she did not have focused eyes and ill complexion. When tapping was performed, it was judged that there was vomiting but no respiration or pulse. At 08:15, an ambulance call was made. Cardiopulmonary resuscitation was started using AED. At 08:20, the ambulance team arrived. The initial waveform was cardiac arrest. Laryngeal tube was inserted to secure the route. At 08:37, adrenaline was administered. At 08:41, the 2nd dose of adrenaline was administered. At 08:42, the patient arrived at a hospital. When the patient arrived at the hospital, monitor check confirmed ROSC. JCS: 300. There was no spontaneous breathing. Cardiac ultrasonography showed visual EF was about 40%, and local asynergy was not noted. Thereafter, CPA occurred again within a short period of time. There was no obvious injury on the body surface. Intubation revealed a large amount of pink foamy sputum. Blood gas showed high degree of mixed acidosis, and chest X-ray test showed prominent butterfly shadow. CT scan was performed. Head: there was no obvious hemorrhage. Chest: extensive ground glass opacities to infiltrative opacities were noted predominately in both lung inner layers, and bilateral pleural effusion were noted. There was no abnormal pericardial effusion. There was no aortic aneurysm or enlargement of aortic diameter. Thickened bronchial wall was noted, and airway inflammation was suspected. Abdomen: there was thinning of the spleen and liver. CPR was then performed for 30 minutes, but the heartbeat did not resume without ROSC. The patient's family member consented to discontinuation of CPR. At 09:47, the patient was confirmed dead. The cause of death was heart disorder. No necropsy was performed. There was a finding of pulmonary congestion, and an adverse reaction to this vaccine was suspected. The outcome of less talkative and less energetic was reported as resolved. The outcome of increased edema of the lower extremities, coxalgia, mixed acidosis, pleural effusion, and pulmonary congestion was unknown. The outcome of acute pericarditis and cardio-respiratory arrest was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: Since pericarditis is suspected based on the symptoms and course, the cause of death is related to adverse events. On 07-Jan-2022, the patient received this vaccine, and on 10-Jan-2022, the patient experienced chest symptoms and cardiac failure with a sudden onset of the symptoms, so the onset of adverse events is temporally related to the timing of administration of this vaccine. The onset of adverse events is not related to concomitant drugs. The onset of adverse events is not related to pathological factors of underlying diseases and complications. Three days after the vaccination with this vaccine, the patient experienced chest discomfort and queasy feeling without any previous symptoms. Throughout the course of the symptoms, diaphragmatic irritation symptoms such as hiccup, neck pain, and queasy feeling, were main, and hypoxia was ongoing without significant change in blood pressure. Therefore, it is considered that the patient experienced acute pericarditis rather than myocarditis. Follow-up received on 09-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 03-Feb-2022. The most recent information was received on 14-Mar-2022 and was forwarded to Moderna on 22-Mar-2022. This case was reported by a physician via a medical representative. On 05-Feb-2022, follow-up information, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site（TASK0022545）. On 07-Feb-2022, follow-up information, reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 14-Mar-2022, follow-up information was received from a physician. Respiratory arrest and no response to calls were assessed as serious by the MAH. On 18-Jun-2021, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 09-Jul-2021, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 21-Jan-2022, at 13:00, the patient received the 3rd dose of this vaccine. On 24-Jan-2022, after 15:00, pyrexia of 38.9 degrees Celsius with chills was noted. No respiratory symptoms, digestive symptoms, or swollen joints were observed. The patient took 2 tablets of acetaminophen 200 mg and was followed up. On 25-Jan-2022, in the morning, the temperature decreased to 36.8 degrees Celsius. Since then, there was

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	no chills or pyrexia, and the patient was followed up. Blood test on the same day showed white blood cells of 20,900 with Neu of 78.0%, CRP of 11.4, NTproBNP of 9,333, Alb of 1.9, GOT of 30, GPT of 23, Na of 128, K of 4.4,and Cl of 95. On 26-Jan-2022, at 02:55, the body temperature was 36.7 degrees Celsius. The patient was awake and responded to calls. At 04:00, the patient did not respond to voice calls, and symptoms of complexion ill and feeling cold were found. The patient was found in a state of respiratory arrest, and the nurse was notified. At 06:45, the patient was confirmed as dead. The cause of death was unknown. No autopsy was performed. The outcome of chills, no response to calls, complexion ill, feeling cold, and respiratory arrest was unknown. The outcome of pyrexia was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The symptom developed on 22-Jan-2022 after vaccination with this vaccine, and the patient died on 26-Jan-2022; therefore, a temporal association between the occurrence of adverse events and the timing of administration of this vaccine cannot be ruled out. Since the patient was continuing to take medications prescribed by the previous physician prior to admission, the occurrence of adverse events was not associated with the concomitant drugs. The occurrence of adverse events is not related to pathological factors of underlying diseases and complications. The symptoms developed on the fifth day after vaccination with this vaccine, and considering the patient's condition before the vaccination, it is suspected that the symptoms were related to the vaccination. However, on 26-Jan-2022, the day of death, when the patient was examined at 02:55, the body temperature was 36.7 degrees Celsius, and the patient was awake and responded to calls. At 04:00, at the visit for examination, the patient was found in a state of respiratory arrest, so the relationship between the death and this vaccine is unknown. Follow-up received on 14-MAR-2022 Updated: Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 08-Feb-2022 and was forwarded to Moderna on 08-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Cause of death unknown) and DEHYDRATION (Nausea, malaise, apathy, lack of response to speech. Initial diagnosis: dehydration) in an 82-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000117A) for COVID-19 vaccination. Patient's information on risk factors or pre-existing diseases included heart failure. Concurrent medical conditions included Cardiac insufficiency. On 05-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 05-Jan-2022, the patient experienced DEHYDRATION (Nausea, malaise, apathy, lack of response to speech. Initial diagnosis: dehydration) (seriousness criterion hospitalization). The patient died on 06-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, DEHYDRATION (Nausea, malaise, apathy, lack of response to speech. Initial diagnosis: dehydration) had not resolved. No concomitant medications were reported. Patient had vaccination in morning. In the evening RTW call was made for nausea, malaise, apathy, lack of response to speech. Initial diagnosis of dehydration was made. Infusion for compensation was done. Patient was admitted to hospital in normal ward. Patient deceased in the morning, cause of death was unclear. Switching on the Kripo showed that there was no indication of third-party fault and the cause of death was unresolved. Several times it was pointed out vaccination without reaction. Company Comment - This regulatory authority case concerns a 82 year old male patient with medical history of heart failure and cardiac insufficiency, who experienced the serious unexpected events of death and dehydration. The events occurred on the same day after a dose of mRNA-1273 vaccine. The outcome was fatal with death occurring 1 day after the onset of events. The reported cause of death was unknown. Patient's medical history of heart failure and cardiac insufficiency remains a confounder. The rechallenge was not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 31-Jan-2022. The most recent information was received on 31-Jan-2022 and was forwarded to Moderna on 14-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH ([The patient] did not show any symptoms before death) in a 68-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 031G21A) for COVID-19 vaccination. Concomitant products included COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) from 03-May-2021 to 26-Jul-2021 for COVID-19 vaccination. On 05-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .3 milliliter. Death occurred on 05-Jan-2022 It is unknown if an autopsy was performed. No treatment information was provided. Company comment include This regulatory case concerns a 68-year-old male patient with history of interchange of vaccine products (two doses of CHADOX1 NCOV-19 vaccine) and no other medical history reported, experienced the Fatal event Death, on same day after receiving a dose of mRNA-1273 (taken as booster dose). Age of patient and Previous vaccine CHADOX1 NCOV-19 remain confounders. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 31-Jan-2022: Significant information (Translation) received on 14-Feb-2022. Event verbatim, Suspect product dose number and route were updated.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 07-Feb-2022. The most recent information was received on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of SHOCK (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly), ACUTE KIDNEY INJURY (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly), CARDIOMEGALY (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly)

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	and GENERALISED OEDEMA (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) in a 77-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005887) for COVID-19 vaccination. The patient's past medical history included Gallbladder stones, Acute myeloid leukaemia on 01-Jan-1993, Humerus fracture and Stroke on 01-Jul-2017. Previously administered products included for SARS-CoV-2 immunisation: COMIRNATY (COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03)) on 25-Mar-2021 and COMIRNATY (COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03)) on 14-Apr-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY. Concurrent medical conditions included Type 2 diabetes mellitus, Hypothyroidism on 01-Jan-1996, Chronic renal insufficiency (stage IV) and Decompensation cardiac (heart disease) on 01-Jan-2021. Concomitant products included LEVOTHYROXINE SODIUM (EUTIROX) for Hypothyroidism, TRAZODONE HYDROCHLORIDE (TRITTICO), FUROSEMIDE (LASIX P), ATORVASTATIN CALCIUM (TORVAST), FLUPHENAZINE DECANOATE (FLUVION), CETIRIZINE, WARFARIN SODIUM (COUMADIN), LANSOPRAZOLE (LANSOX), METOLAZONE (ZAROXOLYN), CALCITRIOL, SERTRALINE HYDROCHLORIDE (ZOLOFT), BISOPROLOL and INSULIN GLARGINE (ABASAGLAR) for an unknown indication. On 15-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 16-Jan-2022, the patient experienced SHOCK (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) (seriousness criterion death), ACUTE KIDNEY INJURY (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) (seriousness criterion death), CARDIOMEGALY (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) (seriousness criterion death) and GENERALISED OEDEMA (acute on chronic renal failure requiring dialysis, shock, anasarcatic congestive state, cardiomegaly) (seriousness criterion death). The patient died on 28-Jan-2022. The reported cause of death was Shock cardiogenic. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-Jan-2022, Abdominal X-ray: negative (Negative) Negative. On 16-Jan-2022, Blood gases: negative (Negative) Negative. On 16-Jan-2022, Blood test: negative (Negative) Negative. On 16-Jan-2022, Chest X-ray: negative (Negative) Negative. On 16-Jan-2022, Specialist consultation: negative (Negative) Negative. On 16-Jan-2022, Ultrasound scan: negative (Negative) Negative. On 17-Jan-2022, Echocardiogram: negative (Negative) Negative. On 17-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. It was reported that on 28-Jan-2022, the patient died from irreversible cardiogenic shock. Treatment mediations were not reported. Senders comment: Clinical report provided by the reporter was attached. On 28 Jan 2022 the patient died of irreversible cardiogenic shock. Company comment: This regulatory authority case concerns a 77-year-old female patient, with relevant medical history of stroke in 2017 and concurrent conditions type 2 diabetes mellitus, cardiac decompensation and chronic renal insufficiency, who experienced the serious, unexpected fatal events of shock, generalized edema, cardiomegaly and acute kidney injury (AESI). The events occurred approximately 2 months after the 3rd dose of mRNA 1273. Additionally, there was an interchange of vaccine products as the patient was previously vaccinated with 2 doses of Comirnaty. The patient passed away12 days after the onset due to irreversible cardiogenic shock. It is unknown whether autopsy was performed. The patient's advanced age, history of stroke and multiple comorbidities (type 2 diabetes mellitus, heart disease and chronic renal insufficiency) remain confounders for the events and the fatal outcome. Additionally, concomitant furosemide is a possible confounder for shock and AKI, fluphenazine for AKI and metolazone for renal insufficiency. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Mar-2022: Follow-up Received : Lab test result (Abdominal X-ray NOS, Arterial blood gases, Blood test NOS, CXR, Echocardiography, COVID-19 PCR test, Nephrologist consultation, Echography) updated.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC ARREST (At 05:00 on January 18, 2022, unexplained cardiac arrest occurred.) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Diabetes (Information from patient and family) and Blood pressure high (Information from patient and family). On 17-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 18-Jan-2022, the patient experienced CARDIAC ARREST (At 05:00 on January 18, 2022, unexplained cardiac arrest occurred.) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood creatine phosphokinase MB: 8.3 8.3 ng/mL. On an unknown date, Blood potassium: 5.4 5.4mEq/L. On an unknown date, Troponin T: 427.0 427.0ng/L. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided. On 17-Jan-2022 at 10:42 the patient received the third dose of Moderna vaccine, Patient general appearance was fair and consciousness was clear. She had no evidence of pain. On 18-Jan-2022 at 05:07, she was sent to ER by EMT (E1V1M1). Her granddaughter reported that, she had chest discomfort

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	last night. Cardiac arrest was found by the EMT at the scene. She was given CPCR with Epinephrine 1mg/ml/amp IV every 3 min. On 18-Jan-2022 at 05:39, there was CPCR failure and at 5:44 there was no spontaneous circulation. Issued a medical certificate for diagnosis: cardiac arrest before admission to hospital. The follow-up care was as follows: On 21-Jan-2022, the patient was called for three consecutive days but no one answered. It was asked to continued follow up with the patient. On 22-Jan-2022 at 10:00/14:54 no one answered the phone. WWID was reported as 4.1(b) [redacted] Company comment This regulatory authority case concerns a 71-year-old female patient, with medical history of Diabetes and Blood pressure high, who experienced the unexpected serious (death) fatal event of CARDIAC ARREST, which occurred on the following day of the third dose of mRNA-1273. Cardiac arrest was found by the EMT at the scene. She was given CPCR with Epinephrine. There was CPCR failure. Issued a medical certificate for diagnosis: cardiac arrest before admission to hospital. The mentioned medical history remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non-Significant Follow up received, updated event verbatim.
4.1(b) [redacted]	This case was initially received via an unknown source (no reference has been entered for a health authority or license partner) on 07-Feb-2022. The most recent information was received on 25-Apr-2022 and was forwarded to Moderna on 25-Apr-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue), MYALGIA (Muscle pain) and VACCINATION SITE PAIN (Vaccination site pain) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 17-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Jan-2022, the patient experienced FATIGUE (Fatigue) (seriousness criterion death), MYALGIA (Muscle pain) (seriousness criterion death) and VACCINATION SITE PAIN (Vaccination site pain) (seriousness criterion death). The patient died on 20-Jan-2022. The reported cause of death was Fatigue, Muscle pain and Vaccination site pain. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications was not reported. It was reported that the patient received the vaccine on 17-Jan-2022 and felt uncomfortable, tired, and sore all over the body in the afternoon, so patient went to hospital for consultations and treatments. The doctor said the symptoms were normal reactions and the patient could return home for observation. On 19-Jan-2022, the patient still felt uncomfortable and sore all over the body, so patient went to the outpatient department of hospital for consultations and treatments. The doctor still said that patient could return home for observation. At 3:30 a.m. on 20-Jan-2022, the husband of the patient found that the patient had no breathing and heartbeat. The following was the follow-up care on 26-Jan-2022 the clinic sent the application on behalf of the family and the son of the patient and the other family members said that they did not want to go through the judicial and anatomical processes. The Worldwide UID was reported as 4.1(b) [redacted] Treatment information were not reported. Company comment: This is a fatal case from Regulatory Authority that concerns a 71-year-old female patient, with no relevant medical history, who experienced the unexpected serious (due to death) events of FATIGUE, MYALGIA and VACCINATION SITE PAIN, on the same day of the third dose of mRNA-1273 vaccine, and she died three days later, the patient was found not breathing and had no heartbeat. The reported cause of death was FATIGUE, MYALGIA and VACCINATION SITE PAIN. It is unknown if an autopsy was performed. No further clinical information was provided for medical reviewing. The benefit-risk relationship of mRNA-1273 is not affected by this report. The seriousness was assessed as per regulatory authority report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received. Events pain at injection site updated to vaccination site pain, muscle soreness updated to muscle pain, death date, cause of death, autopsy details, case narrative were updated.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of RESPIRATORY RATE DECREASED (Weak breathing and change of consciousness) and ALTERED STATE OF CONSCIOUSNESS (Weak breathing and change of consciousness) in a 66-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 19-Jan-2022, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Jan-2022, the patient experienced RESPIRATORY RATE DECREASED (Weak breathing and change of consciousness) (seriousness criterion death) and ALTERED STATE OF CONSCIOUSNESS (Weak breathing and change of consciousness) (seriousness criterion death). The patient died on 22-Jan-2022. It is unknown if an autopsy was performed. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. On 19-Jan-2022, The patient received the second dose of Moderna vaccine. On 22-Jan-2022, the patient was transferred from the nursing center whose personnel stated that the patient had weak breathing and altered consciousness. When the patient was admitted, there was no respiration and patient died on 22-Jan-2022, at 21:22.

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	Treatment information was not provided. WWID was reported as 4.1(b) Company comment: This is a regulatory case concerning a 66 year-old, male patient with no reported medical history, who experienced the serious Fatal unexpected, events of Respiratory rate decreased and Altered state of consciousness, approximately 3 days after the second dose of mRNA-1273 vaccine. The patient died the same day the events started. No further details regarding cause of death was provided, it is unknown whether an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non Significant Follow Up received, updated event verbatim and date of death
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of HYPOTENSION (Low blood pressure, respiratory asthma, and slow heartbeat), ASTHMA (Low blood pressure, respiratory asthma, and slow heartbeat) and BRADYCARDIA (Low blood pressure, respiratory asthma, and slow heartbeat) in a 99-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Hypertension. On 21-Jan-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 22-Jan-2022, the patient experienced HYPOTENSION (Low blood pressure, respiratory asthma, and slow heartbeat) (seriousness criterion death), ASTHMA (Low blood pressure, respiratory asthma, and slow heartbeat) (seriousness criterion death) and BRADYCARDIA (Low blood pressure, respiratory asthma, and slow heartbeat) (seriousness criterion death). The patient died on 22-Jan-2022. The reported cause of death was Sudden cardiac death. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. The patient usually lived in the care center. After the first dose of Moderna vaccine was administered on 21 January 2022, the patient had reactions such as hypotension, respiratory asthma, and slow heartbeat on 22January 2022. Therefore, the care center urgently called phone number 119 and the patient was sent to the emergency department of a hospital. There was no breathing and heartbeat when the patient was sent to the hospital. The patient was declared dead at 02:04 since the DNR was signed. Dead diagnosis was reported as sudden cardiac death. No treatment medications were reported. The worldwide UID was reported as 4.1(b) Company comment. This regulatory case concerns a 99 – year – old, female patient with medical history of hypertension, who experienced the unexpected, serious fatal events of hypotension, asthma, and bradycardia. The events occurred one day after the administration of a dose of mRNA-1273 vaccine, reported as first dose of her COVID – 19 immunization schedules. The report stated that the day after vaccination the patient experienced hypotension, asthma, and slow heartbeat, and when she arrived at the emergency department the patient had died. The reported cause of death was sudden cardiac death. It is unknown if an autopsy was performed. No further details were provided for medical review. Patient´s age and medical history of hypertension remain as confounders for sudden cardiac death. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Significant follow up received. Event verbatim and events updated.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of ALTERED STATE OF CONSCIOUSNESS (Changes in consciousness) in a 77-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006K21A_1110208-CDC) for COVID-19 vaccination. No Medical History information was reported. On 23-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) .25 milliliter. On 24-Jan-2022, the patient experienced ALTERED STATE OF CONSCIOUSNESS (Changes in consciousness) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. On 24-Jan-2022 the patient was sent to the pre-hospital OHCA of the emergency department of Hospital due to sudden coma. Hospital prescribed a diagnosis of death with cardiac arrest and dementia as the cause of death. 26-Jan-2022 the patient's grandson assisted in applying for follow-up drug injury relief. The patient's grandson came to this office for the submission of the VICP documents and uploaded the death certificate on 27-Jan-2022. Concomitant product use was not provided by the reporter. Treatment information was not provided. The Worldwide UID was reported as 4.1(b) Company Comment: This regulatory authority case concerns a 77 year old female with no reported medical history , who experienced Serious (fatal) , unexpected event of altered state of consciousness which occurred one day post vaccination with the 3rd dose of mRNA -1273 vaccine . This patient was brought to the ER department due to sudden onset of coma. The cause of death was reported as cardiac arrest and dementia. Other details surrounding this event were not reported. , It was unknown if an autopsy was done. The age of this patient is considered as a confounder for this case (ageing can

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	affect organs , incrase vulnerability to cardiac or neurologic events) . The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up received is non significant.
4.1(b)	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 07-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST DISCOMFORT (Chest tightness) in a 77-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 21-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 24-Jan-2022, the patient experienced CHEST DISCOMFORT (Chest tightness) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication information was provided. No treatment medication were provided. 2022/01/26 1110121 M(3),1110124 Sudden onset of loss of consciousness and no respiration in this morning. OHCA noted when arrived at ER, Dr. had Informed the critical condition for the families and start resuscitation at the same time. 1110125 he is expired at 17:46 due to Chronic kidney disease in uremic stage complicated with hyperkalemia and Out of hospital cardiac arrest. Company Comment : This regulatory case concerns a 77 year old male with no medical history reported, who experienced Serious (fatal) , unexpected event of chest discomfort which occurred 4 days post vaccination with the 3rd dose of mRNA-1273 vaccine . It was reported that this patient had sudden onset of loss of consciousness with absent respiration , he was brought to the ER 26-01-2022 , 6 days post vaccination) resuscitation was done, the family was made aware of the critical condition of the patient and later on the patient expired. The cause of death was reported as Chronic kidney disease in uremic stage complicated with hyperkalemia and out of hospital cardiac arrest. There were no details if an autopsy was done and death occurred 6 days post vaccination with the 3r d dose of the mRNA-1273 vaccine. The mentioned Chronic kidney disease (and it complications) of this patient (though not mentioned in the medical history) and the age of the patient are considered as a confounders for this case. The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in a 92-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Past medical history include stent placement for heart disease. On 20-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on 22-Jan-2022 It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Authority number reported 4.1(b) As per source document narrative It was reported that patient was 93 year-old female. but in structure field it was given as 92.2 years. She received the AZ vaccine at the health center of fusing township on 19 Jun 20221 and 17Sep 2021 respectively and received the Moderna booster shot at the health fusing center of using township on 20 Jan 2022. She did not report any discomfort after vaccination. On the night of 22 Jan 2022, she went back to her room to rest after dinner and her family found that she was not breathing when they went to her room to check on her. They called 119 and sent the patient to lukang christian Hospital. She passed away on 22 Jan 2022. The patient underwent stent placement for heart disease previously and did not experience discomfort after receiving the third dose. No concomitant information was provided. No treatment medication was reported. Company comment: This is a regulatory case concerning a 92-year-old, female patient with relevant medical history of stent placement for heart disease on an unknown date, who experienced the unexpected Fatal event of Death. The event occurred on 22-Jan-22, 2 days after the third dose of mRNA-1273 vaccine administered on 15-Dec-21 for the indication of COVID-19 vaccination. It is unknown if an autopsy was performed. Patient had previously received two doses of COVID-19 VACCINE ASTRAZENECA (Interchange of vaccine products). Patient's age and underlying heart disease requiring Stent Placement can be considered as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as Serious as per Regulatory Authority report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-Up included no new information was added.
4.1(b)	This spontaneous case was reported by a physician and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Painless acute myocardial infarction) and CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) in an 86-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (batch no. 3005786) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Femoral neck fracture (Left femoral neck fracture) and Lumbar spine compression fracture (Lumbar vertebral compression fracture L4) on 12-Nov-2019. Previously administered products included for Product used for unknown indication: Comirnaty on 18-May-2021 and Comirnaty on 14-Jun-2021. Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty.

Case ID	Narrative (Complete)
	Concurrent medical conditions included Hypertension, Diabetes mellitus, Chronic eczema, Dementia, Insomnia, Late effects of cerebral infarction, Cardiac failure chronic and Low back pain. Concomitant products included ESOMEPRAZOLE MAGNESIUM (NEXIUM EBB), RUPATADINE FUMARATE (RUPAFIN), MEMANTINE HYDROCHLORIDE (MEMANTINE HYDROCHLORIDE OD), SERTRALINE, ACETYLSALICYLIC ACID (BAYASPIRIN), ZOLPIDEM TARTRATE, CELECOXIB and AMLODIPINE for an unknown indication. On 07-Feb-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) .25 milliliter. On 08-Feb-2022, the patient experienced ACUTE MYOCARDIAL INFARCTION (Painless acute myocardial infarction) (seriousness criteria death and medically significant), CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) (seriousness criteria death and medically significant), FEELING ABNORMAL (Strange feeling) and MALAISE (Malaise in the body). The patient died on 08-Feb-2022. The reported cause of death was painless acute myocardial infarction and Cardio-respiratory arrest. An autopsy was not performed. At the time of death, FEELING ABNORMAL (Strange feeling) and MALAISE (Malaise in the body) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 28-Jun-2021, Alanine aminotransferase (10-42): 11 (normal) 11 international unit per litre. On 28-Jun-2021, Aspartate aminotransferase (13-30): 17 (normal) 17 international unit per litre. On 28-Jun-2021, Blood bilirubin (0.4-1.5): 0.5 (normal) 0.5 milligram per decilitre. On 28-Jun-2021, Blood calcium (8.8-10.1): 8.9 (normal) 8.9 milligram per decilitre. On 28-Jun-2021, Blood cholesterol (142-248): 209 (normal) 209 milligram per decilitre. On 28-Jun-2021, Blood creatinine (0.65-1.07): 1.18 (High) 1.18 milligram per decilitre. On 28-Jun-2021, Blood glucose (73-109): 103 (normal) 103 milligram per decilitre. On 28-Jun-2021, Blood lactate dehydrogenase (124-222): 162 (normal) 162 international unit per litre. On 28-Jun-2021, Blood potassium (3.6-4.8): 4.0 (normal) 4.0 millimole per litre. On 28-Jun-2021, Blood sodium (138-145): 143 (normal) 143 millimole per litre. On 28-Jun-2021, Blood triglycerides (40-149): 157 (High) 157 milligram per decilitre. On 28-Jun-2021, Blood urea (8-20): 24 (High) 24 milligram per decilitre. On 28-Jun-2021, Blood uric acid (3.7-7.8): 8.3 (High) 8.3 milligram per decilitre. On 28-Jun-2021, Eosinophil count (Unknown-6.0): 7.6 (High) 7.6 % percent. On 28-Jun-2021, Gamma-glutamyltransferase (13-64): 25 (normal) 25 international unit per litre. On 28-Jun-2021, Glycosylated haemoglobin (4.9-6.0): 6.6 (High) 6.6 % percent. On 28-Jun-2021, High density lipoprotein (40-90): 33 (normal) 33 milligram per decilitre. On 28-Jun-2021, LDL/HDL ratio: 5.3 5.3. On 28-Jun-2021, Low density lipoprotein (65-139): 152 (High) 152 milligram per decilitre. On 28-Jun-2021, Mean cell haemoglobin concentration (31.7-35.3): 31.5 (normal) 31.5 gram per decilitre. On 28-Jun-2021, N-terminal prohormone brain natriuretic peptide (Unknown-125): 164 (High) 164 picogram per millilitre. On 28-Jun-2021, White blood cell count: 7800 7800. On 07-Feb-2022, Blood pressure measurement: 120/82 120/82. On 07-Feb-2022, Body temperature: 36.2 36.2 degree Celsius. On 07-Feb-2022, Heart rate: 96 96. On 08-Feb-2022, Breath sounds: no sound was heard No sound was heard. On 08-Feb-2022, Carotid pulse: no pulse was felt No pulse was felt. On 08-Feb-2022, Heart sounds: no sound was heard No sound was heard. On 08-Feb-2022, Pupillary light reflex tests: disappeared Disappeared. On an unknown date, Body temperature: 36.2 36.2 degree Celsius. For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered ACUTE MYOCARDIAL INFARCTION (Painless acute myocardial infarction), CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest), FEELING ABNORMAL (Strange feeling) and MALAISE (Malaise in the body) to be possibly related. Company comment: This case concerns a 86-year-old male patient with hypertension and diabetes mellitus, who experienced the fatal serious unexpected events of acute myocardial infarction and cardio-respiratory arrest, on the next following day after receiving the third dose of mRNA-1273. It was reported patient appeared to be in good physical condition the night he received the vaccine. The patient experienced malaise in the body and strange feeling. The patient was found seated on the toilet in a state of cardio-respiratory arrest. Pupillary reflex disappeared, no heart sounds or breathing sounds were heard, and no pulse was felt in the carotid artery. Cause of death was reported as painless acute myocardial infarction. Advanced age and patient´s medical history remains as confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 22-Feb-2022: Follow up document received and contains Patient demographic information added, laboratory data added, concomitant product added and event added.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 07-Feb-2022. The most recent information was received on 16-Feb-2022 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by a physician and describes the occurrence of LOSS OF CONSCIOUSNESS (After 15 minutes after the Spikevax booster dose, the subject fell to the ground losing consciousness and beating his head, on my arrival he would emit rales, lost blood from the oral cavity and had no pulse.), CARDIO-RESPIRATORY ARREST (After 15 minutes after the Spikevax booster dose, the subject fell to the ground losing consciousness and beating his head, on my arrival he would emit rales, lost blood from the oral cavity and had no pulse.) and HAEMORRHAGE (After 15 minutes after the Spikevax booster dose, the subject fell to the ground losing consciousness and beating his head, on my arrival he would emit rales, lost blood from the oral cavity and had no pulse.) in a 72-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000033A) for COVID-19 vaccination. The patient's past medical history included Myocardial infarction old. Concomitant products included SERTRALINE HYDROCHLORIDE (ZOLOFT) for Depression, ENALAPRIL MALEATE, HYDROCHLOROTHIAZIDE (ACESISTEM) for Hypertension, ACETYLSALICYLIC ACID (CARDIOASPIRIN) for an unknown indication.

Case ID	Narrative (Complete)
	On 15-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milligram. On 15-Jan-2022, the patient experienced LOSS OF CONSCIOUSNESS (After 15 minutes after the Spikevax booster dose, the subject fell to the ground losing consciousness and beating his head, on my arrival he would emit rales, lost blood from the oral cavity and had no pulse.) (seriousness criterion death), CARDIO-RESPIRATORY ARREST (After 15 minutes after the Spikevax booster dose, the subject fell to the ground losing consciousness and beating his head, on my arrival he would emit rales, lost blood from the oral cavity and had no pulse.) (seriousness criterion death) and HAEMORRHAGE (After 15 minutes after the Spikevax booster dose, the subject fell to the ground losing consciousness and beating his head, on my arrival he would emit rales, lost blood from the oral cavity and had no pulse.) (seriousness criterion death). The patient died on 28-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided. Post vaccination , patient fell down , lost consciousness and hit his head. And patient was unconscious, unresponsive to stimuli emitted rales and had oral cavity bleeding upon arrival. Wrist art was not perceptible. Company comment: This regulatory case concerns a 72 year old male patient with relevant medical history of myocardial infarction, hypertension and concurrent use of acetylsalicylic acid and sertraline, who experienced the fatal unexpected serious events of Cardio-respiratory arrest, Haemorrhage and Loss of consciousness after receiving the unknown dose of mRNA-1273 vaccine. Medical history of myocardial infarction and concurrent hypertension could be confounding for the events. Concomitant acetylsalicylic acid and sertraline could be confounding for the event of haemorrhage. At the time of this report, the events had resolved with sequelae. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 16-Feb-2022: Upon query received from business partner, significant correction was performed on 28-FEB-2022. Events seriousness criteria was updated from Life Threatening to Fatal in the company comment. On 28-Feb-2022: Follow up received on 28-Feb-2022 contains no new information.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL PAIN (Abdominal Pain), SYNCOPE (Faint), ABDOMINAL PAIN UPPER (Epigastric pain , then chest pain and sudden collapse) and CHEST PAIN (Epigastric pain , then chest pain and sudden collapse) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient's past medical history included Heart failure. Concurrent medical conditions included Diabetes mellitus and Hypertension. On 14-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Jan-2022, the patient experienced ABDOMINAL PAIN (Abdominal Pain) (seriousness criterion death), SYNCOPE (Faint) (seriousness criterion death), ABDOMINAL PAIN UPPER (Epigastric pain , then chest pain and sudden collapse) (seriousness criterion death) and CHEST PAIN (Epigastric pain , then chest pain and sudden collapse) (seriousness criterion death). The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. On 03-Jul-2021, the patient received the first dose of Moderna vaccine. On 05-Oct-2021, she received the second dose of Moderna vaccine. On 14-Jan-2022, she received the third dose of Moderna vaccine (booster). On 16-Jan-2022 at 15:00-16:00, she complained of epigastric pain, nausea, stomach discomfort, leg cramps, and general discomfort, followed by chest pain and sudden collapse. On the same day at 16:38, cardiac arrest occurred before arriving at the hospital. CPR was carried out for 10 minutes, but the cardiopulmonary resuscitation was ineffective, and the patient died. On 22-Jan-2022, the hospital reported the adverse event of vaccine, and the dead diagnosis would be uploaded. The Worldwide UID was reported as 4.1(b) [redacted] CC: This regulatory authority case concerns a 73 year old female with relevant medical history of Diabetes Mellitus, hypertension and cardiac failure, received two doses of mRNA-1273 as primary series vaccine, who experienced Serious (fatal), unexpected events of abdominal pain, syncope, abdominal pain, upper and chest pain which occurred 3 days post vaccination with the 3rd dose of mRNA-1273 vaccine. On the afternoon of January 16, the patient developed right upper abdominal pain, nausea, stomach discomfort, leg cramps, chest pain, and general discomfort. This patient was brought to the hospital but the patient was already dead upon arrival at the hospital, resuscitation was done for 10 mins but the patient was not revived and declared dead. There was no reported clear statement re the cause of the death but it was mentioned that this event would be reported as an adverse event from the vaccine. It is unknown if an autopsy was done. The age of this patient and the above medical conditions are considered as confounders for this case (risk factors that can lead to a cardiovascular event). The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received contains non-significant information.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache), VOMITING (Vomiting) and SYNCOPE (Faint) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Renal dialysis (Had been receiving renal dialysis in Clinic for 9 years). Previously administered products included for Product used for unknown indication: Astrazeneca and Astrazeneca. Past adverse reactions to the above products included Fever with Astrazeneca and Astrazeneca. Concurrent medical conditions included Diabetes mellitus (DM). On 19-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Jan-2022, the patient experienced HEADACHE (Headache) (seriousness criterion death), VOMITING (Vomiting) (seriousness criterion death) and SYNCOPE (Faint) (seriousness criterion death). The reported cause of death was Headache, Vomiting and Faint. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient with OHCA was admitted to the emergency department. Company Comment: This regulatory authority case concerns a 72-year-old female patient, with relevant medical history of Diabetes Mellitus and has been receiving hemodialysis procedure for nine years, who experienced the unexpected serious fatal events of Headache, Vomiting and Syncope, which occurred 9 days after receiving a dose mRNA-1273 vaccine taken as third dose of COVID-19 immunization. Interchange of vaccine products is noted in this case as patient received 2 doses of AstraZeneca COVID-19 vaccine on unspecified dates prior to mRNA-1273 administration. The events were accompanied by loss of consciousness which prompted the pre-hospital emergency response. She was noted to have no vital signs prior admission in the emergency room. Death occurred approximately 9 days after receiving the third dose of mRNA-1273 vaccine. The cause of death was reported as Headache, Vomiting and Syncope. It is unknown if an autopsy was performed. Advanced age and medical history remain as confounders for the events and for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per regulatory authority's report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up document received: Medical history was updated, LLT of event syncope was changed to faint and cause of death was added.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of ALTERED STATE OF CONSCIOUSNESS (Changes in consciousness) in an 87-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Dialysis and Stent placement. Concurrent medical conditions included Diabetes, End stage renal failure and Coronary artery disease. On 15-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Jan-2022, the patient experienced ALTERED STATE OF CONSCIOUSNESS (Changes in consciousness) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Authority number-4.1(b) On 15 Jan, the reporter stated patient received the Moderna booster, and then he was continually weak. Two days later, patient had abnormal liver function, increased white blood cells, and improved inflammation index after blood drawing. However, the fatigue continued. On 27 Jan, the patient received dialysis treatment in the morning. Blood pressure was normal at 8:05. At 8:15, they suddenly opened their arms and lost consciousness. After losing consciousness, their blood pressure dropped and their heart stopped. First aid was started immediately. The patient was sent to the emergency department of Hospital to continue the first aid, but the patient was declared dead. No concomitant medication was reported. No treatment information was provided. Company Comment: This regulatory authority case concerns a 87 year old male with relevant medical history of Diabetes mellitus , End stage renal disease on maintenance hemodialysis, known to have Coronary Artery disease S /P stet placement , who experienced Serious (fatal) , unexpected event of altered state of consciousness which occurred 13 days post vaccination with the 3rd dose of mRNA-1273 vaccine . This patient was reported to be continually weak after receiving the vaccine , noted abnormal liver function , increased WBC . 13 days post vaccination with the mRNA=1273 , this patient underwent hemodialysis initially had stable vital signs and after 10 mins of treatment he had loss of consciousness , the BP dropped and the heart beat stopped , Resuscitation was given . Further details regarding this event was not given . This RA case report gave two conflicting possible outcome , the seriousness criteria was captured as Fatal while th outcome was recovering , There were no other details found in the SD that can draw the conclusion because the narrative was not complete. The medical history stated above and the age of this patient are confounders for this case (all are risk factor for possible acute events that can lead to death) . The benefit -risk relationship of mRNA -1273 is not aff Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-Up included non-significant information was added. I-narrative added.
4.1(b)	This case was initially received via an unknown source (no reference has been entered for a health authority or license partner) on 07-Feb-2022. The most recent information was received on 25-Apr-2022 and was forwarded to Moderna on 25-Apr-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of ASTHMA (Respiratory asthma) and CHEST DISCOMFORT (chest tightness) in a 72-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Graft failure (SVG failure), Stent placement (cardiac catheter stent was implanted), CABG (s/p CABG with SVG failure), Bare metal coronary stent placement (s/p DES to proximal and mid LAD and BMS to distal LAD, with ISR in DES in p- and m-LADs/p DEB and BMS, s/p BMS to distal LAD.), Drug-eluting stent placement (s/p DES to proximal) and Dialysis since an unknown date. Previously administered products included for Product used for unknown indication: Aztrazenica. Past adverse reactions to the above products included Chest tightness with Aztrazenica. Concurrent medical conditions included Coronary artery disease (CAD, 3VD) since January 2020, Mitral regurgitation (Moderate) and End stage renal disease (ESRD) (on HD135). On 10-Jan-2022, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 11-Jan-2022, the patient experienced ASTHMA (Respiratory asthma) (seriousness criterion death) and CHEST DISCOMFORT (chest tightness) (seriousness criterion death). The patient was treated with NITROGLYCERIN at an unspecified dose and frequency. The reported cause of death was respiratory asthma, Chest tightness, Heart failure and Kidney failure. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 11-Jan-2022, Blood pressure measurement: 91/60 (Low) 91/60 mmHg and 119/76 119/76 mmHg. On 11-Jan-2022, Body temperature: 36.2 36.2°C;. On 11-Jan-2022, Coma scale: e2v1m3 E2V1M3.

Case ID	Narrative (Complete)
	On 11-Jan-2022, Electrocardiogram: standstill standstill. On 11-Jan-2022, Heart rate: 86 86 BPM. On 11-Jan-2022, Oxygen saturation: 82 82%, and after O2 mask was used, 88 88%, 92 92% and 82 82%. On 11-Jan-2022, Respiratory rate: 36-38 36-38 times/min and 32 32 times/min. On 11-Jan-2022, Vital signs measurement: had no vital signs had no vital signs. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. Company comment: This fatal regulatory authority case concerns a 72-year-old male patient, with medical history of graft failure (reported as SVG failure), coronary artery bypass, bare metal coronary stent placement, coronary artery disease, mitral regurgitation and drug-eluting stent placement, who experienced the serious (due to death) unexpected events of ASTHMA and CHEST DISCOMFORT, on the following day he received a dose of mRNA-1273 vaccine, considered as the second dose of the vaccination schedule, and died on the same day that the events occurred. he previously received, on an unknown date, a dose of AstraZeneca'S COVID-19 vaccine. According to the narrative of the source document, on the following day of the vaccination with mRNA-1273, his USUAL? renal dialysis, due to his end stage renal disease, HAD TO be suspended because of chest discomfort, dyspnea, desaturation and heart rate increased, for what he was sent to the emergency room, where a severe lung edema was found. his electrocardiogram showed standstill and the patient lost his vital signs. The reported cause of death was a natural death due to his heart and kidney failure and the doctor stated that it did not seem to be an acute heart discomfort caused by the vaccination. It is unknown if an autopsy was performed. The history of graft failure, coronary artery bypass, bare metal coronary stent placement, coronary artery disease, mitral regurgitation and drug-eluting stent placement remain as confounders for chest discomfort. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up document contains added cause of death, medical history, lab data, treatment medication, deleted an event (shortness of breath), added new event (respiratory asthma) and updated I-narrative.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in a 70-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Patient medical history includes Urinary calculi, Helicobacter pylori. On 18-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on 25-Jan-2022 The patient died on 25-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Regulatory authority number-4.1(b) Shuanghe Hospital reported (death) - a 70-year-old male, with a history of urinary calculi and Helicobacter pylori, continued to take antibiotics, received the first and second doses of Moderna vaccine on July 13 and October 5 respectively, without special symptoms, and received the third dose of Moderna vaccine on January 18 at Shuanghe Hospital. After vaccination, the patient developed respiratory asthma. On 25 Jan, the patient rested in the car due to respiratory asthma in the parking lot of his home, and then had no breathing and heartbeat. The patient was found by passers-by, and they immediately reported it to 119, the 119 personnel send the patient to the hospital for rescue, but the patient died without treatment. The doctor diagnosed that the cause of death was acute myocardial infarction. Company Comment:This is a regulatory case concerning a 70-year-old, male patient with no medical history reported, who experienced the fatal event of Death, which occurred 7 days after the third dose of mRNA-1273 vaccine. After vaccination, the patient developed respiratory asthma. On 25 Jan, the patient rested in the car due to respiratory asthma in the parking lot of his home, and then had no breathing and heartbeat after moving to hospital for rescue, patient died without treatment. The doctor diagnosed that the cause of death was acute myocardial infarction. Inappropriate schedule of product administration was also noted in the case (interval between dose 1 and dose 2 longer than 35 days), Dose interval is 84 days, and third dose was administered less than 6 months after completing the primary series. Patients elderly age remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The event was assessed as serious as per Regulatory Authority´s report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: no new information added.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest Pain) in an 80-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 18-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Subcutaneous) 1 dosage form. On 21-Jan-2022, the patient experienced CHEST PAIN (Chest Pain) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Subcutaneous), the reporter did not provide any causality assessments. The WWID for the case is4.1(b) This is a fatal case that concerns an 80-year-old female patient with no relevant medical history, who experienced the unexpected serious event of Chest Pain. The event led to the demise of the patient as reported by the regulatory authority. The event occurred in 4 days after receiving the third dose of mRNA-1273 Vaccine. As reported, the patient had chest tightness after receiving the dose of vaccine. The patient unexpectedly had chest pain and died shortly after being sent to hospital. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes:

Case ID	Narrative (Complete)
	On 25-Apr-2022: Follow Up received with Non-Significant information: the WWID added in I-narrative.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in a 69-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Current conditions included Hypertension. On 15-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on 15-Jan-2022 It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Relevant concomitant product usage were not reported by the reporter. No treatment details were added. The patient received the third dose of Moderna vaccine on the morning of January 15, 2022 and died at 15:40 (the patient died at home; when the family found him, the patient had been dead for more than 1 hour and was not sent to hospital). The daughter of the patient was asked and said that the patient had no chronic diseases. January 28, 2022 The family member of the patient was called and said that the patient had a history of hypertension many years ago, and did not take medicines in recent years after weight loss and exercise control. On the morning of January 15, after the patient was vaccinated, the family members returned home at 1 p.m. thinking that the patient was resting. They visited the patient at more than 3 p.m. and found that the patient was dead and became stiff. The ambulance personnel arrived at the scene and said that the patient had been dead for a long time and they did not send the patient to the hospital. The administrative test indicated that the patient died of cardiogenic shock. The WWID of the case is 4.1(b) Company Comment: This is a regulatory case concerning a 69-year-old male patient with a past medical history of hypertension, who presented with unexpected event of death. Event death occurred on the same day after the received third dose of mRNA 1273 vaccine. Patient was found dead by family members hours after the vaccine and administrative test indicated that the patient died of cardiogenic shock. It is unknown if an autopsy was performed. The reporter did not provide any causality assessment. The benefit risk relationship of vaccine is not affected by this report Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non significant Follow up appended. No new information added.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (Fever), THROMBOCYTOPENIA (Thrombocytopenia) and CEREBRAL HAEMORRHAGE (Intracerebral hemorrhage (ICH)) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 05-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Jan-2022, the patient experienced PYREXIA (Fever) (seriousness criterion death), THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criterion death) and CEREBRAL HAEMORRHAGE (Intracerebral hemorrhage (ICH)) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. The patient received the Moderna vaccine as the second dose on 05-OCT-2021 and sought medical attention at the emergency room of the hospital on 11-JAN-2022 due to fever/chills, general weakness. Lab data were reported as Oxygen saturation: 96%, blood pressure: 114/56 mmHg, pulse: 109 beats/minute, temperature: 40°C. Prescription by the emergency room: (Later transferred to the inpatient ward) Acetaminophen 500 mg/tab 1 ST PO, CEFEEPIME 500mg/vial 1g ST IV, Lenograstim 250mcg/vial 1 ST Subcutaneous. On 13-Jan-2022 Hb: 6.5 treated with LRRBC 2U, and PLT:1000 treated with LRPH 2U. On 14-Jan-2022 B/C: E coli, based on the bacterial culture results, the antibiotics was adjusted to Ertapenem 1000mg IVD ST+QD. On 15-Jan-2022 poor appetite treated with B-fluid 1000ml QD, and fever at 38.6 degrees and PLT 3000 treated with PLPH 1U for 2 days (15-Jan and 16-Jan) On 16-Jan-2022 Diarrhea treated with smetcta 1pk po st, and fever at 38.4 degrees treated with Acetaminophen 1tab po PRNQ6H. The patient reported bilateral rib pain, so tramacet 1tab po q6h was administered. After taking tramacet, the patient vomited, so IMperam 2 ml IV ST was administered and Furosemdie [sic: Furosemide] 20mg IV ST was administered for edema of lower extremities; CXR: deterioration of bilateral lungs. The patient's family reported that when assisting the patient in turning over, the patient had an altered state of consciousness to E1V1M1, vomited and muscle strength in all extremities was 0 points. The altered state of consciousness was due to thrombocytopenia, so ICH was suspected and the patient was transferred to the intensive care unit as her medical condition was unstable. Brain CT: cerebral hemorrhage. At 11.02 p.m., the hospital pronounced the patient dead due to the altered state of consciousness (pulse 0 beats/minute, respiratory rate 0 breaths/minute, blood pressure 0). As the possibility that cerebral hemorrhage was induced by the vaccine could not be ruled out, it was reported as an adverse reaction. The patient received the Moderna vaccine as the second dose on 05-OCT-2021 and sought medical attention at the emergency room of the hospital on 11-JAN-2022 due to fever/chills, asthenia and generalized weakness. Lab data: Oxygen saturation: 96%, blood pressure: 114/56 mmHg, pulse: 109 beats/minute, temperature: 40°C). Prescription by the emergency room: Acetaminophen, ST Pocefepime, ST IVLenograstim SC 01/13/2022 Hb:6.5 LRRBC 2U was administered, PLT:1000 LRPH 2U was administered. 14-jan-2022 B/C: E coli, based on the bacterial culture results, the antibiotics was changed to Ertapenem 1000mg IVD ST+QD 01/15/2022 B-fluid 1000ml QD was administered due to poor appetite; fever of 38.6°C, PLT 3000 PLPH 1U was administered for 2 days smetcta was administered for diarrhea, Acetaminophen 1tab was administered for fever of 38.4°C The patient reported bilateral rib pain, so tramacet 1tab was administered. After taking tramacet, the patient vomited, so IMperam 2 ml IV ST was administered and Furosemdie 20mg IV ST was administered for edema of lower extremities; CXR: deterioration of bilateral lungs. When assisting the patient in turning over, the patient had an altered state of consciousness to E1V1M1, vomited and muscle strength in all extremities was 0 points. The altered state of consciousness was due to thrombocytopenia, so ICH was suspected and the patient was transferred to the intensive care unit as her medical condition was

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	unstable. Brain CT: cerebral hemorrhage. At the hospital pronounced the patient dead due to the altered state of consciousness. As the possibility that cerebral hemorrhage was induced by the vaccine could not be ruled out, it was reported as an adverse reaction. Patient took both doses of Moderna. Past medical history: hypertension, acute myeloid leukemia, blindness in left eye underwent right eye cataract surgery previously. her arm swelled and was painful and she had a poor appetite after she returned home from receiving the second dose but did not seek medical attention. She was diagnosed with acute leukemia on 29-Nov-2021. Between 11-Jan-2022 and 16-Jan-2022 patient sought medical attention at the emergency room at the Hospital due to fever/chills, and generalized weakness and was accompanied by her family. (Oxygen saturation: 96%, blood pressure: 114/56 mmHg, pulse: 109 beats/minute, body temperature: 40°C). The patient was subsequently transferred to an inpatient ward and administered with antibiotics. During this period, she had persistent high fever and was administered with symptomatic treatment. On 17-Jan-2022, the patient reported bilateral rib pain, vomiting, and edema of lower extremities, and the patient was found to have deterioration of bilateral lungs upon CXR examination. Patient's family reported that when assisting the patient in turning over, the patient had an altered state of consciousness to E1V1M1, vomited and muscle strength in all extremities was 0 points. The altered state of consciousness was due to thrombocytopenia, so ICH was suspected and the patient was transferred to the intensive care unit as her medical condition was unstable. The patient was found to have cerebral hemorrhage through a brain computed tomography. At 11.02 p.m., the hospital pronounced the patient dead due to the altered state of consciousness after emergency treatment proved ineffectual. At 10.10 a.m. on 26-Jan-2022, the center for disease control of the district called the patient's son to show concern. The relevant staff confirmed the patient's past medical history and expressed concern. The patient's son was informed that they could apply for VICP and the committee will clarify and determine whether there is a correlation. The patient's son accepted that. Death diagnosis were reported as nontraumatic intra cerebral hemorrhage and acute myeloid leukemia. Company comment: This Regulatory Authority case concerns a 72-year-old, female patient with relevant medical history of hypertension, acute myeloid leukemia, blindness in left eye secondary to RTA, and right eye cataract surgery, who experienced the unexpected fatal AESI events of Cerebral Hemorrhage, Thrombocytopenia, and Pyrexia. The events occurred approximately 3 months 13 days after the second dose of mRNA-1273 (Moderna covid-19 vaccine). Patient experienced a painful arm swelling (not reported as events by RA) on an unspecified date after the second dose of mRNA-1273. Approximately 3 months 13 days post second dose of mRNA-1273, the patient was hospitalized for fever/chills, asthenia, and generalized weakness; and treated with antibiotics and symptomatic treatment for the persistent fever. Patient complained of bilateral rib pain, edema of lower extremities, vomiting, and was found to have deterioration of bilateral lungs upon chest X-ray. She was found to have altered state of consciousness, vomiting, and muscle strength in all extremities was 0 points. Altered state of consciousness was reported as secondary to thrombocytopenia. Intracerebral hemorrhage was suspected, medical condition became unstable, and patient was moved to ICU. Patient subsequently died of cerebral hemorrhage as showed by brain CT. However, this pat
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL PAIN (Abdominal pain) and ALTERED STATE OF CONSCIOUSNESS (Changes in consciousness) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 050F21A_1110124-CDC) for COVID-19 vaccination. The patient's past medical history included Chronic ischemic heart disease, unspecified, Essential hypertension (Primary), End stage renal disease (ESRD) (ESRD under Hemodialysis), Colon cancer stage II (S-D junction colon cancer (pT3N0M0,stage IIA)) and Hemodialysis (ESRD under Hemodialysis). On 11-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 milliliter. On 17-Jan-2022, the patient experienced ABDOMINAL PAIN (Abdominal pain) (seriousness criterion death) and ALTERED STATE OF CONSCIOUSNESS (Changes in consciousness) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not provided. The patient received the first dose of Astrazeneca vaccine on 17-Jun-2021. The patient received the second dose of Astrazeneca vaccine on 28-Sep-2021, and received the third dose of Moderna vaccine on 01-Jan-2022. On 11-Jan-2022, at 09:34 A.M, the patient received booster dose of Moderna vaccine. The patient had sought medical treatment at the Emergency room of the hospital due to abdominal pain for five days. The patient had undergone some blood tests and results were as follows : Creatinine (B): 7.24(mg/dL), eGFR (Glomerular filtration rate): 7.4 (ml/min/1.73 m^2), Na (sodium): 134 (meq/L), CRP (C-reactive protein): 21.43 (mg/dL), WBC: (white blood cells): 15.6 (10 ^3/uL), Hb (hemoglobin): 9.5 (g/dL). The patient had undergone CT scan of abdomen (display) and result found was right pleural effusion, left lower lobe pneumonia, bilateral renal calculi and ruled out the possibility of spleen inflammation. Patient was treated with 0.9 percent saline (500ml/bag) 500ml IVD STAT, 0.9 percent saline (500mL/bag) 100mL+Flomoxef (1g/vial) 1000mg STAT IVD, Ketorolac (30mg/amp) 30mg STAT IVP . The patient was suggested to receive a treatment at hospital after consultation with the emergency physician. On 17-Jan-2022, the patient sought medical treatment at the Emergency Room due to abdominal pain for five days. On 17-Jan-2022, the COVID-19 PCR test came back as negative, with abnormal CK-MB and Troponin I values, right pleural effusion, left lower lobe pneumonia, bilateral renal calculi and ruled out possibility of spleen inflammation. The patient was admitted to the hospital for treatment. Company comment-This regulatory authority case concerns a 75 year old male , with relevant medical history of hypertension, chronic ischemic heat disease (unspecified) , End stage renal dsease on maintenance hemodialysis , Colon CA stage 2 , initially vaccinated with 2 doses of Covid 19 vaccine Astra Zeneca, who experienced Serious (fatal) , unexpected events of abdominal pain and altered state of consciousness which occurred 10 days post vaccination with the 3rd dose of mRNA-1273 vaccine . This patient was seen at the General hospital ER because of abdominal pain occurring for the past 5 days. Laboratories were done noted to have increased Serum creatinine , decreased hemoglobin , increased WBC and CRP . Treatment given was I V saline with Flomoxef and I V ketorolac. Ct scan of the abdomen was done which revealed : Right pleural effusion, left lower lobe pneumonia, bilateral renal calculi and r/o spleen inflammation. The patient was advised admission at the hospital . RT PCR test done which revealed negative results. One day after there was increased chest and abdominal pain and shortness of breath. The physician did 12L ECG, X-ray, and blood tests K: 4.3 (meq/L), CK: 104 (U/L), CK-MB (mass): 22.5 (ng/mL), Troponin I: 4404.5 (pg/mL), D-dimer: 6.680 (mg/L, with an impression of Myocardial infarction, nitroglycerin (NTG)0.6mg 1# ST PO was given. The assessment of Chest x-ray showed suspected aortic dissection so a CT scan of the abdomen was done which revealed negative for dissection however this patient's sensorium deteriorated transferred to ICU , brain CT scan revealed Subarrachnoid

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	hemorrhage , referred to neurosurgery service and surgery was done , post operation patient still had elevations in trop I and CPKMB, this patient went to Cardiac arrest , CPR done however it was not successful and this patient died after three days of hospitalization. The age of this patient , history of vaccinatiojn for 2 doses with Covid 19 Vaccine Astra Zeneca and the above medical conditions are considered as confounders for this case. The benefit - risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. Also dosage for this booster dose was reported as 0.5mL not the recommended 0.25mL booster dose, hence Accidental overdose occurred. The Worldwide UID was reported as 4.1(b) [redacted] Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow Up received is non significant.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of SYNCOPE (Faint) and ALTERED STATE OF CONSCIOUSNESS (Change of consciousness) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006K21A_1110208-CDC) for an unknown indication. No Medical History information was reported. On 25-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 25-Jan-2022, the patient experienced SYNCOPE (Faint) (seriousness criteria death and medically significant) and ALTERED STATE OF CONSCIOUSNESS (Change of consciousness) (seriousness criteria death and medically significant). It is unknown if an autopsy was performed. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported On 25-Jan-2022 it was reported that the patient had a history of diabetes, asthma and hemodialysis, received the third dose of Mo in vaccination station on 25-Jan-2022 (the first two doses were AZ).After taking rest for 15 minutes, the patient was accompanied by her spouse and left on foot. At 9:10, her spouse said that the patient had just got onto the bus and had shock and became unconscious. At 9:11, 119 was called and the on-site doctors performed CPR, oxygen inhalation and epinephrine injection. After that, the blood pressure was restored to 74/50, the heart rate was restored to 143, the SpO2 was restored to 49, and the blood glucose was resorted to 195. After the ambulance arrived at the site and coordinated treatment was given, the ambulance left at 9:24 and sent the patient to hospital in the district. Later, it was notified by hospital that the patient had died before arriving at the hospital. The Worldwide UID was reported as 4.1(b) [redacted] Company comment: This regulatory case concerns a 72-year-old female patient with medical history of diabetes, asthma and haemodialysis, experienced fatal events Syncope and Altered state of consciousness, within minutes after the third dose of mRNA-1273. Within fifteen minutes after taking the dose, the patient left the vaccination center but lost consciousness in the car. CPR, oxygen, and epinephrine were administered but the blood pressure did not recover to normal. He was shifted to a hospital in an ambulance but was declared dead on arrival. Patient's elderly age, medical history remain confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received contains non-significant information.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Hypertension and Parkinson's disease (Taking Amantadine). On 04-Nov-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 28-Dec-2021, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria death and life threatening). The patient died on 24-Jan-2022. The reported cause of death was Heart failure. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Dec-2021, Alanine aminotransferase increased: 117 * iu/l 117 * IU/L. On 31-Dec-2021, Angiogram: negative study (Negative) Negative study. On 31-Dec-2021, Blood bilirubin: 0.58 mg/dl 0.58 mg/dL. On 31-Dec-2021, Blood creatinine: 1.50 mg/dl 1.50 mg/dL. On 31-Dec-2021, Blood gases: ph: 7.22 *, pco2: 38 mmhg, po2: 10 * mmhg pH: 7.22 *, pCO2: 38 mmHg, pO2: 10 * mmHg, HCO3-: 15.6 * mmol/L. On 31-Dec-2021, Blood glucose: 305 *mg/dl 305 *mg/dL. On 31-Dec-2021, Blood pressure measurement: 80/63 mmhg 80/63 mmHg. On 31-Dec-2021, Blood sodium: 132 * mmol/l 132 * mmol/L. On 31-Dec-2021, Blood urea: 32 * mg/dl 32 * mg/dL. On 31-Dec-2021, Body temperature: 35.3'c 35.3'C. On 31-Dec-2021, C-reactive protein abnormal: 13.95 mg/dl 13.95 mg/dL. On 31-Dec-2021, Chest X-ray: widened mediastinum can't exclude aortic dissectio widened mediastinum cannot exclude aortic dissection.. On 31-Dec-2021, Computerised tomogram: no evidence of aortic aneurysm, aortic dissection No evidence of aortic aneurysm, aortic dissection, or pulmonary embolism. On 31-Dec-2021, Echocardiogram: poor lv systolic performance Poor LV systolic performance and hypokinesia Hypokinesia. On 31-Dec-2021, Ejection fraction: 20-30 % by visual estimate, anteroseptal wall akin 20-30 % by visual estimate, anteroseptal wall akinesis to dyskinesis, no pericardial effusion or acute MR.. On 31-Dec-2021, Electrocardiogram: wide complex tachycardia, st elevation at avr Wide complex tachycardia, ST elevation at aVR and precordial leads suspect LM to LAD disease.. On 31-Dec-2021, Heart rate: 104/min 104/min. On 31-Dec-2021, Lipase: 21 u/l 21 U/L.

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	On 31-Dec-2021, Respiratory rate: 30 30. On 20-Jan-2022, Body temperature: 36.2 36.2. On 20-Jan-2022, Heart rate: 90 90. On 20-Jan-2022, Oxygen saturation: 94 94. On 20-Jan-2022, Respiratory rate: 27 27. On 24-Jan-2022, Anti-platelet factor 4 antibody test: negative (Negative) Negative. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. WWID number for the case was 4.1(b) [redacted] Concomitant medication was not reported. Patient had chest pain with back pain for 3 days (28-DEC-2021) and had visited local clinic. However, hypotension was noted, and she was transferred to ER on 31-DEC-2021. Initially G.C.S was E4M6V5. Due to progressed hypotension, VA-ECMO was inserted. BE -11.4(mmol/L). The patient was diagnosed with cardiogenic shock, s/p VA-ECMO, suspected myocarditis related since 31-DEC-2021. Coronary artery only LAD 50% stenosis without occlusion. On 21-Jan-2022 Uploaded Anti-PF4 Ab test report, 1/20 ICU, on ECMO, hemodialysis, with G.C.S as E1VtM. On 24-Jan-2022 Uploaded Anti-PF4 negative report. On 26-JAN-2022, the patient was living in the ICU and symptoms became worse last week, shock symptoms appeared, and ECMO was installed. The conditions continued to deteriorate and patient died. Company comment: This is a regulatory case concerning a 65-year-old female patient with a medical history of hypertension and Parkinson's disease, who experienced the unexpected event of Myocarditis. The event occurred approximately 54 days after the second dose of mRNA – 1273 vaccine. Patient had chest pain 3 days prior to admission and had progressing hypotension and diagnosed with cardiogenic shock. Patient's condition deteriorated, diagnosed with heart failure and eventually expired. It is unknown if an autopsy was performed. The reporter's assessment was not provided. The benefit-risk relationship of the vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-Up received and had no new information.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of LOSS OF CONSCIOUSNESS (Unconsciousness, no breathing and heartbeat), APNOEA (Unconsciousness, no breathing and heartbeat) and CARDIAC ARREST (Unconsciousness, no breathing and heartbeat) in a 72-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 050F21A-1110124-CDC) for COVID-19 vaccination. No Medical History information was reported. On 17-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Jan-2022, the patient experienced LOSS OF CONSCIOUSNESS (Unconsciousness, no breathing and heartbeat) (seriousness criteria death and medically significant), APNOEA (Unconsciousness, no breathing and heartbeat) (seriousness criteria death and medically significant) and CARDIAC ARREST (Unconsciousness, no breathing and heartbeat) (seriousness criteria death and medically significant). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not reported. No treatment information was provided by the reporter. On 21 Jan 2022, the 91 staff reported that the patient fell on the floor in the dining room and was brought to this hospital by the 91 staff. The patient had no heartbeat upon arrival. The patient's family said that the patient received the third dose of the COVID 19 Moderna vaccine on 17 Jan. On 25 Jan 2022, The patient died. After asking the person in charge at Sanyi Township Health Center, the patient's family has applied for a death certificate at the Sanyi Township Health Center. The Health Center has been requested to close the patient after uploading the death diagnosis. On 25 Jan 2022: Since the patient lived in Sanyi Township, assistance was provided in the processing of the case withdrawal. 21 Jan 2022 The family members came to the Health Center for an administrative review and said that they did not want to perform an autopsy or report. After the explanation, the family members said that they would consider it again. The WWID of this case 4.1(b) [redacted] Company Comment: This regulatory authority case concerns a 72-year-old, male patient with unknown medical history, who experienced the unexpected serious (seriousness criterion- Results in death) events of Loss of consciousness, Apnoea, and Cardiac arrest. All the events occurred 4 days after the third dose of mRNA-1273 VACCINE and had a fatal outcome. The patient reportedly fell on the floor and was brought to the hospital where he had no heartbeat upon arrival. However, the date and cause of death were not specified, and an autopsy was not performed. The patient's age remains a confounder. The benefit-risk relationship of MODERNA COVID-19 VACCINE is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non-significant follow-up appended. No new information added.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (Fever) and DECREASED APPETITE (Loss of appetite) in an 86-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 072F21A_1110129-CDC) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Astrazeneca (1st dose) on 15-Jun-2021 and Astrazeneca (2nd dose) on 18-Sep-2021. Past adverse reactions to the above products included No adverse effect with Astrazeneca and Astrazeneca. Concurrent medical conditions included Bronchiectasis (Suffered from bronchiectasis for many years.and received treatment.).

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	On 20-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 25-Jan-2022, the patient experienced PYREXIA (Fever) (seriousness criterion death) and DECREASED APPETITE (Loss of appetite) (seriousness criterion death). The patient was treated with PARACETAMOL (PANADOL) at an unspecified dose and frequency. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication was not provided. Patient's family member complained that after the first two doses of AZ there was no special discomfort and reaction, but recently the patient was weak and had a poor appetite. The patient was ill the next day after returning home. Patient took Panadol but her body was still weak. Till January 25, the patient was sleepy and could not be woken up and later died, without being sent to see a doctor. On Jan'28-2022 The daughter of the patient explained that her mother had passed away and she will consider whether to apply for VICP after the Spring Festival. Treatment information was not reported. Company comment: This is a regulatory case concerning an 86 year-old, female patient with a history of Bronchiectasis and Interchange of vaccine products (vaccination with two doses of COVID-19 vaccine AstraZeneca approximately 3 months prior), who experienced the serious Fatal unexpected, events of pyrexia and Decreased appetite, approximately 5 days after the booster dose of mRNA-1273 vaccine. It was reported she felt unwell, weak, sleepy and was found dead 5 days after the vaccination, cause of death was not further specified and there was no hospital visit. It is unknown whether an autopsy was performed. The mentioned medical history and patient´s advanced age remain as confounders for the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up received and had no new information.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of COUGH (Cough) in a 72-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 939599-CDC) for an unknown indication. No Medical History information was reported. On 08-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Aug-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced COUGH (Cough) (seriousness criterion death). It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The Worldwide UID was reported as 4.1(b) On July 8, 2021, the patient received the first dose of Moderna and developed a cough at the end of July. She was hospitalized at the China Medical University Hospital on August 16. The patient was diagnosed with lung cancer, treated with chemotherapy and targeted drugs and discharged from hospital on September 3. The patient was hospitalized again on September 22 for respiratory distress and continued to suffer from low oxygen levels and shortness of breath during her stay. The patient dead on October 18, 2021. January 20, 2022 The patient's son wanted to apply for vaccination victimization relief and was assisted in notification. On 22 January 2022 The patient's son wanted to apply for vaccination victimization relief and was assisted in material submission. The last date of administration of COVID-19 Vaccine was on 07 Jul 2021. No concomitant product use was provided by the reporter. No treatment medication was provided. Company Comment: This regulatory authority case concerns a 72-year-old male patient, with no medical history reported, who experienced the unexpected serious event of Cough. The event occurred approximately 39 days after receiving the first dose of mRNA-1273 Vaccine. The patient was diagnosed with lung cancer, treated with chemotherapy and targeted drugs and discharged from hospital. A few days after discharge, patient was readmitted due to respiratory distress, low oxygen levels and shortness of breath. Patient died approximately 26 days from the last admission. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non significant follow-up appended
4.1(b)	This case was initially received via European Medicines Agency (Reference number: NL-LRB-00783632) on 08-Feb-2022. The most recent information was received on 16-Feb-2022 and was forwarded to Moderna on 16-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC ARREST (Cardiac arrest died within 24 hours of vaccination) in an 82-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Venous thromboembolism, Gastroesophageal reflux disease, Post herpetic neuralgia (chronic nerve pain due to shingles.), Renal function disorder and Syncope on 27-Nov-2021. Previously administered products included for Product used for unknown indication: COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST (COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST) in February 2021, COVID-19 vaccin Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST (COVID-19 vaccin Pfizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST) in April 2021 and griepprik INFLUENZAVACCIN (NIET GESPECIFICEERD) (griepprik INFLUENZAVACCIN (NIET GESPECIFICEERD)) on 11-Nov-2021.

Case ID	Narrative (Complete)
	Past adverse reactions to the above products included Flu-like illness with COVID-19 vaccin Pfizer COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; Flu-like symptoms with COVID-19 vaccine Pfizer COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; and No adverse event with griepprik INFLUENZAVACCIN (NIET GESPECIFICEERD). Concurrent medical conditions included Short stature (original length 1.60 m, severe osteoporosis made very shrunk. Intestines and lungs were oppressed .), Epilepsy since 1993, Hypertension (doubt if she had high blood pressure. I think so and that was brought down with medication.) and Osteoporosis. Concomitant products included CALCIUM CARBIMIDE (CALCIUMCARBIMIDUM), FENTANYL (FENTANYL CT), IPRATROPIUM BROMIDE (IPRATROPIUM BR), LIDOCAINE HYDROCHLORIDE (LIDOCAINE NMD), SIMVASTATINE, DENOSUMAB, GABAPENTINE and LEVETIRACETAM (LEVETIRACETAM TEVA) for an unknown indication. On 12-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Dec-2021, the patient experienced MALAISE (immediately after vaccination, chillful and general malaise) and CHILLS (immediately after vaccination, chillful and general malaise). On 13-Dec-2021, the patient experienced CARDIAC ARREST (Cardiac arrest died within 24 hours of vaccination) (seriousness criterion death). The patient died on 13-Dec-2021. The reported cause of death was cardiac arrest after booster vaccination. An autopsy was not performed. At the time of death, MALAISE (immediately after vaccination, chillful and general malaise) and CHILLS (immediately after vaccination, chillful and general malaise) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In November 2021, Specialist consultation: she collapsed during shopping a week or 3 before t She collapsed during shopping a week or 3 before the booster, and no cause has been found. There was consultations with the neurologist about epilepsy at the time, but it was not related to that.. Treatment information was not provided. Company comment: This is a regulatory authority case concerning a 82-year-old, female patient with relevant medical history of venous thromboembolism, hypertension and syncope, relevant concurrent medical conditions of osteoporosis with intestinal and lung compression, epilepsy and renal function disorder and relevant concomitant use of fentanyl, who experienced the unexpected serious event of cardiac arrest, the unexpected non-serious event of general malaise and expected non-serious event of chills. The events general malaise and chills occurred 1 hour after the unknown dose number of mRNA-1273 vaccine administration while the event cardiac arrest occurred 22 hours after the unknown dose number of mRNA-1273 vaccine administration. The event cardiac arrest resulted to death. The reported cause of death is cardiac arrest. Autopsy was not performed. The medical history of venous thromboembolism, hypertension, syncope, concurrent medical conditions of osteoporosis with intestinal and lung compression, epilepsy, renal function disorder and the concomitant use of fentanyl remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 16-Feb-2022: Follow up received on 16-Feb-2022 and contains updated relevant medical history and concomitant medication added.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (found dead by the husband in the morning (23.01.22).) in a 78-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 216045) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Tachyarrhythmia absoluta, Tetraplegia, Lung fibrosis, COVID-19 in February 2021, Leg venous thrombosis in 2017 and Myopathy. Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 30-Jul-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2. On 22-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 22-Jan-2022, the patient experienced INFLUENZA LIKE ILLNESS (Strong freezing, nausea and vomiting, after a few hours of improvement, went to bed). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, INFLUENZA LIKE ILLNESS (Strong freezing, nausea and vomiting, after a few hours of improvement, went to bed) had not resolved. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications details were not reported by the reporter. Treatment details was not reported by the reporter. Company comment: This case concerns a 78-year-old female patient with medical history of Tachyarrhythmia absoluta, Tetraplegia, Lung fibrosis, COVID-19 in February 2021, Leg venous thrombosis in 2017 and Myopathy, who died on unknown date after administration of mRNA-1273. The cause of death was not reported. It is unknown if an autopsy was performed. It was also reported that the patient experienced non-serious INFLUENZA LIKE ILLNESS on the same day after vaccine administration. The patient's medical history of Tachyarrhythmia absoluta, Tetraplegia, Lung fibrosis and Leg venous thrombosis remain strongly confounding. The reporter did not provide causality assessment. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Having in mind that this patient received the COVID-19 VACCINE PFIZER prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of HYPERTHERMIA MALIGNANT (Malignant hyperthermia) in a 75-year-old female patient who received mRNA-1273 (Spikevax) (batch no. W0539-1) for COVID-19 vaccination. Concurrent medical conditions included Morbid obesity, Depression, Fibrillation paroxysmal atrial, Hypoacusis, COPD, Atheromatosis (severe aortic artery with ulcerated plaque and hematoma at the level of the abdominal aorta), Dyslipidaemia and Diabetes.

Case ID	Narrative (Complete)
	Concomitant products included VENLAFAXINE HYDROCHLORIDE (DOBUPAL) from 09-May-2018 to an unknown date and FLUOXETINE HYDROCHLORIDE (DEPRAX [FLUOXETINE HYDROCHLORIDE]) from 28-Jan-2016 to an unknown date for Adjustment reaction with prolonged depressive reaction, ATORVASTATIN CALCIUM (ATORVASTATINA MK) from 31-May-2019 to an unknown date for Aortic valve disease, AMIODARONE HYDROCHLORIDE (TRANGOREX) from 02-Apr-2014 to an unknown date and BISOPROLOL FUMARATE (BISOPROLOL EG) from 01-Apr-2014 to an unknown date for Atrial fibrillation, OLODATEROL HYDROCHLORIDE, TIOTROPIUM BROMIDE MONOHYDRATE (SPIOLTO) from 24-Aug-2017 to an unknown date for Chronic bronchitis, AMLODIPINE MALEATE (AMLODIPINO RAAM) from 23-Aug-2017 to an unknown date for Essential hypertension, SPIRONOLACTONE from 02-Apr-2014 to an unknown date for Heart failure, DORZOLAMIDE HYDROCHLORIDE (TRUSOPT) from 16-May-2017 to an unknown date for Ocular hypertension, SOLIFENACIN SUCCINATE (VESICARE) from 26-Oct-2017 to an unknown date for Urine incontinence. On 18-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Subcutaneous) 1 dosage form. On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced HYPERTHERMIA MALIGNANT (Malignant hyperthermia) (seriousness criterion death). The reported cause of death was Hyperpyrexia malignant. It is unknown if an autopsy was performed. mRNA-1273 (Spikevax) (Subcutaneous) dosing remained unchanged. For mRNA-1273 (Spikevax) (Subcutaneous), the reporter did not provide any causality assessments. Treatment information was not provided. Time Interval between Beginning of Drug Administration and Start of Reaction / Event was 2 days. Company comment: This case concerns a 75-year-old female patient with medical history of Morbid obesity, Depression, Fibrillation paroxysmal atrial, Hypoacusis, COPD, Atheromatosis, Dyslipidaemia, Diabetes, Essential hypertension and Heart failure who experienced serious unexpected event of malignant hyperthermia and subsequently died. Very limited information provided precluding comprehensive assessment. The event occurred two days after the dose of mRNA-1273. The reported cause of death was Hyperpyrexia malignant. It is unknown if an autopsy was performed. Causality is confounded with concomitant use of Atorvastatin. Furthermore, patient's advanced age and significant medical history could have contributed to the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Incorrect route of product administration should have been considered in this particular case as the vaccine was administered by subcutaneous route. Most recent FOLLOW-UP information incorporated above includes: On 09-Feb-2022: Translation received on 15-Feb-2022 includes Event description, concomitant medication reported by the Primary Source Translated and narrative was updated accordingly.
4.1(b) [redacted]	This spontaneous case was reported by a consumer and describes the occurrence of ANAPHYLACTIC REACTION (anaphylaxis due to COVID-19 vaccination) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Anaphylactic reaction to drug (Albuterol). Previously administered products included for Wheezing: Albuterol; for Shortness of breath: Albuterol. Past adverse reactions to the above products included Allergic reaction with Albuterol and Albuterol. Concurrent medical conditions included Hypertension, Environmental allergy and Reactive airways disease. On 23-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 23-Mar-2021, the patient experienced ANAPHYLACTIC REACTION (anaphylaxis due to COVID-19 vaccination) (seriousness criteria death, hospitalization and medically significant). The patient was hospitalized from 23-Mar-2021 to 24-Mar-2021 due to ANAPHYLACTIC REACTION. The patient died on 24-Mar-2021. The reported cause of death was anaphylaxis due to covid-19 vaccination. An autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Mar-2021, Heart rate: lost pulses (abnormal) lost pulses. No concomitant medications were reported. No treatment medications were reported. It was reported that the patient struggled to breathe after receiving her first Moderna vaccine. She was taken to the hospital and died the next day. The autopsy says she had a medical history of hypertension, environmental allergies and reactive airway disease (not asthma), with previous anaphylactic reaction to Albuterol. The patient started to have reaction 15 to 20 minutes after receiving the vaccine. She began to complain of feeling as though her airway was becoming blocked. She had severe respiratory distress with labored breathing and stridor and poor oxygen saturation. She was intubated and taken to the emergency room. Upon arrival to the hospital, she was reintubated for airway tube positioning and lost pulses. CPR was initiated and return of spontaneous circulation was achieved but her condition continued to decline. The family elected not to have her resuscitated at 11:40 a.m. on March 24, 2021. She dies at 11:55 a.m. The patients autopsy revealed she had a history of allergic reactions which caused her throat to close. Company comment: This spontaneous case concerns a 68-year-old female patient with relevant medical history of environmental allergy, anaphylactic reaction to albuterol and reactive airway disease, who experienced serious, unexpected event of Anaphylactic reaction. The event is assessed as unexpected due to fatal outcome. The first symptoms of the event occurred 15-20 minutes after the 1st dose of mRNA-1273. It was reported that 15-20 min after the vaccination, the patient complained of airway obstruction as she struggled to breathe followed by the occurrence of stridor and poor oxygen saturation. She also had throat closing sensation. The patient was intubated and taken to the emergency room. for respiratory distress. Upon arrival, the patient was reintubated for airway tube positioning and lost pulses. The CPR was performed and return of spontaneous circulation was achieved, but her condition continued to decline. The family decided on not to be resuscitated. The reported cause of death was "anaphylaxis due to COVID-19 vaccination" as per the autopsy report. The medical history of reactive airway disease, environmental allergy and anaphylactic reaction to medication are possible confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Case ID	Narrative (Complete)
	Most recent FOLLOW-UP information incorporated above includes: On 10-Feb-2022: Live follow-up received Past medical historical information was updated. On 14-Feb-2022: Follow-up received contains additional significant information that include newevent (throat to close) and new reporter. Hypertension and reactive airway disease had been updated to current conditions. Event anaphylaxis is updated to anaphylactic reaction to vaccine. Events respiratory distress, dyspnoea, stridor, oxygen saturation decreased and condition aggravated were subsumed under event anaphylactic reaction to vaccine.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 09-Feb-2022. The most recent information was received on 21-Mar-2022 and was forwarded to Moderna on 21-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of CIRCULATORY COLLAPSE (Person collapsed 10 minutes after vaccination), DYSPNOEA (CPR setting, < 2 minutes after vaccine pale and gasping, CPR started), MYOCARDIAL INFARCTION (At autopsy, there was a pinpoint lumen and a huge plug in the coronary artery just after the deflection downwards (forgot the 3 letters of the abbreviation for a moment). In short: he is unmistakable died of a heart attack) and PALLOR (CPR setting, < 2 minutes after vaccine pale and gasping, CPR started) in a 77-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 094F21A) for COVID-19 vaccination. The patient's past medical history included CVA (No Family history). Previously administered products included for Product used for unknown indication: COMIRNATY on 02-Jun-2021 and COMIRNATY on 07-Jul-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY. On 18-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Jan-2022, the patient experienced CIRCULATORY COLLAPSE (Person collapsed 10 minutes after vaccination) (seriousness criterion death) and MYOCARDIAL INFARCTION (At autopsy, there was a pinpoint lumen and a huge plug in the coronary artery just after the deflection downwards (forgot the 3 letters of the abbreviation for a moment). In short: he is unmistakable died of a heart attack) (seriousness criterion death). 18-Jan-2022, the patient experienced DYSPNOEA (CPR setting, < 2 minutes after vaccine pale and gasping, CPR started) (seriousness criterion death) and PALLOR (CPR setting, < 2 minutes after vaccine pale and gasping, CPR started) (seriousness criterion death). The patient died on 18-Jan-2022. The reported cause of death was hartinfarct. An autopsy was performed. The autopsy-determined cause of death was hartinfarct. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Autopsy: unmistakably died due to myocardial infarction. Obduction revealed a pinpoint lumen and huge gag in the coronaria artery just after the deflection down (forgot the 3 letters of the abbreviation). In short: he has unmistakably died due to myocardial infarction.. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by reporter. Treatment information was not provided. Company comment: This case concerns a 77-year-old male patient with medical history of CVA, who experienced serious due to death, unexpected events of pallor, dyspnea, circulatory collapse and myocardial infarction. The events occurred on the same day after receiving a dose of mRNA-1273 Vaccine. Additionally, there was an interchange of vaccine products as the patient was previously vaccinated with 2 doses of Comirnaty. Reportedly, less than 2 minutes after vaccination, the patient became pale, started gasping and collapsed. Cardiopulmonary resuscitation was initiation however, the patient passed away. The autopsy report showed that the patient passed away from myocardial infarction. The patient's advanced age and history of CVA suggesting unreported cardiovascular disease are possible confounders. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The events reported and seriousness assessment retained as per regulatory authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 21-Mar-2022: Significant follow-up information received on 21-MAR-2022. Historical condition CVA, Death date, Autopsy result, cause of death added, Laboratory data, New Events cardiovascular collapse and myocardial infarction were added, Event gasping and pale seriousness updated from life threatening to death, Outcome of events gasping and pale updated from unknown to fatal. On 21-Mar-2022: Translation document received on 29-Mar-2022. Reaction/event as reported by primary source were translated, contains non-significant information.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 09-Feb-2022 and was forwarded to Moderna on 09-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Patient underwent a third dose vaccine on the morning of 19/01/2022. Alee at 15.20 the patient is found dead in bed) in a 79-year-old male patient who received mRNA-1273 (Spikevax) (batch no. VVJAQDD2LBC5H) for COVID-19 vaccination. Previously administered products included for Booster: SPIKEVAX on 19-Jan-2022. Past adverse reactions to the above products included Death from natural causes with SPIKEVAX. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 19-Jan-2022 The patient died on 19-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Treatment information was not provided. Company Comment: This regulatory case concerns a 79-year-old, male patient with no medical history reported, who experienced the unexpected, serious event of death. The patient received the third dose of the Moderna mRNA-1273 vaccine on the morning of 19Jan2022. At 15:20, the patient was found dead in bed. The cause of death was not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC ARREST (sudden cardiac death) and SUDDEN CARDIAC DEATH (sudden cardiac death) in an 80-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination.

Case ID	Narrative (Complete)
	Concurrent medical conditions included Alzheimer's disease. Concomitant products included RIVASTIGMINE (EXELON [RIVASTIGMINE]) and ESCITALOPRAM for an unknown indication. On 01-Dec-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 08-Dec-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced CARDIAC ARREST (sudden cardiac death) (seriousness criteria death and medically significant) and SUDDEN CARDIAC DEATH (sudden cardiac death) (seriousness criteria death and medically significant). The patient died on 08-Dec-2021. The reported cause of death was Cardiac arrest. An autopsy was not performed. No allergy reported, no alcohol consumption reported, non-smoker. No cardiovascular disease reported. There were no recent acute events reported. Chronically taken Exelon and Escitalopram (unspecified dosages). The patient received the booster dose with Spikevax vaccine on 01 Dec 2021. No information on previous doses known. Lot not known. The patient tolerated vaccination well (no acute adverse reactions were reported). However, on 08 Dec 2021, or one week after the booster vaccination, the sudden death of the patient was reported, probably in the context of cardiac arrest (relatively unexpected sudden death, most likely sudden cardiac death. The attending physician wrote as the cause of death- sudden heart failure). No autopsy was performed. No treatment medications were reported. Company comment: This is a regulatory case concerning an 80 year-old, female patient with a history of Dementia Alzheimer's type and concomitant use of Escitalopram, who experienced the serious Fatal unexpected, AESI of sudden cardiac death and the event cardiac arrest, approximately 7 days after the booster dose of mRNA-1273 vaccine. The patient died 7 days after vaccination, on the onset date of the events, no autopsy was performed and the cause of death was reported as cardiac arrest. The event was considered unrelated to the vaccine per the reporter’s assessment. The mentioned medical history, concomitant medication and patient´s advanced age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. sudden heart death/sudden heart failure
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 09-Feb-2022. The most recent information was received on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of SUDDEN DEATH (My aunt died suddenly the same day. Established cause of death: 'sudden death') in an 87-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 216041) for COVID-19 vaccination. The patient's past medical history included Ulcus cruris (No family history) in 2017, Hearing decreased (No family history) in November 2021, Weight loss (No family history) in December 2020, Subclinical hypothyroidism (No family history) in 2013 and Cataract (No family history) in 2015. Previously administered products included for Product used for unknown indication: HYDROCHLOORTHIAZIDE from 08-Feb-2011 to 02-Jun-2011, HYDROCHLOORTHIAZIDE from 05-Mar-2013 to 17-Oct-2014, METOPROLOL (METOPROLOL TABLET MGA 50MG (SUCCINAAT) from 11-Apr-2013 to 17-Oct-2014, COMIRNATY on 12-Apr-2021 and COMIRNATY on 17-May-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY, COMIRNATY, HYDROCHLOORTHIAZIDE, HYDROCHLOORTHIAZIDE and METOPROLOL. Concurrent medical conditions included Hypertension (no drug therapy, keep an eye on and No family history) in 2011, Parkinsonian gait (Mobility problems, possibly parkinsonism and No family history) in August 2020 and Walking aid user (used walker, but could still climb the stairs and walked above with stool and No family history). On 15-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. The patient died on 15-Jan-2022. The reported cause of death was mors subita has been identified by a doctor as a cause of death. mors subita can be caused by cardiac arrhythmias and cardiac arrhythmias may be caused by myocarditis.. An autopsy was not performed. Concomitant medications were not provided. Treatment information was not provided. Company comment: This is a regulatory case concerning a 87-year-old, female patient with medical history of Ulcus cruris, Hypertension, Hearing decreased, Parkinsonian gait, Walking aid user, Weight loss, Subclinical hypothyroidism and Cataract, who experienced the unexpected, Fatal event of Sudden death. The event occurred on 15-Jan-22, same day after the first dose of mRNA-1273. The reported cause of death was mors subita has been identified by a doctor. An autopsy was not performed. Above mentioned patient's medical history and advanced age might have contributed to fatal outcome. Patient had previously received two doses of COVID-19 VACCINE PFIZER (Interchange of vaccine products). The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case was assessed as Serious as per Regulatory Authority report. Most recent FOLLOW-UP information incorporated above includes: On 09-Feb-2022: Translation received on 15-Feb-2022 included event verbatim and cause of death was updated. On 22-Feb-2022: Follow up information received and included Patient Autopsy detail was updated from Unknown to No and New patient medical history and past drug history was added.
4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Cause of death unknown, suspected cardiac arrest) in a 77-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Diabetes (Type II diabetes resolved as a result of weight loss in oncological context). Concurrent medical conditions included Smoker (Tobacco: yes), Lung cancer, Colon cancer (Recently diagnosed colonic cancer.) and Hypercholesteraemia. Concomitant products included PREDNISONE (PREDNISONE TEVA) from 26-Feb-2021 to an unknown date, FOLIC ACID (ACIDUM FOLICUM), SIMVASTATIN (SIMCORA), DUTASTERIDE, TAMSULOSIN HYDROCHLORIDE (DUODART), ETILEFRINE HYDROCHLORIDE (EFFORTIL), DICLOFENAC SODIUM (SOLARAZE) and PARACETAMOL (DAFALGAN) for an unknown indication.

Case ID	Narrative (Complete)
	On 03-Dec-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. Death occurred on 04-Dec-2021 The patient died on 04-Dec-2021. An autopsy was not performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered DEATH (Cause of death unknown, suspected cardiac arrest) to be unlikely related. Patient was taking medications (unknown dosage and starting date of therapy, assumed to have been taken for some time): prednisone 5 mg, folic acid 5 mg, Simcora 5 mg, Duodart 0.5/0.4 mg, Effortil 10 drops as required, Solaraze gel 3%, Dafalgan 1 g as required. The first dose of Spikevax was performed on 27 Jan 2021 (lot 300042460 indicated), the second dose on 26 Feb 2021 (lot 300042723 indicated) and the third booster dose on 03 Dec 2021 (lot unknown). The day after the third dose (04 Dec) the patient died, cause unknown, probably from heart disease. There is no death / autopsy letter available. Despite the suggestive temporal correlation, considering the numerous risk factors presented by the patient, his age, in the absence of further information, the causal link is judged as unlikely. No treatment medications were provided. Company comment: This is a regulatory case concerning a 77 year-old, male patient with a history of Lung neoplasm malignant, Colon cancer, Tobacco user, Hypercholesterolaemia, Diabetes mellitus and polypharmacy, who experienced the serious Fatal unexpected, event of death (reported as cause of death unknown, suspected cardiac arrest), approximately 1 day after the booster dose of mRNA-1273 vaccine. Cause of death was reported as probably from heart disease, an autopsy was not performed. The event was considered unrelated to the vaccine per the reporter's assessment. The mentioned medical history and patient´s advanced age remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 09-Feb-2022: Translation received on 15-Feb-2022 included event verbatim and dosage text was updated.
4.1(b) [redacted]	This regulatory authority case was reported by a pharmacist and describes the occurrence of VACCINATION FAILURE (vaccination breakthrough) and COVID-19 PNEUMONIA (COVID-19 pneumonia) in an 86-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Nicotine abuse (smoking: status after nicotine abuse, 20 pack years). Concurrent medical conditions included Chronic renal failure (Chronic kidney failure KDIGO G3a and Acute to chronic renal failure AKIN 1(Fe urea 46% (prerenal)).). Concomitant products included ACETYLSALICYLIC ACID (ASPIRIN CARDIO), APIXABAN (ELIQUIS), FOLIC ACID (ACIDUM FOLICUM HAENSELER), TORASEMIDE (TORASEMID SANDOZ), CALCIUM CARBONATE, COLECALCIFEROL (CALCIMAGON D3), PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTOPRAZOL SANDOZ), DUTASTERIDE, TAMSULOSIN HYDROCHLORIDE (DUODART) and RUXOLITINIB PHOSPHATE (JAKAVI) for an unknown indication. On 29-Nov-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 50 microgram. On 26-Dec-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced VACCINATION FAILURE (vaccination breakthrough) (seriousness criteria death and hospitalization). On an unknown date, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death and hospitalization). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Dec-2021, Computerised tomogram: abnormal (abnormal) Significant over the course progressive frosted glass-like clouding on both sides. Better decarking varicose bronchiectasis. Detection of small lung cysts. No pleural effusion. Only small consolidation basally on both sides.. On 27-Dec-2021, Polymerase chain reaction: negative (Negative) PCR negative - SARS-CoV-2 Ak quantitative:5.9 u/ml - 2x2 BK 27.12., 30.12.2021 and 02.01.2022 each 2x2 negative and results not provided (Inconclusive) Results not provided. On 27-Dec-2021, SARS-CoV-2 test: positive (Positive) Positive. On 30-Dec-2021, Polymerase chain reaction: negative (Negative) PCR negative, culture: Klebsiella oxytoca - sputum. On 02-Jan-2022, Computerised tomogram: abnormal (abnormal) Progressive right-based consolidations, progressive ARDS. No pulmonary embolism. On 07-Jan-2022, Culture throat: results not reported (Inconclusive) Results not reported. On 07-Jan-2022, Polymerase chain reaction: normal (normal) PCR without germ detection. On 07-Jan-2022, Urine analysis: normal (normal) none relevant leukocyturia, culture without growth - blood cultures 07.01.2022:2x2 no growth until 09.01.2022.. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. The case is serious as death and hospitalization was there. It was reported that patient received COVID-19 vaccine third dose. No treatment medication was given. Company comment: This fatal regulatory authority case concerns an 86-year-old male patient with relevant medical history of smoking and chronic renal failure, who experienced serious unexpected events of vaccination failure and COVID-19 pneumonia (AESI). The events occurred approximately less than a month after the 3rd dose of the mRNA-1273. The patient was hospitalized and subsequently passed away due to the events. The patient's relevant medical history is a possible confounder that may contributed to worse clinical course and fatal outcome of the event of COVID-19. Based on the current available information, the mRNA-1273 does not contain a virus capable of causing COVID-19 infection after vaccination. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events reported and seriousness assessment retained as per regulatory authority reporting.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 10-Feb-2022 and was forwarded to Moderna on 10-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Death NOS) in a 73-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 057G21A) for COVID-19 vaccination.

Case ID	Narrative (Complete)
	The patient's past medical history included Insufficiency cardiac, Hypertensive heart disease NOS, Pulmonary oedema and Arterial stent insertion. On 14-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form once per month. Death occurred on 19-Dec-2021 The patient died on 19-Dec-2021. The reported cause of death was death related to cardiovascular pathology. An autopsy was not performed. No concomitant medications were reported. No treatment medications were reported. Company comment: This is a regulatory authority case concerning a 73-year-old, male patient with relevant medical history of arterial stent insertion, cardiac insufficiency, hypertensive heart disease NOS and pulmonary edema, who experienced the unexpected serious event of death NOS. The event death NOS occurred approximately 5 days after the unknown dose number of mRNA-1273 vaccine administration. The reported cause of death was death related to cardiovascular pathology. It was unknown if autopsy was done. The medical history of arterial stent insertion, cardiac insufficiency, hypertensive heart disease NOS and pulmonary edema remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 11-Feb-2022. The most recent information was received on 10-Mar-2022 and was forwarded to Moderna on 15-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (right frontal hemorrhage was seen in the drainage pathway with known hydrocephalus), CEREBRAL INFARCTION (Cerebral infarction), PARTIAL SEIZURES (focal seizures due to increased pressure in the brain), CEREBELLAR HAEMORRHAGE (Hemorrhage from right cerebellar vermis with expansion to fourth ventricle and also blood in the side ventricle on the right) and DEVICE DISLOCATION (On 13-Jan the drain was luxated, followed by frequent consciousness checks) in a 69-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Throat cancer (End date in: 2020, Family history-No For which radiotherapy, no OK. Treated in University Center), Basal cell carcinoma (Family History: No) in 2004 and Breast carcinoma (treated in perfieer hospital Family History: No) in 2012. Previously administered products included for Product used for unknown indication: COMIRNATY on 08-May-2021 and COMIRNATY on 12-Jun-2021. Past adverse reactions to the above products included No adverse reaction with COMIRNATY; and Urticaria with COMIRNATY. Concurrent medical conditions included Hypertension (Family history-No) and Smoker (16-20 per day Family History: No). Concomitant products included PERINDOPRIL ERBUMINE (PERINDOPRIL GA) and LORAZEPAMUM for an unknown indication. On 05-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced CEREBRAL INFARCTION (Cerebral infarction) (seriousness criterion hospitalization). On 07-Jan-2022, the patient experienced CEREBELLAR HAEMORRHAGE (Hemorrhage from right cerebellar vermis with expansion to fourth ventricle and also blood in the side ventricle on the right) (seriousness criterion hospitalization). On 13-Jan-2022, the patient experienced CEREBRAL HAEMORRHAGE (right frontal hemorrhage was seen in the drainage pathway with known hydrocephalus) (seriousness criterion death), PARTIAL SEIZURES (focal seizures due to increased pressure in the brain) (seriousness criterion life threatening) and DEVICE DISLOCATION (On 13-Jan the drain was luxated, followed by frequent consciousness checks) (seriousness criterion hospitalization). The patient died on 16-Jan-2022. The reported cause of death was Cerebral hemorrhage. An autopsy was not performed. At the time of death, CEREBRAL INFARCTION (Cerebral infarction), CEREBELLAR HAEMORRHAGE (Hemorrhage from right cerebellar vermis with expansion to fourth ventricle and also blood in the side ventricle on the right) and DEVICE DISLOCATION (On 13-Jan the drain was luxated, followed by frequent consciousness checks) was resolving and PARTIAL SEIZURES (focal seizures due to increased pressure in the brain) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 06-Jan-2022, Computerised tomogram head: abnormal (abnormal) Focal stenosis in proximal parietal M2 left without perfusion defects. No significant neck vessels further intracranial. stenosis in the. On 06-Jan-2022, Electrocardiogram: abnormal (abnormal) SR 65/min with one-time PAC with compensatory break, IMHA, long QtC time, further normal conductivity times, no ST deviation. On 06-Jan-2022, Laboratory test: abnormal (abnormal) Glucose 5.8 mmol/1; PT INR 1 .12 INR; Hemoglobin 7.6 Platelet 204 x10 9/1; Leucocytes 7.4 x10 9/1; 7.6 mmol/1; Sodium +125 mmol (low!!!) /l; Potassium 3.5 mmol/1; (MDRD) 144 ml/min; EGFR (CKD-EPI) 104 Kreatinine 38 mol/1; Clearance ml/min/1.73 m2; Urea 3.6 mmol/1. On 06-Jan-2022, Physical examination: abnormal (abnormal) A/free B/VAG bdz slightly expiratory humming, which 98% without oxygen. C RR/210/100P 80/min sinus rhythm. Clear awareness, makes good contact. Language: naming 0/5, simple understanding disturbed, executes simple assignment once, not otherwise. HZ: isocore pupils, absent threat reflex right, symmetrical face, M: Barre does not try bdz, symmetrical spontaneous motor skills, squeezes bdz reasonable force. VZR: mutually plantar. Hall/stand: independent undisturbed. On 07-Jan-2022, Computerised tomogram head: abnormal (abnormal) Hemorrhage from cerebellum/vermis re involving expansion to fourth ventricle and also blood in the side ventricle right. hydrocephalus. Tzt MRI Consider (Yet) None. On 09-Jan-2022, Laboratory test: abnormal (abnormal) Hb 8.4 Sodium: 138 mmol/1 Potassium: 2.9 mmol/l Kreatinine: 36 umol/1 MDRD:153 ml/min. On 13-Jan-2022, Computerised tomogram head: abnormal (abnormal) New severe bleeding in the drain-trajectory right frontal, hydrocephalus and previous cerebellar hemorrhage are globally consistent. On 14-Jan-2022, Chest X-ray: abnormal (abnormal) Gastric tube in the stomach. Low rotated recording. good limitation. Bright sinus pleural. Heart, Diaphragm Domes are hili and mediastinum show no abnormalities. Normal pulmonary vessel drawing. There are no abnormalities in both lung fields. No indications for infiltrate or congestive heart failure and abnormal (abnormal) Gastric tube in the stomach. Low rotated recording. good limitation. Bright sinus pleural. Heart, Diaphragm Domes are hili and mediastinum show no abnormalities. Normal pulmonary vessel drawing. There are no abnormalities in both lung fields. No indications for infiltrate or congestive heart failure.

Case ID	Narrative (Complete)
	No treatment information was provided. The husband and daughter thought that perindopril is not the particular antihypertensive drug that patient uses (perindopril was known at the pharmacy). Daughter watches this at home. Company comment This regulatory authority case concerns a 69-year-old, female patient with medical history of Throat cancer, basal cell carcinoma, breast cancer, smoking and hypertension, who experienced the unexpected AESI fatal event of Cerebral haemorrhage, unexpected life-threatening event of Partial seizures and unexpected serious (hospitalization) events of Cerebral infarction (AESI), Cerebral haemorrhage and Device dislocation. Event Cerebral infarction occurred on the next day (6-Jan-22), followed by Cerebral haemorrhage on the second day (7-Jan-22) and Focal epilepsy, Device dislocation and Cerebral haemorrhage occurred approximately 8 days (13-Jan-22) after a dose of mRNA-1273 vaccine. Computerised tomogram head done on 7-Jan-22 revealed Hemorrhage from cerebellum/vermis re involving expansion to fourth ventricle and also blood in the side ventricle right & hydrocephalus. Computerised tomogram head done on 13-Jan-22 revealed New severe bleeding in the drain-trajectory right frontal, hydrocephalus and previous cerebellar hemorrhage are globally consistent. The patient died 11 days (16-Jan-22) after vaccination. The reported cause of death was Cerebral haemorrhage. It is unknown if an autopsy was performed. The patient was noted to have received two doses from COMIRNATY approximately 7 months prior to current vaccination with mRNA1273 (Interchange of vaccine products). Patient´s medical history of Throat cancer, basal cell carcinoma, breast cancer, smoking and Concurrent medical condition of Hypertension remains as a confounder for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness of the events retained as per Regulatory Authority report. Most recent FOLLOW-UP information incorporated above includes: On 10-Mar-2022: Translation document received on 15-Mar-2022. Significant information received. Results of tests, events translated.
4.1(b) [redacted]	This regulatory authority case was reported by a physician and describes the occurrence of HEAD INJURY (Head trauma on falling at home), ASTHENIA (Severe asthenia) and DEATH (Death) in an 85-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Urinary infection (Infection treated) from 31-Oct-2021 to 07-Nov-2021, Ischemic cardiomyopathy (Chronic ischemic heart disease on monovasal, arrhythmic coronary heart disease on atria fibrillation), Gout, Peripheral obliterative arteriopathy (Leriche-Fontaine Stage II Peripheral Obliterating Arterial Disease) and Cardiac pacemaker insertion (Pacemaker dual-chamber pocket infection, generator change in 2009 generator change in 2017) in 2008. Concurrent medical conditions included Chronic renal impairment (Chronic Kidney Disease Stage Ga3 sec. KDIGO), Metastatic malignant melanoma (Melanoma in right forearm with lymph node metastases, suspected secondary disorders in liver) in 2019, Anemia hypochromic (Moderate Normocytic Hypochromic Anemia), Drug allergy (amoxicillin) and Chronic venous insufficiency. On 15-Jun-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 15-Jun-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form once a day. On 16-Dec-2021, received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form once a day. On 17-Dec-2021, the patient experienced HEAD INJURY (Head trauma on falling at home) (seriousness criteria death, hospitalization and medically significant) and ASTHENIA (Severe asthenia) (seriousness criteria death, hospitalization and medically significant). The patient died on 18-Dec-2021. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Dec-2021, Blood test: normocytic normochromic anemia (abnormal) normocytic normochromic anemia and worsening of known kidney disease (abnormal) worsening of known kidney disease. On 17-Dec-2021, Chest scan: pleural effusion (abnormal) mild right-sided pleural effusion. On 17-Dec-2021, Computerised tomogram head: brain hemorrhage ruled out Brain hemorrhage ruled out. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter considered ASTHENIA (Severe asthenia) to be possibly related and HEAD INJURY (Head trauma on falling at home) and DEATH (Death) to be unlikely related. On Dec 17, the patient went to the emergency room for profuse asthenia and dropped at home (not clear the dynamics) with consequent head trauma (head injury following fall at home). The patient was hemodynamically stable, without fever, objective examination without particularities. It manifests occipital and ear swelling (probably after falling) and dehydration of the skin and mucous membranes. The patient had a Palliative Performance Scale of 50 percent and Palliative Prognostic Score of B, Charlson Comorbidity Index of 14 (age factored) and l'indice di Barthel for daily activities of 50. Rated as patient B stable. The patient was admitted to palliative care with symptomatic treatment of disorders. Suspended therapy with Torasemide (for dehydration) and set hydration and potassium for intravenous. The patient's condition worsens rapidly, the patient becomes more asthenic and hypothesive, with hyporeacting pupils and vesicular murmure. On the day Dec 18, the patient was dead, without showing signs of suffering. The UptoDate database describes asthenia following the Comirnaty vaccine, the other Pfizer mRNA vaccine [1]. However, Spikevax's adverse reactions include fatigue that may have contributed to the development of asthenia. It should be considered that the patient, known for advanced metastatic melanoma and chronic renal failure, was already heavily weakened by his pre-existing pathological condition. Cannot ruled out that the vaccine may have contributed to increasing asthenia. The exact dynamics of the fall that caused the head injury was unknown and the cause of death has not been defined, so it was difficult to relate these events to the vaccine. It can only be speculated that death occurred due to the pathological conditions presented for a long time by the elderly patient such as metastatic melanoma, renal failure, etc. Therefore, considering the close time correlation, the data in monograph, but not being able to exclude the patient's previous condition, the causal link with asthenia is considered possible. Otherwise, in the absence of further details on the dynamics of the fall and the cause of death, considering the numerous risk factors presented by the patient and his age, despite the plausible time correlation, a relationship between vaccine and head trauma and death is unlikely. On Dec 17, the patient went to the emergency room due to severe asthenia and a fall at home with consequent head injury. The patient was hemodynamically stable, with no fever; physical examination with no specific findings. The patient had swollen occipital lymph nodes and swollen ear (likely following the fall) and dehydrated skin and mucous membranes. The patient presented with a Palliative Performance Scale of 50% and Palliative Prognostic score of B, Charlson Comorbidity Index of 14 (age factored) and Barthel Index for daily activities of 50. Assessed as stable B patient. The patient was hospitalized under palliative care with symptomatic treatment for his conditions. Most recent FOLLOW-UP information incorporated above includes: On 09-Feb-2022: Translation received on 15-Feb-2022: Event, medical history, lab, narrative updated.

Case ID	Narrative (Complete)
	Company comment: This case concerns a 85-year-old male patient, with medical history of Ischemic cardiomyopathy (with arrhythmic coronary heart disease on atria fibrillation), Peripheral obliterative arteriopathy, cardiac pacemaker, Chronic renal impairment, Metastatic malignant melanoma and Chronic venous insufficiency, who experienced the unexpected events of head injury, asthenia and death, considered serious per seriousness criteria of death, hospitalization and medically significant. The events occurred approximately 1 day after the third dose of mRNA-1273, and the patient died 2 days after third dose. As reported, the patient went to the emergency room for profuse asthenia and fall at home with consequent head trauma. The patient was hemodynamically stable, without fever, objective examination without particularities and manifested occipital and ear swelling (probably after falling) and dehydration of the skin and mucous membranes, as reported. On computerised tomogram brain hemorrhage was ruled out. The patient was admitted for palliative care, his condition worsened rapidly, the patient became more asthenic and hypotensive and died. An autopsy was not performed. Per reporter, the likely cause of death was metastatic melanoma. Above mentioned multiple comorbidities remain as additional confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 11-Feb-2022 and was forwarded to Moderna on 11-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of CIRCULATORY COLLAPSE (Cardiovascular collapse), SHOCK (Shock) and SUDDEN DEATH (Sudden death unexplained) in a 65-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216045) for COVID-19 vaccination. The patient's past medical history included Smoker. On 10-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Jan-2022, the patient experienced CIRCULATORY COLLAPSE (Cardiovascular collapse) (seriousness criteria death, hospitalization and life threatening), SHOCK (Shock) (seriousness criteria death, hospitalization and life threatening) and SUDDEN DEATH (Sudden death unexplained) (seriousness criteria death, hospitalization and life threatening). The patient died on 27-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication of the patient was not reported. No treatment information was provided by the reporter. Company Comment: This regulatory authority case concerns a 65-year-old male patient, with no relevant medical history, who experienced the unexpected serious events of Circulatory collapse, Shock, and Sudden death. The events occurred approximately 17 days after receiving a dose of mRNA-1273 Vaccine and resulted in a life threatening condition, hospitalization and death. The cause of death was not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 14-Feb-2022 and was forwarded to Moderna on 14-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of COUGH (Coughing), SUDDEN DEATH (Sudden death unexplained) and HAEMOPTYSIS (Sputum bloody) in a 65-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination. The patient's past medical history included Hypertension and COPD. On 19-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Jan-2022, the patient experienced COUGH (Coughing) (seriousness criterion death) and HAEMOPTYSIS (Sputum bloody) (seriousness criterion death). The patient died on 14-Jan-2022. The cause of death was not reported. An autopsy was not performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment information was reported. Company Comment: This regulatory authority case concerns a 65-year-old male patient, with relevant medical history of Hypertension and COPD, who experienced the unexpected serious events of Cough and Hemoptysis. The events occurred approximately 23 days after receiving a dose of mRNA-1273 Vaccine which resulted to Sudden death. The cause of death was not reported. An autopsy was not performed. The patient's medical history of Hypertension and COPD remain as confounders for the occurrence of the events. Event seriousness assessed as per Regulatory Authority report. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 11-Feb-2022 and was forwarded to Moderna on 11-Feb-2022. This regulatory authority case was reported by an attorney and describes the occurrence of NARCOLEPSY (atypical parkinsonism, no drug intake, Modern vaccine dose 9.4.2021, intestinal blockage, death 23.4.2021), INTESTINAL PSEUDO-OBSTRUCTION (atypical parkinsonism, no drug intake, Modern vaccine dose 9.4.2021, intestinal blockage, death 23.4.2021) and MUSCULAR WEAKNESS (atypical parkinsonism, no drug intake, Modern vaccine dose 9.4.2021, intestinal blockage, death 23.4.2021) in a 74-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3001655-01) for COVID-19 vaccination. Concurrent medical conditions included Parkinsonism. On 09-Apr-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 11-Apr-2021, the patient experienced NARCOLEPSY (atypical parkinsonism, no drug intake, Modern vaccine dose 9.4.2021, intestinal blockage, death 23.4.2021) (seriousness criterion death), INTESTINAL PSEUDO-OBSTRUCTION (atypical parkinsonism, no drug intake, Modern vaccine dose 9.4.2021, intestinal blockage, death

Case ID	Narrative (Complete)
	23.4.2021) (seriousness criterion death) and MUSCULAR WEAKNESS (atypical parkinsonism, no drug intake, Modern vaccine dose 9.4.2021, intestinal blockage, death 23.4.2021) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported by reporter. The patient died on 23-Apr-2021. No treatment medications provided by the reporter. Company comment: This is a fatal case from Regulatory Authority that concerns a 74-year-old male patient, with no relevant medical history, who experienced the unexpected fatal events of NARCOLEPSY, INTESTINAL PSEUDO-OBSTRUCTION and MUSCULAR WEAKNESS. The events occurred 2 days after the dose of mRNA-1273 vaccine (number of dose no reported). He died fourteen days after the vaccination and it is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. The seriousness was assessed as per regulatory authority report. Most recent FOLLOW-UP information incorporated above includes: On 11-Feb-2022: Follow-up information received contains no new information. On 08-Apr-2022: Follow up received that contains non significant information.
4.1(b) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] on 14-Feb-2022. The most recent information was received on 03-Mar-2022 and was forwarded to Moderna on 08-Mar-2022. This case was reported by a physician via the Drug Information Center. On 03-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, the patient received the 2nd dose of this vaccine. On 10-Feb-2022, the patient was in drug treatment in the reporting hospital for hypertension and was in good general condition. At 09:18, the patient received the 3rd dose of this vaccine after a medical interview. The patient's physical condition did not change after returning home. On 11-Feb-2022, around 09:00, the patient woke up. The patient had mild pain at the vaccination site but did not feel any change in physical condition and spent time as usual. Around 16:00, the patient took a bath. A family member accompanied the patient, but there was no change in the patient's complexion or movements. After 17:00, the family member went to check on the patient, who was found submerged in the bathtub. An ambulance call was made, and the patient was transported to a hospital. The patient was in cardio-respiratory arrest when the ambulance team arrived, and resuscitation was attempted, but there was no recovery. At 17:30, the patient was confirmed dead. The cause of death was drowning. No autopsy was performed. On an unknown date, an autopsy was carried out by the police, and drowning was suspected. The outcome of mild pain at the vaccination site was unknown. The outcome of cardio-respiratory arrest was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The reporting hospital did not examine the patient for death, but the autopsy by the police suspected drowning. Follow-up received on 03-MAR-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. Reporter's comments: There is no temporal relationship between the occurrence of adverse events and the timing of administration of this vaccine. The occurrence of adverse events is not related to concomitant drugs. The occurrence of adverse events is not related to pathological factors of underlying disease and complications. The cause of death is not related to adverse events. The cause of death is not related to adverse events. See "narrative" section
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 14-Feb-2022. The most recent information was received on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of RESPIRATORY FAILURE (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), PNEUMONIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), CEREBROVASCULAR ACCIDENT (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), COMA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), BLADDER SPHINCTER ATONY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), ACUTE KIDNEY INJURY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA), SEPTIC SHOCK (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) and APHASIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) in an 87-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006322) for COVID-19 vaccination. The patient's past medical history included Neurocognitive deficit (MMSE 13/30) on 01-Apr-2021. Previously administered products included for SARS-CoV-2 vaccination: COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 02-Apr-2021 and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 23-Apr-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03). Concurrent medical conditions included COPD, Hypertension arterial and Renal failure chronic. Concomitant products included AMLODIPINE BESILATE (NORVASC), POTASSIUM CANRENOATE (KANRENOL), TRAZODONE HYDROCHLORIDE (TRITTICO), QUETIAPINE and PIROXICAM (FOSTER [PIROXICAM]) for an unknown indication. On 23-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 21-Jan-2022, the patient experienced RESPIRATORY FAILURE (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), PNEUMONIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), CEREBROVASCULAR ACCIDENT (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), COMA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), BLADDER SPHINCTER ATONY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), ACUTE KIDNEY INJURY (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death), SEPTIC SHOCK (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death) and APHASIA (sphincter release, aphasic, septic shock, coma state, respiratory failure, bilateral pneumonitis, suspected stroke, IRA) (seriousness criterion death). The patient died on 27-Jan-2022. The reported cause of death was Shock septic. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):

Case ID	Narrative (Complete)
	On 21-Jan-2022, Angiogram cerebral: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Blood gases: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Blood test: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, CSF culture: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Chest X-ray: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Computerised tomogram head: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Echocardiogram: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Electrocardiogram: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Electroencephalogram: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, Physical examination: inconclusive (Inconclusive) Inconclusive. On 21-Jan-2022, SARS-CoV-2 test negative: inconclusive (Inconclusive) Inconclusive. On 22-Jan-2022, Blood culture: inconclusive (Inconclusive) Inconclusive. On 22-Jan-2022, Tracheal aspirate culture: inconclusive (Inconclusive) Inconclusive. On 25-Jan-2022, Specialist consultation: inconclusive (Inconclusive) Inconclusive. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment medication were not reported. Company comment: This regulatory case concerns an 87-year-old elderly male patient with medical history of COPD, hypertension arterial, renal failure chronic, neurocognitive deficit, and interchange of vaccine products (two doses of Comirnaty Covid19 vaccine), experienced the unexpected Fatal events Respiratory failure, Pneumonia, Cerebrovascular accident, Coma, bladder sphincter atony, Acute kidney injury, Septic shock, and Aphasia, one month twenty-nine days after a dose of mRNA-1273. The cause of death was reported as Septic shock. Autopsy was not performed. Advanced age of the patient could be a risk factor. Medical history of COPD, hypertension arterial, renal failure chronic could be confounding. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 22-Feb-2022: Added patient's medical history, lab data, concomitant medications, events (bilateral pneumonia, stroke, coma, bladder sphincter atony, renal failure acute, aphasia), updated seriousness, verbatim for events (respiration failure, septic shock) and deleted event (sopor). On 07-Mar-2022: Non-significant follow up appended, Senders comment updated
4.1(b)	This spontaneous case was reported by a physician and describes the occurrence of DEATH (Death) and ANGINA PECTORIS (Angina pectoris) in a 72-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) for COVID-19 vaccination. No Medical History information was reported. On 13-Feb-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced ANGINA PECTORIS (Angina pectoris) (seriousness criterion medically significant). The patient died on 13-Feb-2022. The cause of death was not reported. An autopsy was performed, but no results were provided. At the time of death, ANGINA PECTORIS (Angina pectoris) outcome was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna Intramuscular Injection) (Intramuscular), the reporter considered DEATH (Death) and ANGINA PECTORIS (Angina pectoris) to be possibly related. COMPANY COMMENT : This spontaneous case concerns a 72-year-old male patient with no medical history reported who had fatal outcome of with unexpected serious event of death (seriousness criterion Death, medically significant) and angina pectoris (seriousness criterion medically significant) .The patient died on same day after the third dose of the mRNA-1273 vaccine. On an unknown date, an autopsy was performed, and the results indicated angina pectoris. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness assessment has been retained as per Regulatory Authority reporting.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b) on 14-Feb-2022. The most recent information was received on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of SARS-COV-2 TEST POSITIVE (Covid-19 infection), PYREXIA (hiti), PNEUMONIA (pneumonia bacterial), IMMUNE SYSTEM DISORDER (The immune system collapses), COVID-19 PNEUMONIA (Covid-19 pneumonia), RESPIRATORY FAILURE (Respiratory failure), DEEP VEIN THROMBOSIS (deep vein thrombosis), ORGAN FAILURE (Organ failure) and PULMONARY EMBOLISM (pulmonary embolism) in a 74-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for COVID-19 immunisation and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for COVID-19 immunisation. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form, TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form and first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (unknown route) 1 dosage form. On an unknown date, the patient experienced SARS-COV-2 TEST POSITIVE (Covid-19 infection) (seriousness criteria hospitalization and life threatening), PYREXIA (hiti) (seriousness criteria hospitalization and life threatening), PNEUMONIA (pneumonia bacterial) (seriousness criteria hospitalization and life threatening), IMMUNE SYSTEM DISORDER (The immune system collapses) (seriousness criteria hospitalization and life threatening), COVID-19 PNEUMONIA (Covid-19 pneumonia) (seriousness criteria hospitalization, medically significant and life threatening), RESPIRATORY FAILURE (Respiratory failure) (seriousness criteria death, hospitalization, medically significant and life threatening), COVID-19 IMMUNISATION (A booster vaccination with a different vaccine), DEEP VEIN THROMBOSIS (deep vein thrombosis) (seriousness criteria hospitalization and life threatening), ORGAN FAILURE (Organ failure) (seriousness criteria death, hospitalization and life threatening) and PULMONARY EMBOLISM (pulmonary embolism) (seriousness criteria hospitalization and life threatening). The patient died on 10-Dec-2021. The

Case ID	Narrative (Complete)
	reported cause of death was Respiratory failure and Organ failure. It is unknown if an autopsy was performed. At the time of death, SARS-COV-2 TEST POSITIVE (Covid-19 infection), PYREXIA (hiti), PNEUMONIA (pneumonia bacterial), IMMUNE SYSTEM DISORDER (The immune system collapses), COVID-19 PNEUMONIA (Covid-19 pneumonia), COVID-19 IMMUNISATION (A booster vaccination with a different vaccine), DEEP VEIN THROMBOSIS (deep vein thrombosis) and PULMONARY EMBOLISM (pulmonary embolism) outcome was unknown. No concomitant products were reported.The patient was diagnosed with Covid-19 infection and Covid-19 pneumonia after the hospitalization on the 01/Dec/2021. He was also diagnosed with bacterial pneumonia couple of days later. Later the third infection was diagnosed, however they were not able to find the infection focus. The patient had 40 degree fever, embolism is diagnosed both in lungs and a DVT in his feet. No treatment information was reported.The organs start to fail and the cause of death is reported as respiratory failure. COMPANY COMMENT : This regulatory authority case concerns a 74-year-old male patient, with no medical history reported, who had fatal outcome with unexpected serious AESI events of SARS-COV-2 test positive (seriousness criteria hospitalization and life threatening), covid-19 pneumonia (seriousness criteria hospitalization and life threatening, medically significant), deep vein thrombosis (seriousness criteria hospitalization and life threatening), pulmonary embolism (seriousness criteria hospitalization and life threatening) and unexpected serious events of pyrexia ,pneumonia ,immune system disorder (seriousness criteria hospitalization and life threatening),respiratory failure ,organ failure (seriousness criteria hospitalization, death, and life threatening) .Patient received mRNA-1273 vaccine as the second dose of COVID-19 vaccination schedule that included a first dose of CHADOX 1 NCOV 19 (VAXZEVRIA) vaccine and a third dose with Tozinameran Interchange of vaccine products is noted. The patient died on 10-Dec-2021.Patient was diagnosed with Covid-19 infection and Covid-19 pneumonia after the hospitalization on on the 01/Dec/2021. He was also diagnosed with bacterial pneumonia few days later. Embolism is diagnosed both in lungs and a DVT in his feet. The reported cause of death is respiratory failure and organ failure. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 22-Feb-2022: Follow up received and new events added. Narrative updated. Cause of death updated to respiratory failure and organ failure, outcome updated.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC ARREST (Cardiac arrest, cause unspecified) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 19-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 31-Jan-2022, the patient experienced CARDIAC ARREST (Cardiac arrest, cause unspecified) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. On January 19 2022, patient received the third dose of the COVID-19 (Moderna) vaccine. On January 31 2022, the patient sought medical attention at the emergency department of the hospital. Before reaching the hospital, the patient had no breathing and heart beat. Due to no breathing and heart beat before reaching the hospital, the patient was sent to the emergency department at 21:18 on January 31, 2022, but resuscitation failed. The patient was announced dead at 21:30 on January 31, 2022. A judicial examination found that the patient had sudden death, but the family members felt that this was caused by the vaccine. No Concomitant medication provided. No treatment medication reported. Company comment: This regulatory authority case concerns a 71-year-old female patient with no reported medical history who experienced serious unexpected event of cardiac arrest, that occurred approximately 12 days after the 3rd dose of the mRNA-1273 . The patient passed away due to the event. Prior to hospital arrival, the patient had no breathing and heart beat. The resuscitation failed at the emergency department and the patient was pronounced dead. The benefit-risk relationship of mRNA-1273 is not affected by this report. The seriousness assessment retained as per regulatory authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up information received on 25-Apr-2022 contains Non-significant information.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of INSOMNIA (Insomnia) in a 66-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 25-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 25-Jan-2022, the patient experienced INSOMNIA (Insomnia) (seriousness criteria death and hospitalization prolonged). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was provided. 25-Jan-2022, After vaccination of Moderna vaccine, chest discomfort and SOB occurred, and the patient was unable to sleep; so, the patient went to the emergency department for consultations and treatments On follow-up on 08-Feb-2022, the patient's son said that his father was in normal status after he was discharged on 29-Jan-2022. The patient went to the bed after 8 o'clock that night and got up in the midnight to go to the toilet. At thet time he had a dialogue with his mother. After 2 o'clock on 30-Jan-2022, his mother found that his father's quilt was not covered with the quilt, his body was cold and there was no breathing and heartbeat. The patient died on 30-Jan-2022, and the forensic doctor was expected to examine the body this afternoon. It was told to the son about the VICP application procedure, and the son said understood. Now the patient's funeral was being handled, and documents would be sent to the health center after they were prepared. No treatment medication reported. The Worldwide UID was reported as 4.1(b) [redacted].

Case ID	Narrative (Complete)
	Company comment: This regulatory authority case concerns a 66-year-old male patient, with no reported medical history, who experienced the unexpected serious due to hospitalization and fatal event of insomnia. The event occurred after the 3rd dose of mRNA-1273. Reportedly the patient developed chest discomfort and shortness of breath that led to inability to fall asleep so the patient went to ER. Four days later, the patient was discharged from the hospital however, on the next morning, the patient's wife found him with a cold body and no breathing and heart beat. At the time of the report, details regarding planned autopsy were provided. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The events reported and seriousness assessment retained as per regulatory authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up contains non-significant information.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of THROMBOCYTOPENIA (Thrombocytopenia), SEPSIS (Sepsis) and DEATH (Death) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient had a medical history of GERD. On 15-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Jul-2021, the patient experienced THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criterion death), SEPSIS (Sepsis) (seriousness criterion death) and DEATH (Death) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Relevant concomitant product usage were not reported by the reporter. No treatment details were added. Patient received the first dose of Moderna's COVID-19 vaccine on July 15, 2021 and visited the Emergency Room on July 22 for fever and chills. Patient's relevant examination results showed low platelet count noted 49,000/uL, blast of 1.9%, N.band of 2.8% and elevated CRP of 11.23mg/dL. Patient was diagnosed with thrombocytopenia and right pneumonia and was admitted to the Hematology & Oncology Department for treatment. The patient was treated for the infection with Moxifloxacin, injections, and Acetaminophen during hospitalization, and requested discharge on July 23 and visited the Clinic for follow-up. On August 4, the patient was admitted to the hospital again for nausea and dizziness, and was treated with Betamethasone and Metoclopramide. On August 5, the patient underwent bone marrow examination, and was diagnosed with Myelodysplastic syndrome with excess blasts. On August 6, the patient had the symptoms improved, and was discharged. Later, the patient underwent Vidaza chemotherapy on August 16, September 29, November 1, and December 4, and visited the Clinic of the Hematology & Oncology Department on January 10, 2022, and then transferred to the Emergency Room for fever. The patient had body temperature of 38℃, 134/74mmHg, pulse of 140 times/min, and breathing of 20 times/min. Lab revealed WBC:1.88*10^3/uL, N.band: 0.5%, N.seg: 43.5%, (ANC: 827). Hb: 6.9g/dL, PL: 16 *10^3/uL, CRP: 5.29 mg/dL, Na: 131 mmol/L, urine routine no UTI. The CXR showed cardiomegaly, KUB yiled ileus. Further abdomen CT showed no hollow organ perforation. Blood transfusion with LPRBC and PLPH was given at ER. EKG displayed sinus tachycardia with frequent and consecutive premature ventricular. The patient was then admitted to the Hematology & Oncology Department for hospitalization and treatment. During the hospitalization, the patient's infection was controlled with Cefepime, Targocid and Fluconazole, and both traditional Chinese doctors and Western doctors were referred to. Meanwhile, the patient was given continuous blood transfusion for blood cell hypoplasia. On January 19, the patient developed redness, swelling and heat in the left thigh, and the computed tomography showed abscess. The Plastic Surgery Department was consulted, and the doctor said the patient was not in a physical condition good enough for surgery, and recommended strong antibiotics. On January 22, the patient was transferred to ICU for acute respiratory failure, and later developed hematuria, recurrent seizures, and hypotension. Under the expectation of family members for peaceful and palliative treatment, the patient died on January 29. The patient's family members suspected that MDS symptoms caused by the vaccine eventually led to the death of the patient, so the medical staff reported adverse reactions to the vaccine. Cause of death: A. Septic shock with multiple organ failure; B. Thigh abscess complicated with bacteremia; C. Myelodysplastic syndrome with whole blood cell hypoplasia. On the 5th to 7th day after the vaccination, the patient developed redness and swelling of the face; the patient then visited the Emergency Room for sagging facial muscles and had allergic germ and typical allergy; the patient underwent various examinations and was transferred to the Hematology & Oncology Department and given antibiotic injections for 2 days. The patient paid a revisit a week later and was hospitalized for 4 days for spinal fluids. The patient applied three times for targeted treatment, and received the second targeted treatment after platelet transfusion, and got blood indexes improved. However, the patient visited the Emergency Room again for the side effects of the targeted treatment. The patient received the third targeted treatment and got improved after visiting a traditional Chinese doctor. The patient then bought oral blood cancer drugs and received the fourth targeted treatment. After that, the patient had fever again and underwent tomography, which showed cellulitis. The patient was transferred to ICU, and died 4 days later; On January 29, 2022, the patient died. Company Comment: This Regulatory Authority case concerns a 67-year-old female patient, with no relevant medical history reported in the case, who experienced the fatal AESI of Thrombocytopenia and the serious unexpected adverse event of Sepsis. The events Thrombocytopenia and Sepsis were reported to occur approximately 8 days after the administration of the first dose of the mRNA-1273 vaccine, but further information provided states that the patient was hospitalized 8 days after the administration of the first dose of the mRNA-1273 vaccine due to thrombocytopenia and pneumonia and received medical treatment and was discharged. Approximately one month later the patient was re hospitalized and after a bone marrow examination, was diagnosed with Myelodysplastic syndrome with excess blasts. Patient received four chemotherapy cycles and on January 22 the patient was admitted to ICU due to respiratory failure, hematuria, seizures, and hypotension. The patient died four days later. Cause of death was reported as Septic shock with multiple organ failure; Thigh abscess complicated with bacteremia; and Myelodysplastic syndrome with whole blood cell hypoplasia. No further information regarding autopsy report (if performed) was disclosed. All the events were assessed by the reporter with the seriousness criteria of Death. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. It is to be noticed that reported events have different dates on structured field and narrative informed by the RA.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of PRESYNCOPE (Near-syncope, cold sweating) and COLD SWEAT (Near-syncope, cold sweating) in an 84-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.

Case ID	Narrative (Complete)
	Concurrent medical conditions included Hypertension and Diabetes. On 29-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 30-Jan-2022, the patient experienced PRESYNCOPE (Near-syncope, cold sweating) (seriousness criterion death) and COLD SWEAT (Near-syncope, cold sweating) (seriousness criterion death). The patient died on 30-Jan-2022. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Jan-2022, Blood pressure measurement: 178/81 mmhg 178/81 mmHg at 07:50, 80/53 mmhg 80/53 mmHg at 7:26 and 105/51 mmhg 105/51 mmHg at 09:39. On 30-Jan-2022, Electrocardiogram: showed asystole showed asystole at 18:11. On 30-Jan-2022, Heart rate: 52 bpm 52 BPM at 7:26 and 50 bpm 50 BPM at 09:39. On 30-Jan-2022, Oxygen saturation: 100% 100% at 7:26 and 100% 100% at 09:39. On 30-Jan-2022, Respiratory rate: 18 times/min 18 times/min at 7:26 and 20 times/min 20 times/min at 09:39. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not provided. On 30-Jan-2022, the patient sought medical attention at the ER and complained of shortness of breath. The patient's family expressed that the patient suddenly limped when waking up in the morning and walking. The patient had clear consciousness but was unable to describe discomfort.. At 7:26 GCS was E4V5M6, pain score as 0 point. At 7:50, the patient had cold sweats, difference in blood pressure in both arms. The doctor suggested that the patient receive computed tomography and blood test. At 09:39, patient's consciousness changed and GCS was E1V2M4. At 18:11 doctor announced that the heartbeat stopped. Cc: This Regulatory Authority case concerns a 84-year-old, male patient with relevant medical history of hypertension and diabetes, who experienced the unexpected fatal events of Presyncope and Cold Sweating. The events occurred approximately 1 day after the third dose of mRNA-1273 (Moderna covid-19 vaccine). The patient presented to the emergency department 1 day post vaccination with a complaint of shortness of breath. His physiological tests were pulse:52 bpm; respiration:18 beats/min; right arm blood pressure:80/53mmHg; oxygen saturation: 100%; pain index: 0 point; about 30min after, patient experienced cold sweats, decreased blood pressure in both arms. The physician recommended that the patient undergo CT and blood test (no results provided). Cardiac consult discussed treatment regimen, but family member declined surgery and signed a DNR. ECG showed asystole and the emergency physician announced that the patient had cardiac arrest (not reported as event by RA). However, this patient's multiple underlying medical conditions and advanced age remains a confounder. The benefit-risk relationship of mRNA-1273 (Moderna covid-19 vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received and had no new information
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC ARREST (Out of hospital cardiac arrest) in a 78-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Atrial fibrillation and Hypertensive heart disease (HCVD). On 27-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Feb-2022, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced CARDIAC ARREST (Out of hospital cardiac arrest) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product usage was not provided. Patient had blood type O. The patient received two doses of AZ's vaccine on June 24 and September 27, 2021. The family member said the patient fainted suddenly after going to the toilet, and found no breath or heartbeat, so 119 was called, GCS: E1V1M1, cold limbs; skin: intact; tube on body: none; rupillary reaction: both eyes 5mm (-), chest press ongoing. The patient was examined and was sent to the Emergency Room. Follow up information: On 02-Feb-2022, the patient was found fainted and unconscious at home after going to the toilet, and was sent to hospital, and died before arrival. The first aid failed, and the patient died. No further details regarding treatment medications were disclosed. Company comment: This case concerns a 78-year-old female patient with medical history of Atrial fibrillation and Hypertensive heart disease, who experienced serious unexpected event of Cardiac arrest which ended with fatal outcome. The event occurred 6 days after the patient had received the mRNA-1273 vaccine (as third dose, booster). Reportedly, the patient fainted suddenly after going to the toilet, and was found with no breath or heartbeat. The patient was examined and sent to the Emergency Room (ER), however, the first aid failed and the patient died before arrival to the ER. It remained unknown whether an autopsy was performed. The underlying medical history of Atrial fibrillation and Hypertensive heart disease, as well as the patient's elderly age, remain major confounding factors for the reported event. The rechallenge is not applicable since the patient died. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Having in mind that this patient received AstraZeneca COVID-19 Vaccine prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non-significant follow-up received.

Case ID	Narrative (Complete)
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL PAIN (Abdominal pain) in a 65-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 21-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 24-Jan-2022, the patient experienced ABDOMINAL PAIN (Abdominal pain) (seriousness criterion death). It is unknown if an autopsy was performed. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product usage were not provided. On 24-Jan-2022, After receiving Moderna vaccine on 21-Jan-2022, the patient had abdominal pain and visited the emergency room of hospital. The doctor arranged for hospitalization. On 07-Feb-2022, the patient was transferred from intensive care unit to hospice ward and died on 09-Feb-2022 . Treatment details were not provided. Worldwide UID reported as 4.1(b) . This is a regulatory authority case concerning a 65-year-old, male patient with no reported medical history, who experienced the unexpected serious event of Abdominal Pain. The event occurred 3 days after the third dose of mRNA-1273 COVID 19 Vaccine. Patent was rushed to the emergency room. Treatment details were not provided. Patient died 26 days after the third dose of mRNA-1273 COVID 19 Vaccine. It is unknown if autopsy was performed. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received and contains non-significant information.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in a 67-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 17-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on 28-Jan-2022 The patient died on 28-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No treatment drug information provided. No concomitant drug information provided. The family members reported a death case induced by suspected adverse reaction after administration of COVID-19 vaccine. A 68 -year-old female patient where her family members reported no history of past diseases. She received the first and second doses of Moderna vaccine on 07/13/2021 and 10/18/2021, respectively. She received at the third booster dose of the Moderna vaccine on 01/17/2022. After vaccination, she developed symptoms of chest tightness and breathlessness from time to time and went to Clinic for medical treatment on January 28. On January 29, she went to Clinic for medical treatment due to heart discomfort and respiratory asthma. She was referred by the clinic to the emergency department and after entering the emergency department, she went to the emergency area as she was out of breath. The patient died after the first aid was ineffective. CC: This Regulatory Authority case concerns a 67-year-old female patient, with no medical history reported in the case, who experienced fatal serious unexpected event of Death. Cause of death not provided; Autopsy was also not done. Death was reported to occur approximately 11 days after the administration of the 3rd dose of the mRNA-1273 vaccine. After the vaccination, the patient experience symptoms of chest tightness and shortness of breath and heart discomfort that leads to hospitalization and died after the first aid failed. Event seriousness assessed as per Regulatory Authority as Death; limited information was provided at this time. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received and had no new information.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of ASTHMA (Respiratory asthma) and MUSCULAR WEAKNESS (Limb weakness) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 072F21A_1110129) for COVID-19 vaccination. The patient's past medical history included Stroke and Weakness of limbs (The patient had a history of Left limb weakness). Concurrent medical conditions included Diabetes, Hypertension and Hyperlipidemia. On 21-Jan-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Jan-2022, the patient experienced ASTHMA (Respiratory asthma) (seriousness criterion death) and MUSCULAR WEAKNESS (Limb weakness) (seriousness criterion death). The reported cause of death was respiratory asthma and limb weakness. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In January 2022, Blood glucose: 354 354 mg/dl. In January 2022, Blood pressure measurement: 226/112 226/112 mmHg. In January 2022, Body temperature: 37.1 37.1 degrees. In January 2022, C-reactive protein: elevated Elevated. In January 2022, Chest X-ray: bilateral pneumonia Bilateral pneumonia. In January 2022, Echocardiogram: 56% of cardiac output, valvular insufficiency 56% of cardiac output, valvular insufficiency. In January 2022, Electrocardiogram: st segment abnormality ST segment abnormality. In January 2022, Heart rate: 119 119 BPM.

Case ID	Narrative (Complete)
	In January 2022, Respiratory rate: 23 23 times/min. In January 2022, SARS-CoV-2 test: negative (Negative) Negative. In January 2022, White blood cell count: elevated Elevated. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. WWID was reported as 4.1(b) . No concomitant medication information was reported Patient went for consultations and treatments and there was no problem concerning falling, home environment safety and living alone. The patient got up in the morning and went to the toilet and found that left weakness and respiratory asthma occurred. The patient went to the emergency department for treatment. On 29-Jan-2022 family member carried out discussions and decided to take the patient back to home before the patient was dead. On 26-Jan, the patient was sent to the emergency department for consultations and treatments due to cough, phlegm, dyspnea and general weakness. The patient was hospitalized for treatment. On 29-Jan, due to worsened respiratory failure, the family member refused first aid and voluntarily had the patient discharged and returned home. No treatment medication information was reported. Company Comment :This is a fatal case from Regulatory Authority that concerns a 71-year-old female patient, with medical history of stroke and weakness of limbs, who experienced the unexpected serious (due to death) events of ASTHMA and MUSCULAR WEAKNESS (reported as Limb weakness), 5 days after the first dose of mRNA-1273 vaccine. The reported cause of death was asthma and weakness of limb. As per narrative of the source document, five days after vaccination she consulted due to cough, phlegm, dyspnea, and general weakness. Elevated blood pressure and tachycardia were found. A negative COVID-19 PCR test was performed, and the patient received oxygen as treatment. A bilateral pneumonia was diagnosed, and a valvular insufficiency was observed in the echocardiography with a ST segment abnormality in the electrocardiogram. The patient was hospitalized for treatment, but after three days the family refused first aid due to worsened respiratory failure and voluntary had the patient discharged and returned home and she died. The date of death w Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Significant follow-up contains additional events and updated I narrative.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (Fever) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. Concurrent medical conditions included CVA and Hypertension. On 19-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Feb-2022, the patient experienced PYREXIA (Fever) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided. On 29 Jan 2022, patient visited ER due to fever, Vital Signs: BP:59/32mmHg, HR: 75/min, RR: 20, BT: 38.8°C G.C.S.: E 4 M 6 V 4. Patient mentioned that after the doctor's diagnosis and treatment, the diagnosis was bilateral lung infiltration and the patient was hospitalized. Empirical antibiotics brosym was given since 29 Jan 2022. On 01 Feb 20211, evening, patient had shortness of breath with much sputum and ABG showed CO2: 56. AfRVR was found on 01 Feb 2021 midnight then Aminodarone pump also given. On 02 Feb 2022: Acute respiratory failure was suspected. CVP was inserted and transferred to MICU for further care. Patient took Brosym (29/01-02/02), changed Cefepime (02/02-) for progress pneumonia. On 04 Feb 2022: tachycardia keep BiSoProlol 1.25mg/Tab PO BID. The patient vital sign and hemodynamic status was relatived stable, therefore he was transferred to an ordinary ward on 111/02/04. On 06 Feb 2022: patient's sudden consciousness changed, on EKG monitor showed PEA. Epinephrine was injection, but in vain, when the family arrived at the ward, they asked discharge, so arrange critical AAD. On 12 Feb 2022: patient's Cause of death was Pneumonia and respiratory failure. Company comment: This is a fatal regulatory case concerning a 83-year-old male patient with hypertension and previous history of cerebrovascular accident, who experienced the serious unexpected events pneumonia with respiratory failure that leads to Death. Approximately 10 days after the third dose of mRNA-1273, patient visited ER due to fever and was admitted with bilateral pneumonia. 3 to 4 days later developed dyspnoea and respiratory failure and was transfer to ICU. Atrial fibrillation with a rapid ventricular response (AfRPR) was also diagnosed and started treatment with amiodarone and bisoprolol. Patient died after 8 days of hospitalization. The described cause of death was Pneumonia and respiratory failure. It is unknown if an autopsy was performe Reporter did not allow further contact Most recent FOLLOW-UP information incorporated above includes: On 14-Feb-2022: Upon query received from business partner, non-significant correction was performed on 23-FEB-2022. Cause of death field was updated. On 25-Apr-2022: Follow-up information included no new information.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIO-RESPIRATORY ARREST (Respiratory and cardiac arrest during sleep) in a 65-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported.

Case ID	Narrative (Complete)
	On 06-Jan-2022, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 04-Feb-2022, the patient experienced CARDIO-RESPIRATORY ARREST (Respiratory and cardiac arrest during sleep) (seriousness criterion death). An autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Regulatory Authority number-4.1(b) No concomitant medication information was provided. No treatment information was provided. Patient had no breathing and heartbeat when sleeping on 02/04/2022. On 11-Feb-2022 it was reported that the patient had no history of chronic disease, prison inmate. Patient received the first dose of Modena vaccine on 12/7/2021 and the second dose on 01/06/2022.The patient was sent to the hospital for emergency medical treatment at 9:00 p.m. on the evening of 4th Feb but died before arriving at the hospital. First aid was ineffective.The disease summary was uploaded, Forensic autopsy was performed on 4th Feb and the cause of death in the initial report of the forensic autopsy was Aortic dissection and Cardiac lumen tamponade. Contact information of the family members was provided. Company comment This regulatory authority case concerns a 65-year-old male patient, with no reported medical history, who experienced the unexpected serious (death) fatal event of CARDIO-RESPIRATORY ARREST, which occurred approximately 1 month after receiving the second dose of mRNA-1273 vaccine. It was reported that the patient had no history of chronic disease, prison inmate. The patient was sent to the hospital for emergency medical treatment but died before arriving at the hospital. First aid was ineffective. Forensic autopsy was performed and the cause of death in the initial report of the forensic autopsy was Aortic dissection and Cardiac lumen tamponade. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events seriousness captured as per Regulatory Authority assessment in Source Document. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up included no new information was added.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 16-Feb-2022 and was forwarded to Moderna on 16-Feb-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PUPIL FIXED (pupils wide and light rigid), UNRESPONSIVE TO STIMULI (no longer available/no longer responsive), HAEMORRHAGE INTRACRANIAL (intracranial mass hemorrhage), ACCIDENT (accident, - was found lying on the ground), SUBDURAL HAEMORRHAGE (Traumatic subdural hemorrhage: without an open intracranial wound), CONTUSION (bruise of the knee) and CRANIOCEREBRAL INJURY (Circulated brain injury: without open intracranial wound) in an 81-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004218) for COVID-19 vaccination. The patient's past medical history included Fall (Sturz) on 20-May-2021, Hospitalization (fall, hospitalized for several weeks) on 20-May-2021, Contusion (severe bruises) on 20-May-2021, Gait instability (gait uncertainty) on 20-May-2021, Escherichia coli infection (ESBL E. coli 3MRGN in urine) in July 2021, Condition aggravated (condition worsens more and more), Hallucination NOS, Inappetence, Activities of daily living impaired (There was a clear improvement in mobility and ADLs under physio and occupational therapy), Movements disturbance NOS (There was a clear improvement in mobility and ADLs under physio.- and occupational therapy), Memory impaired, Recurrent urinary tract infection (Rez. urinary tract infections), Demented (suddenly completely dement), Feeling unwell, Nicotine abuse (z.n. Nicotine abuse), MRSA wound infection (MRSA detection in nose, throat and wounds (inner bone ulcers bds.)) in June 2021, Urinary tract infection bacterial (ESBL E. coli 3MRGN in urine) in July 2021, Nutritional condition abnormal (Reduced EZ), Decompensation cardiac (heart failure with recurrent cardiac decompensations), Sarcopenia (Sarcopenia/severely fall at risk) and Anticoagulant therapy (blood thinning drugs atrial fibrillation (DOAK)) since an unknown date. Previously administered products included for Product used for unknown indication: COVID-19 VACCINE MODERNA (Moderna LOT 3001531) on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 Vaccine Moderna on 16-Apr-2021, COVID-19 Vaccine Moderna on 16-Apr-2021, COVID-19 Vaccine Moderna on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021, COVID-19 Vaccine Moderna on 16-Apr-2021, COVID-19 Vaccine Moderna on 16-Apr-2021, COVID-19 VACCINE MODERNA on 16-Apr-2021 and COVID-19 VACCINE MODERNA on 16-Apr-2021. Past adverse reactions to the above products included Activities of daily living impaired with COVID-19 VACCINE MODERNA; Condition aggravated with COVID-19 VACCINE MODERNA; Contusion with COVID-19 Vaccine Moderna; Demented with COVID-19 Vaccine Moderna; Escherichia coli infection with COVID-19 VACCINE MODERNA; Fall with COVID-19 Vaccine Moderna; Feeling unwell with COVID-19 Vaccine Moderna; Gait instability with COVID-19 VACCINE MODERNA; Hallucination with COVID-19 Vaccine Moderna; Inappetence with COVID-19 VACCINE MODERNA; Infection MRSA with COVID-19 VACCINE MODERNA; MRSA wound infection with COVID-19 VACCINE MODERNA; Memory impaired with COVID-19 VACCINE MODERNA; Movements disturbance NOS with COVID-19 VACCINE MODERNA; Neurocognitive deficit with COVID-19 VACCINE MODERNA; Nutritional condition abnormal with COVID-19 VACCINE MODERNA; Sarcopenia with COVID-19 VACCINE MODERNA; and Urinary tract infection bacterial with COVID-19 VACCINE MODERNA. Concurrent medical conditions included Hyperlipidaemia (hyperlipidemia), Hepatic lesion (cystoid liver lesion), Atrial fibrillation (atrial fibrillation (DOAK)), Hernia hiatal (Hiatushernie), MRSA wound infection (MRSA - Colonation of Chron Ulc. Inner bone (ankle) (eradication 09-10-2021)), Hypoproteinaemia (protein deficiency), Ulcus cruris (open leg veins Ulcera crur. chron. mall. med. bilateral (left healed for several years)), Neurocognitive deficit (moderate neurocognitive impairment, 18/30 MMSE from 7/2021), Struma nodosa (Struma nodosa li.), Cerebral vascular disturbance (cAVK), Cholecystolithiasis (Cholecystolithiasis), Cardiac insufficiency (heart failure with recurrent cardiac decompensations), Neurocognitive deficit (moderate neurocognitive impairment, 18/30 MMSE from 7/2021), Chronic venous insufficiency (Chronic venous insufficiency), Hypertension arterial (Arterial hypertension), Latent hypothyroidism (latent hypothyroidism), Peripheral arterial occlusive disease (PAvK), Infection MRSA (MRSA detection in nose, throat and wounds (inner bone ulcers bds.)) since June 2021, Hip prosthesis insertion (z.n. hip tep), Kidney angiomyolipoma (Angiomyolipom re. Niere), Chronic renal insufficiency (Chronic renal failure), Chronic antral gastritis (chronic antral gastritis) and Goiter (left goiter). Concomitant products included METAMIZOLE SODIUM (NOVALGINA), CARBOHYDRATES NOS, LIPIDS NOS, MINERALS NOS, PROTEINS NOS (PROTIFAR), BISOPROLOL FUMARATE (CONCOR), FOLIC ACID (FOLSAN), RIVASTIGMINE (EXELON [RIVASTIGMINE]), RIVAROXABAN (XARELTO), DIOSMIN, HESPERIDIN (DAFLON 1000), PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTOLOC), FUROSEMIDE (LASIX SPECIAL), ROSUVASTATIN (ROSUMIBE [ROSUVASTATIN]) and RETINOL (OLEOVIT [RETINOL]) for an unknown indication.

Case ID	Narrative (Complete)
	On 23-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Oct-2021, the patient experienced PUPIL FIXED (pupils wide and light rigid) (seriousness criteria hospitalization and medically significant), UNRESPONSIVE TO STIMULI (no longer available/no longer responsive) (seriousness criteria hospitalization and medically significant), HAEMORRHAGE INTRACRANIAL (intracranial mass hemorrhage) (seriousness criteria death, hospitalization and medically significant), ACCIDENT (accident, - was found lying on the ground) (seriousness criterion hospitalization), SUBDURAL HAEMORRHAGE (Traumatic subdural hemorrhage: without an open intracranial wound) (seriousness criteria hospitalization and medically significant), CONTUSION (bruise of the knee) (seriousness criterion hospitalization) and CRANIOCEREBRAL INJURY (Circulated brain injury: without open intracranial wound) (seriousness criteria hospitalization and medically significant). The patient died on 09-Oct-2021. It is unknown if an autopsy was performed. At the time of death, PUPIL FIXED (pupils wide and light rigid), UNRESPONSIVE TO STIMULI (no longer available/no longer responsive), ACCIDENT (accident, - was found lying on the ground), SUBDURAL HAEMORRHAGE (Traumatic subdural hemorrhage: without an open intracranial wound), CONTUSION (bruise of the knee) and CRANIOCEREBRAL INJURY (Circulated brain injury: without open intracranial wound) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In July 2021, Mini mental status examination: 18/30 18/30. On 29-Jul-2021, Blood albumin (35-52): 31.80 gl (Low) 31.80 gl. On 29-Jul-2021, Blood alkaline phosphatase (35-104): 151 u/l (High) 151 U/l. On 29-Jul-2021, C-reactive protein (0.0-5.0): 14.6 mg/l (High) 14.6 mg/l. On 29-Jul-2021, CSF red blood cell count (4.00-5.00): 3.88 t/l (Low) 3.88 T/l. On 29-Jul-2021, Eosinophil count (1.0-4.0): 4.6 % (High) 4.6 %. On 29-Jul-2021, Gamma-glutamyltransferase (0-35): 112 u/l (High) 112 U/l. On 29-Jul-2021, Haematocrit (38.0-44.0): 35.0% (Low) 35.0%. On 29-Jul-2021, Haemoglobin (12.0-16.0): 10.8 g/dl (Low) 10.8 g/dl. On 29-Jul-2021, Lymphocyte count (20.0-40.0): 19.4% (Low) 19.4%. On 29-Jul-2021, Platelet count (150-360): 370 g/l (High) 370 G/L. On 08-Sep-2021, SARS-CoV-2 test: negative (Negative) negatively. On 07-Oct-2021, SARS-CoV-2 test: negative (Negative) negatively. On 08-Oct-2021, Coma scale: at 4 (abnormal) at 4,The CCT showed mass intr
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 16-Feb-2022 and was forwarded to Moderna on 16-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of HEMIPLEGIA (the patient a few minutes (about 5 min) after the administration of the Moderna dose booster vaccine presents: right hemiplegia with dysarthria. Conscious and space-time oriented.) and DYSARTHRIA (the patient a few minutes (about 5 min) after the administration of the Moderna dose booster vaccine presents: right hemiplegia with dysarthria. Conscious and space-time oriented.) in a 68-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 030G21A) for COVID-19 vaccination. Co-suspect product included non-company product ENOXAPARIN SODIUM (INHIXA) solution for injection for Venous thrombophlebitis. The patient's past medical history included Venous thrombophlebitis on 14-Dec-2021. On 14-Dec-2021, the patient started ENOXAPARIN SODIUM (INHIXA) (Subcutaneous) 6000 kilo-international unit once a day. On 07-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) .25 milliliter. On 07-Jan-2022, the patient experienced HEMIPLEGIA (the patient a few minutes (about 5 min) after the administration of the Moderna dose booster vaccine presents: right hemiplegia with dysarthria. Conscious and space-time oriented.) (seriousness criterion death) and DYSARTHRIA (the patient a few minutes (about 5 min) after the administration of the Moderna dose booster vaccine presents: right hemiplegia with dysarthria. Conscious and space-time oriented.) (seriousness criterion death). The patient died on 09-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication information was provided. No treatment medication information was provided. the patient presented a few minutes after administration of the anti-ovid vaccine SPIKEVAX LOTTO 030G21A EXP. 05/Mar/22 (booster dose 0.25 ml) hemiplegia dx with dysarthria. the patient was on high-dose anticoagulant therapy with inhixa 6000 Ui x2. The anticoagulant undertaken since 14/Dec/21 for thrombophlebitis AI was reported as a suspected drug. It was suspected di a stroke of nature to be defined. Update of 31/Jan/2022: Following the death of the patient, on 09/Jan/2022, s COMPANY COMMENT: This fatal regulatory authority case concerns a 68-year-old female patient with relevant medical history of Venous thrombophlebitis in treatment with ENOXAPARIN SODIUM since December 14, 2021 who experienced serious unexpected events of HEMIPLEGIA and DYSARTHRIA The events occurred the same day of the booster dose 0.25 ml of mRNA-1273 vaccine. The patient passed away 3 days after the event onset Patient's medical history of Venous thrombophlebitis is a possible confounder. The benefit-risk relationship of drug is not affected by this report Terms and onset dates were captured as provided The case was assessed as serious by the Regulatory Authority´s report due to Death Most recent FOLLOW-UP information incorporated above includes: On 28-Feb-2022: Follow up contains non significant information. Pharmaceutical form (Dosage form) updated.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 16-Feb-2022 and was forwarded to Moderna on 16-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (cause of death unknown) and THROMBOSIS (blood clots in the brain) in a 79-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004235) for COVID-19 vaccination.

Case ID	Narrative (Complete)
	No Medical History information was reported. On 14-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 2 dosage form. In January 2022, the patient experienced THROMBOSIS (blood clots in the brain) (seriousness criterion medically significant). The patient died on 17-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, THROMBOSIS (blood clots in the brain) had not resolved. No concomitant medication provided. No treatment information mentioned. Company Comment: This regulatory case concerns a 79-year-old, female patient with no reported medical history, who experienced the unexpected, serious events of Death and Thrombosis (reported as blood clots in the brain). The event of Death occurred 3 days after receiving the second dose of mRNA-1273 vaccine while Thrombosis occurred on an unspecified day after receiving the second dose of the vaccine. The clinical course leading to demise and the cause of death were not reported. It is unknown if autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report..
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b)) on 15-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. . .This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a pharmacist, was received via the PMDA (Ref, 4.1(b)). On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (unknown product name). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (unknown product name). On 08-Feb-2022, at 16:00, the patient received the 3rd vaccination with this vaccine. At 20:30, the patient was found in bathroom with apnoea and cardiac arrest and was raced to a hospital. At 21:45, the patient was confirmed dead in the hospital where she was transported. On an unknown date, whole-body postmortem CT was performed for detailed examination. On closer examination of the cause of death by CT, there was no traumatic or hemorrhagic cause of death. The cause of death could be explained by drowning in bathroom. As a cause, decreased consciousness due to heat shock, drowning into the bathtub, passive inflow of bathwater into the airway and asphyxial pulmonary oedema, or pulmonary oedema due to pump malfunction with acute left cardiac failure in the bathtub. The outcome of drowning in bathroom, apnoea, cardiac arrest, diffuse pulmonary oedema in both lungs, acute left cardiac failure, and decreased consciousness was reported as fatal. Follow-up investigation will be made. 【Whole-body postmortem CT】 Head：postoperative right frontotemporal craniotomy and right middle cerebral artery bifurcation aneurysm clipping. The right temporal lobe had obsolete infarction. The right ventricle had traction dilatation. There was no cerebral hemorrhage or subarachnoid hemorrhage. The obfuscation of the white/gray matter boundary and the hyperabsorption of the venous sinus changed after death. There was fluid accumulation in nasopharynx and paranasal sinus. Neck：there was no cervical vertebra fracture. Chest：intracardiac hyperdense horizontal plane formation showed findings of sudden death due to massive release of plasminogen activator from the vascular endothelium. Coronary artery calcification was mild. Diffuse pulmonary oedema in both lungs was noted. Fluid accumulation in the tracheal lumen could be explained only by airway reflux of exudates, but there was also the possibility of passive inflow of bathwater. Subclavian vein, brachiocephalic vein, and gas just below the free wall of the right atrium and ventricle were changed after resuscitation by aeration during infusion and carbon dioxide evolution with anaerobic metabolism. Right ventricular dilatation, left ventricular wall thickening, and increased absorption level (postmortem rigidity) changed after death. Abdomen：the gastric food residue was filled, and the residue flowed backward into the esophagus due to the post-resuscitation change. Hepatic intravascular gas changed after resuscitation (intracardiac gas flowed backward into the hepatic vein from the inferior vena cava, and gastrointestinal gas flowed into the portal vein from the weakened mucosa). Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. This regulatory authority case concerns an 80-year-old female patient, with history of craniotomy and intra-cerebral aneurysm clipping, who experienced the fatal events of near drowning, apnoea, cardiac arrest, depressed level of consciousness, pulmonary oedema and cardiac failure acute that occurred on the same day after receiving a third dose of mRNA-1273. According to the provided narrative, the cause of death could be explained by drowning in the bathroom with events occurring as it follows: decreased consciousness due to heat shock, drowning into the bathtub, passive inflow of bathwater into the airway and asphyxial pulmonary oedema or pulmonary oedema due to pump malfunction with acute left cardiac failure in the bathtub. A whole-body postmortem CT was performed and showed no cerebral or subarachnoid hemorrhage, at chest level intracardiac hyperdense horizontal plane formation showed findings of sudden death due to massive release of plasminogen activator from the vascular endothelium, and fluid accumulation in the tracheal lumen could be explained only by airway reflux of exudates, but there was also the possible of passive inflow of bathwater. Patient's mentioned medical history remains as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 15-Feb-2022. The most recent information was received on 31-Mar-2022 and was forwarded to Moderna on 07-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref. 4.1(b)). On 31-Mar-2022, follow-up information was received from a physician. The vaccine recipient received dialysis treatment three times a week for chronic renal failure originating from glomerulonephritis. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 12-Feb-2022, the patient underwent blood dialysis treatment. On 13-Feb-2022, at 13:30, the patient received the 3rd vaccination with this vaccine. The patient did not complain of physical deconditioning. On 14-Feb-2022, at 06:00, the patient woke up. Around 12:00, the patient ate lunch and spent time at home. Around 18:00, the patient had dinner at home with her family. Around 19:00, the patient took a bath. At 19:10, lethal arrhythmia developed. At 19:20, the family member went to check on the patient and found her unconscious in the bathtub. Cardio-respiratory arrest was observed. At 19:25, an ambulance call was made. At 20:13, the patient was transported to a hospital. At 20:45, the patient was confirmed death. Necropsy showed findings of acute death, finding of micro fibrosis around the coronary arteries on the side of the endomyocardium of the left ventricle, finding of dialysis kidney, and systemic atherosclerosis. The cause of death was diagnosed as lethal arrhythmia. The results of qualitative examinations of drug and toxic substance and alcohol testing were negative. The outcome of systemic arteriosclerosis, lethal arrhythmia, and cardio-respiratory arrest was reported as fatal. No follow-up investigation will be made.

Case ID	Narrative (Complete)
	Reporter comments: It is considered that there is some temporal relationship between the occurrence of adverse events and the timing of administration of the vaccine. Since patients undergoing dialysis may die suddenly, it cannot be said that the occurrence of adverse events is not related to pathological factors of underlying diseases and complications at all. The occurrence of adverse events is not related to concomitant drugs. The death occurred the day after the vaccination with this vaccine. As the patient had originally been receiving blood dialysis, the heart must have been stressed. However, necropsy showed no ascites, no pleural effusions, and no pulmonary edema. Therefore, the patients condition was probably well controlled by dialysis. Necropsy also revealed a finding of acute death, detecting micro fibrosis around the small coronary arteries on the side of the endomyocardium of the left ventricle, but this finding was not significant. Sudden death while bathing is likely to occur in the elderly person, but in this case, there was no evidence of aspiration of water, so an acute death is considered to have occurred while bathing. Obviously, the patients condition, including dialysis, is considered to have influenced the sudden death, but it is also reasonable to assume that this vaccine also had some effect on death. Follow-up received on 31-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments. Company Comment: As for renal atrophy, since the onset of this event requires a time-lapse on the order of years, and the patient is undergoing dialysis for renal failure chronic, which is a complication, the onset of this event after the administration of ELASOMERAN is considered to be due to a complication, and there is no causal relationship between the administration of ELASOMERAN and the onset of this event.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 15-Feb-2022. The most recent information was received on 30-Mar-2022 and was forwarded to Moderna on 07-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b) . On 30-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (unknown product name). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (unknown product name). On 12-Feb-2022, at 11:15, the patient received the 3rd vaccination with this vaccine. After that, the patient performed normal daily activities. On 13-Feb-2022, around 19:30, the patient took a bath. Around 20:00, the patient experienced lethal arrhythmia. Around 21:15, a family member was suspicious that the patient did not get out of a bath and went to the bathroom to find her unconscious in the bathtub. The patient was already in a state of cardio-pulmonary arrest. An ambulance call was made, and the patient was transported to a hospital receiving resuscitation measures. After being transported to a hospital, the patient was confirmed dead. The results of qualitative examination for urine drug and toxic substance and blood alcohol were negative. An autopsy was performed to reveal mild fibrosis on the left ventricular endocardium, mild lipofuscin deposition in the left ventricle, and moderate fatty infiltration in the right ventricle. In addition, mild lymphocytic infiltration was seen in the right kidney. Congestion was seen in other various internal organs. The autopsy revealed evidence of acute death and showed no other diseases that could be the cause of death, and toxicological examination also showed no abnormalities; therefore, the cause of death was judged as lethal arrhythmia. The outcome of lethal arrhythmia, cardio-pulmonary arrest and congestion of various internal organs was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The occurrence of the adverse events is not associated with pathological factors of underlying diseases and complications because the patient had no underlying diseases. Considering that the death occurred on the day after the vaccination and based on the patients daily life and medical history, the causality cannot be completely ruled out, and it was reasonable to consider that the vaccination had some impact on the death. Therefore, there is a relationship between the cause of death and the adverse reactions. Considering that the patient, who had no medical history and was in a healthy condition, experienced sudden death while taking a bath on the day after the vaccination with this vaccine, it was considered highly probable that the vaccination may have had some impact on the death rather than concluding that there was no causality at all. Obviously, it is difficult to make a conservative determination; therefore, accumulation of results of detailed autopsy, as in this case, is considered necessary. Follow-up received on 30-MAR-2022 Updated: Patient Information, Lab Data, Event Information, Narrative, Reporter Comments Company Comment: Arrhythmia can be also considered as an accidental disease although it developed after the administration of ELASOMERAN.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 16-Feb-2022 and was forwarded to Moderna on 16-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (death on the day of vaccination, not yet autopsy) in a 67-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000128A) for COVID-19 vaccination. No Medical History information was reported. On 12-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 12-Jan-2022 The patient died on 12-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant product usage were not provided. Treatment details were not provided. Company Comment: This regulatory case concerns a 67-year-old, male patient with no reported medical history, who had a fatal outcome with unexpected serious event of Death. The event occurred on the same day of the third dose of vaccination of mRNA-1273. The clinical course leading to demise and the cause of death were not reported. The patient reportedly died at home without any external signs of violence. At the time of reporting, autopsy has not been conducted. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of ABSCESS LIMB (no feeling of hunger, confusion, weight loss of over 30 kilograms, none own care possible, on the buttocks -surgery,), DEMENTIA (First reaction black border of puncture spot. Not two weeks later fainting, then diagnosis of dementia!), DEATH (cause of death unknown), WEIGHT DECREASED (no feeling of hunger, confusion, weight loss of over 30 kilograms, none own care possible, on the buttocks -surgery,), ABSCESS DRAINAGE (no feeling of hunger, confusion, weight loss of over 30 kilograms, none own care possible, on the buttocks -surgery,), SYNCOPE (First reaction black border of puncture spot. Not two weeks later fainting, then diagnosis of dementia!) and CAREGIVER (no feeling of hunger, confusion, weight loss of over 30 kilograms, none own care possible, on the buttocks -surgery,) in a 67-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported.

Case ID	Narrative (Complete)
	On 18-Jun-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In June 2021, the patient experienced SYNCOPE (First reaction black border of puncture spot. Not two weeks later fainting, then diagnosis of dementia!) (seriousness criterion medically significant). In 2021, the patient experienced DEMENTIA (First reaction black border of puncture spot. Not two weeks later fainting, then diagnosis of dementia!) (seriousness criterion medically significant). On 18-Jun-2021, the patient experienced VACCINATION SITE REACTION (First reaction black border of puncture spot. Not two weeks later fainting, then diagnosis of dementia!). On an unknown date, the patient experienced ABSCESS LIMB (no feeling of hunger, confusion, weight loss of over 30 kilograms, none own care possible, on the buttocks -surgery,) (seriousness criterion hospitalization), DEATH (cause of death unknown) (seriousness criterion death), WEIGHT DECREASED (no feeling of hunger, confusion, weight loss of over 30 kilograms, none own care possible, on the buttocks -surgery,) (seriousness criterion medically significant), ABSCESS DRAINAGE (no feeling of hunger, confusion, weight loss of over 30 kilograms, none own care possible, on the buttocks -surgery,) (seriousness criterion hospitalization) and CAREGIVER (no feeling of hunger, confusion, weight loss of over 30 kilograms, none own care possible, on the buttocks -surgery,) (seriousness criterion medically significant). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, ABSCESS LIMB (no feeling of hunger, confusion, weight loss of over 30 kilograms, none own care possible, on the buttocks -surgery,), VACCINATION SITE REACTION (First reaction black border of puncture spot. Not two weeks later fainting, then diagnosis of dementia!), DEMENTIA (First reaction black border of puncture spot. Not two weeks later fainting, then diagnosis of dementia!), WEIGHT DECREASED (no feeling of hunger, confusion, weight loss of over 30 kilograms, none own care possible, on the buttocks -surgery,), ABSCESS DRAINAGE (no feeling of hunger, confusion, weight loss of over 30 kilograms, none own care possible, on the buttocks -surgery,), SYNCOPE (First reaction black border of puncture spot. Not two weeks later fainting, then diagnosis of dementia!) and CAREGIVER (no feeling of hunger, confusion, weight loss of over 30 kilograms, none own care possible, on the buttocks -surgery,) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Allergic to Fructose. Top healthy, unrecognizable after two weeks - a care case. Dead six months later. Not recovering, just broken down. This is a regulatory authority case concerning a 67-year-old, female patient with no reported medical history, who experienced the unexpected serious events of Abscess limb, Dementia, Death, Weight decreased, Abscess drainage, Syncope, Caregiver and unexpected non-serious event of Vaccination site reaction. The event Vaccination site reaction occurred on the same day after the unknown dose of mRNA-1273 COVID 19 Vaccine. While the events Syncope occurred around June 2021. while Dementia occurred on 2021. The events Abscess limb, Weight loss, Abscess drainage, death and caregiver occurred on an unknown date. Cause of death was unknown. The events were reported as not resolved. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST DISCOMFORT (Chest heaviness) in an 88-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for an unknown indication. No Medical History information was reported. On 22-Dec-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 10-Feb-2022, the patient experienced CHEST DISCOMFORT (Chest heaviness) (seriousness criterion death). It is unknown if an autopsy was performed. Not Provided For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications reported. No treatment medications provided. The patient had chest heaviness. Company Comment: This is a regulatory case concerning an 88-year-old female patient with no medical history reported, who experienced the unexpected serious event of Chest discomfort that led to fatal outcome death, which occurred 50 days after a dose of mRNA-1273 vaccine (dose number not specified). The cause of death was not reported. It is unknown if an autopsy was performed. Patient´s advance age remains as confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The event was assessed as serious as per Regulatory Authority´s report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of STAPHYLOCOCCAL SEPSIS (Staphylococcal sepsis), ATRIAL FIBRILLATION (Atrial fibrillation), ENDOTRACHEAL INTUBATION (Intubation NOS), RESPIRATORY FAILURE (Respiratory failure), TACHYCARDIA (Tachycardia), CARDIAC FAILURE (Cardiac failure aggravated) and RENAL FAILURE (Renal failure aggravated) in a 71-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Chronic renal failure, COPD, Heart failure, Emphysema and Myelomatosis (Immunosuppressed with daratumumab + bortezomib (Velcade) + dexamethasone, due to multiple myeloma.). Previously administered products included for Vaccination: Comirnaty and Comirnaty. Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty. Concomitant products included DARATUMUMAB, BORTEZOMIB and DEXAMETHASONE for Myelomatosis. On 04-Oct-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 09-Oct-2021, the patient experienced ATRIAL FIBRILLATION (Atrial fibrillation) (seriousness criterion death), ENDOTRACHEAL INTUBATION (Intubation NOS) (seriousness criterion death), RESPIRATORY FAILURE (Respiratory failure) (seriousness criterion death), TACHYCARDIA (Tachycardia) (seriousness criterion death) and RENAL FAILURE (Renal failure aggravated) (seriousness criterion death). On an unknown date, the patient experienced STAPHYLOCOCCAL SEPSIS (Staphylococcal sepsis) (seriousness criterion death), COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) and CARDIAC FAILURE (Cardiac failure aggravated) (seriousness criterion death). The patient died on 22-Oct-2021. It is unknown if an autopsy was performed. At the time of death, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Oct-2021, Echocardiogram: ejection fraction in the 20s. Ejection fraction in the 20s..

Case ID	Narrative (Complete)
	On 09-Oct-2021, X-ray: x-ray thorax found densification basal on the left X-ray thorax found densification basal on the left side.. On 10-Oct-2021, Echocardiogram: improvement of left ventricular function in sinus Improvement of left ventricular function in sinus rhythm. Left ventricular ejection fraction: 35-40 percent.. On 13-Oct-2021, Glomerular filtration rate: 17 17 millilitre per minute per 1.73 square metre. On 17-Oct-2021, Magnetic resonance imaging: mri caput noted two small point-shaped cerebral in MRI caput noted two small point-shaped cerebral infarctions, one of which with a slight connected subarachnoidal hematoma. This could not explain the comatose state.. On 22-Oct-2021, Body temperature: 40 40 degree Celsius. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered STAPHYLOCOCCAL SEPSIS (Staphylococcal sepsis), ATRIAL FIBRILLATION (Atrial fibrillation), ENDOTRACHEAL INTUBATION (Intubation NOS), RESPIRATORY FAILURE (Respiratory failure), TACHYCARDIA (Tachycardia), CARDIAC FAILURE (Cardiac failure aggravated) and RENAL FAILURE (Renal failure aggravated) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). No treatment medication details were provided. Company comment: This regulatory authority case concerns a 71-year-old male patient, with relevant medical history of myelomatosis under immunosuppressed treatment, heart failure, COPD, emphysema and CRF, who experienced the fatal AESI of respiratory, cardiac and renal failure, atrial fibrillation and serious (death) unexpected events of staphylococcal sepsis, tachycardia and endotracheal intubation after the third dose of mRNA-1273. It was reported that the patient was hospitalized due to clinical pulmonary edema, respiratory failure and kidney failure (aggravated) 6 days after receiving the mRNA-1273 vaccine. Then, the patient was intubated due to respiratory failure, electrical cardioversion was reported. The patient did not responded to repeated awakening attempts and developed a Staphylococcal sepsis. The patient died 19 days after the third dose of mRNA-1273. No information regarding if an autopsy was performed. Cause of death was not further specified. Patient´s underlying diseases remain contributing factors. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 PNEUMONIA (SARS-CoV-2 pneumonia) and VACCINATION FAILURE (Vaccination failure) in an 89-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004834) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination. The patient's past medical history included Aneurysm of aorta, Carotid artery atheroma, Hypertension arterial, Infarct myocardial in 2017, Artificial cardiac pacemaker wearer in 2015, AFib and Coronary arterial stent insertion in 2017. Concurrent medical conditions included Tabaquism. Concomitant products included FINASTERIDE for Disorder urinary tract, PANTOPRAZOLE for Gastritis prophylaxis, BISOPROLOL FUMARATE (BISOCE) for Hypertension arterial, ACETYLSALICYLATE LYSINE (KARDEGIC) and ATORVASTATIN CALCIUM (TAHOR) for Prevention, ENOXAPARIN SODIUM (LOVENOX HP) for Thromboembolism prophylaxis. On 06-Mar-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 2 dosage form. On 01-Apr-2021, received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to 2 dosage form. On 29-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 07-Jan-2022, the patient experienced COVID-19 PNEUMONIA (SARS-CoV-2 pneumonia) (seriousness criteria death and hospitalization) and VACCINATION FAILURE (Vaccination failure) (seriousness criteria death and hospitalization). The patient died on 15-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment information was provided. Company comment: This Fatal Regulatory Authority case concerns a 89-year-old, male patient, with medical history of tabaquism, hypertension, atrial fibrillation and myocardial infarction, who experienced the unexpected, serious (death/hospitalization) and AESI of COVID-19 pneumonia. Vaccination failure was also reported, however, the patient received previously as first and second dose of his COVID-19 vaccination schedule two doses of Cominarty's COVID-19 vaccine. The event occurred 3 months and 9 days after receiving a dose of mRNA-1273 vaccine, reported as R1 and he died 8 days after. Cause of death was not reported. Autopsy report is not available. Patient's age, gender, medical history of tabaquism, hypertension, atrial fibrillation and myocardial infarction remain as confounders. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 16-Feb-2022. The most recent information was received on 16-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 16-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 12-Feb-2022, the patient received the 3rd vaccination with this vaccine. On 13-Feb-2022, around 16:00, consciousness disturbed developed. The patient was found collapsed and was transported by ambulance. The patient was suspected to have developed heat illness in a hot environment due to difficulty moving due to an unforeseen accident or a preceding disease. The patient was already in multi-organ failure, in shock, and difficult to save the patients life. CT showed the possibility of multiple cerebral infarctions but could not be confirmed. There was a suspected cerebral infarction due to chronic atrial fibrillation. On 14-Feb-2022, the patient was confirmed dead. The cause of death was heat illness. No autopsy was performed. The outcome of consciousness disturbed, possible multiple cerebral infarctions, difficulty in moving, suspected heat illness, multi-organ failure and shock was reported as fatal. No follow-up investigation will be made. Reporter's comment: The causal relationship between the progress and this vaccination is unknown. There is a possibility that cerebral infarction caused the difficulty in moving, resulting in heat illness, but the possibilities that the cause was atrial fibrillation, that the cerebral infarction was a result rather than a cause, and that the patient had no cerebral infarction from the beginning were also cannot be ruled out. Other factors include the possibility of suspected cerebral infarction due to chronic atrial fibrillation. The relationship between cause of death and adverse events is unknown. The cause of the heat illness was a fall in a bedrock bath facility, which may have been caused by cerebral infarction. Since it cannot be denied that cerebral infarction

Case ID	Narrative (Complete)
	may be caused by thrombosis or chronic atrial fibrillation due to vaccination with this vaccine, it is unclear whether the occurrence of adverse events is temporally related to the timing of administration of this vaccine. The occurrence of adverse events may be associated with pathological factors of chronic atrial fibrillation. Neither the presence or absence of cerebral infarction nor the association of cerebral infarction with this vaccination, if any, can be determined. Follow-up received on 16-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments LP Company Comment: As for heat illness, the event developed after the administration of ELASOMERAN, but it could also be due to the patient's environment, or other influences. As for cerebral infarction, the event developed after the administration of ELASOMERAN, but it could also be due to the patient's medical history or concurrent events, or other influences. Company comment: This spontaneous case concerns a 76-year-old, male patient with medical history of Diabetes mellitus and Atrial fibrillation, who experienced unexpected serious events of Cerebral infarction (seriousness criterion: Fatal, Hospitalisation, Medically significant), Heat illness (seriousness criterion: Fatal, Hospitalisation, Medically significant), Multiple organ dysfunction syndrome (seriousness criterion: Fatal, Medically significant), Shock (seriousness criterion: Fatal, Medically significant), Movement disorder (seriousness criterion: Fatal, Hospitalization) and Altered state of consciousness (seriousness criterion: Fatal, Hospitalisation, Medically significant). It was reported that a day after receiving the mRNA-1273 vaccine (as third dose), the patient developed disturbed consciousness. The patient was found collapsed and was transported by ambulance. The patient was suspected to had developed heat illness in a hot environment due to difficulty moving due to an unforeseen accident or a preceding disease. The patient was already in multi-organ failure and shock. CT showed the possibility of multiple cerebral infarctions due to chronic atrial fibrillation, but it could not be confirmed. The cause of death was heat illness and no autopsy was performed. The outcome of consciousness disturbed, possible multiple cerebral infarctions, difficulty in moving, suspected heat illness, multi-organ failure and shock was reported as fatal. Underlying medical history of atrial fibrillation remains a major confounder for Cerebral infarction which could contribute to movement disorder and altered state of consciousness. The patient's elderly age remains an additional confounder. Having in mind that this patient received Comrinaty vaccine prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] on 17-Feb-2022. The most recent information was received on 15-Mar-2022 and was forwarded to Moderna on 23-Mar-2022. This case was reported by a pharmacist via the Drug Information Center. On 15-Mar-2022, follow-up information was received from a physician. Respiratory arrest was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 15-Feb-2022, around 17:00, the patient received the 3rd vaccination with this vaccine. There was no change in the physical condition immediately after that. On 16-Feb-2022, at 00:55, when a nurse went to check on the patient, body temperature was 37.3 degrees Celsius. SpO2 was 93% under 2L of O2. Large amount of white viscous sputum could be aspirated. There was no remarkable change. At 04:16, in the morning, when a nurse went to check on the patient for the injection, the patient was found in respiratory arrest. The patient refused resuscitation (DNAR), so life-saving measures were not taken. This case was reported to a physician. At 08:10, the patient was confirmed dead by the physician. The cause of death was prostate cancer. No necropsy was performed. The outcome of respiratory arrest, large amount of white viscous sputum and pyrexia was unknown. No follow-up investigation will be made. Reporter comments continuation: The occurrence of adverse events is related to pathological factors of prostate cancer because the patient's general condition was likely to be unstable due to diseases. The patient originally had advanced prostate cancer, and it can be assumed that the general condition was prone to instability. Therefore, administration of this vaccine is not necessarily the cause, but on the other hand, vitals such as blood pressure were stable until the previous day, and it was difficult to determine the direct cause of death. Adverse events associated with administration of this vaccine may have developed. There was no relationship between cause of death and adverse events. Follow-up received on 15-MAR-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 17-Feb-2022. The most recent information was received on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of ANURIA (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP), MULTIPLE ORGAN DYSFUNCTION SYNDROME (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) and SEPTIC SHOCK (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) in a 74-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005887) for COVID-19 vaccination. The patient's past medical history included Respiration failure on 01-Nov-2015, Amnestic disorder, Recovered smoker (end date- 01-Jan-1992), Septicaemia (01/10/2021: admitted again for septicemia) on 01-Jan-2020, Diaphragmatic hernia, Obstructive arteriosclerosis of lower extremities on 01-Sep-2021, Aortic valve replacement, Lactic acidosis (iatrogenic) on 01-Aug-2015, Hypertensive heart disease, Anemia (severe enteric loss anemia) on 01-Aug-2015, Hyperuricaemia, Hepatic steatosis on 01-Jan-2010, Acute pulmonary oedema on 01-Jan-2007, Cerebral infarct on 01-Jan-2007 and Femur fracture (dx) on 01-Jan-1972. Previously administered products included for SARS-CoV-2 immunisation: COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 06-Apr-2021 and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) on 27-Apr-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY (BIONTECH MANUFACTURING GMBH) (J07BX03). Concurrent medical conditions included Diabetic retinopathy, Insulin-requiring type 2 diabetes mellitus on 01-Jan-2007, Hypertension arterial and Atrial fibrillation. Concomitant products included INSULIN GLARGINE (TOUJEO), ATORVASTATIN CALCIUM (TORVAST), ACETYLSALICYLIC ACID (CARDIOASPIRIN), DIGOXIN (LANOXIN), APIXABAN (ELIQUIS), FUROSEMIDE (LASIX P), SERTRALINE, POTASSIUM CANRENOATE (KANRENOL), BISOPROLOL FUMARATE (SEQUACOR), LANSOPRAZOLE (LANSOX) and INSULIN ASPART (NOVORAPID) for an unknown indication. On 22-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 30-Jan-2022, the patient experienced ANURIA (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death), MULTIPLE ORGAN DYSFUNCTION SYNDROME (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death) and SEPTIC SHOCK (anuria, urinary septic shock with MOF, cardiopathic, diabetic, AOCP) (seriousness criterion death). The patient died on 10-Feb-2022. The reported cause of death was Shock septic. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Jan-2022, Blood test: inconclusive (Inconclusive) Inconclusive.

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	On 30-Jan-2022, Chest X-ray: inconclusive (Inconclusive) Inconclusive. On 30-Jan-2022, SARS-CoV-2 test negative: inconclusive (Inconclusive) Inconclusive. On 30-Jan-2022, Vital signs measurement: inconclusive (Inconclusive) Inconclusive. On 31-Jan-2022, Blood gases: inconclusive (Inconclusive) Inconclusive. On an unknown date, Ultrasound scan: inconclusive (Inconclusive) Inconclusive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Reporter states first dose on 06/04/2021 comirnaty vaccine lot: et7205 sc: 31/07/2021, the second dose on 27/04/2021 comirnaty vaccine lot: ex3599 sc: 31/08/2021. Concomitant pathologies includes diabetes mellitus, heart disease and aocp. Company Comment: This is a Regulatory case concerning a 74-year-old male patient with interchange of vaccine administration (COVID-19 vaccine, 2 doses of Comirnaty 6-7 months (interval of 21 days) prior to mRNA-1273 dose and medical history of Septicaemia (recurrence: 2020 & Oct 2021), Obstructive arteriosclerosis of lower extremities (2021), Aortic valve replacement, Severe enteric loss anemia (2015), Hepatic steatosis (2010), Hyperuricaemia, Acute pulmonary oedema (2007), Cerebral infarct (2007), and concurrent Type 2 diabetes mellitus (15y), Diabetic retinopathy, Hypertension arterial, Atrial fibrillation, Heart disease and AOCP. The patient experienced the serious fatal unexpected events of Anuria (AESI), Multiple Organ Dysfunction Syndrome and Septic shock. The events occurred approximately 2 months 9 days after a dose of mRNA-1273 received as the third dose for COVID-19 Vaccination. The patient died on 10-Feb-2022 (11 days after events onset). The reported cause of death was Shock septic. An autopsy was not performed. Diagnostic workup (Blood test, Chest X-ray, Vital signs, blood gases) was reported with inconclusive results, however an urinary origin of the septic shock was described. Treatment information was not provided. The increased risk of developing infections and sepsis due to type 2 diabetes remains a confounder. Suggestive urinary tract infection could be contributory for septic shock. Septic shock is a contributing cause of MODS and anuria. Patient's advanced age, vast comorbidities and heart disease remain as confounders and increase risk for fatal outcome. Moreover case could be confounded by polypharmacy. The benefit-risk relationship of COVID-19 Vaccine Moderna (mRNA-1273) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Mar-2022: Follow Up received with Non-Significant information. On 07-Mar-2022: Follow up received contains medical history, concomitant medications and event details.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 18-Feb-2022 and was forwarded to Moderna on 18-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC DEATH (Sudden cardiac death) and DEATH (cause of death unknown) in a 67-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent condition included Epilepsy. On 20-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. The patient died on 25-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant medication were reported. No treatment information was provided by the reporter. Patient had no evidence of cardiac disease before. Company comment:This regulatory case concerning a 67-year-old female patient with concurrent medical condition of Epilepsy, who experienced the unexpected serious event of Cardiac death that led to fatal outcome, which occurred 5 days after a dose of mRNA-1273 vaccine (dose number not specified.). Patient died 5 days after the vaccination. The cause of death was reported as unknown. It is unknown if an autopsy was performed. Patient's concurrent medical condition of Epilepsy remains as a confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The event was assessed as serious as per Regulatory Authority´s report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 21-Feb-2022 and was forwarded to Moderna on 21-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of NAUSEA (Nausea), VOMITING (Vomiting), VACCINATION SITE PAIN (Vaccination site pain) and DEATH (Found dead (cause undetermined)) in an 85-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 05-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced NAUSEA (Nausea) (seriousness criterion death), VOMITING (Vomiting) (seriousness criterion death) and VACCINATION SITE PAIN (Vaccination site pain) (seriousness criterion death). The patient died on 06-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided. It was reported that the patient took booster vaccination. The first and second vaccination was with Comirnaty. No treatment medications were provided. Company comment: This case concerns a 85-year-old female patient with no medical history reported, who experienced the unexpected, serious (fatal) events of nausea, vomiting and vaccination site pain the same day after the booster dose of mRNA-1273. The patient was found dead 1 day after vaccine administration,

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	though cause of death is reported as unknown. Interchange of vaccine products, as well as patient's age, could be a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number 4.1(b) [redacted]) on 18-Feb-2022. The most recent information was received on 18-Feb-2022 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 PNEUMONIA (SARS-CoV-2 pneumonia) and VACCINATION FAILURE (Vaccination failure) in a 91-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 091F21A) for COVID-19 vaccination. Co-suspect product included non-company product COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) for SARS-CoV-2 vaccination. The patient's past medical history included Hypertension arterial, Coronary stent user, AFib, Colon cancer and Benign prostatic hyperplasia. Concurrent medical conditions included Ischaemic heart disease, Disease coronary artery, Systolic murmur and Hyperthyroidism. Concomitant products included ATENOLOL and RIVAROXABAN for AFib, FINASTERIDE and ALFUZOSIN HYDROCHLORIDE (ALFUZOSINE UNO) for Disorder urinary tract, PERINDOPRIL and FUROSEMIDE for Hypertension arterial, POTASSIUM CHLORIDE (DIFFU K) for Potassium supplementation. On 25-Mar-2021, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (Intramuscular) 1 dosage form. On 16-Jul-2021, received second dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (VAXZEVRIA) (Intramuscular) dosage was changed to 1 dosage form. On 15-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced COVID-19 PNEUMONIA (SARS-CoV-2 pneumonia) (seriousness criteria death and hospitalization) and VACCINATION FAILURE (Vaccination failure) (seriousness criteria death and hospitalization). The patient died on 17-Jan-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment drug was provided by reporter. COMPANY COMMENT : This is a regulatory authority case concerning a 91-year-old male patient with Hypertension arterial, Ischaemic heart disease, Disease coronary artery, Coronary stent user, AFib and Colon cancer, who had fatal outcome with unexpected serious AESI of COVID-19, which occurred on an unknown day after a dose of mRNA-1273 (third dose of COVID-19 vaccine; previous vaccination with Chadox1 NCOV-19 Aztrazeneca). Vaccination failure was captured as an event as per Regulatory Authority assessment. The patient died on 17-Jan-2022, one month and 2 days after receiving mRNA-1273. Clinical course and treatment details were not provided. It is unknown if an autopsy was performed. Patient´s advanced age and medical conditions remains as confounder for the event and the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 18-Feb-2022: Upon internal review on 24-Feb-2022, significant correction was performed. The seriousness criteria of the event SARS-CoV-2 pneumonia was updated. On 18-Feb-2022: Upon query received from business partner, non-significant correction was performed on 03-Mar-2022. The age and gender of patient was updated from 45-year-old female to 91-year-old male in company comment.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 21-Feb-2022. The most recent information was received on 16-Jun-2022 and was forwarded to Moderna on 16-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of INTRACRANIAL ANEURYSM (medical workers called it a rupture of a brain aneurysm, and it happened exactly 7 days after the 2nd dose of the Moderna vaccine was administered.) in a 71-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 045G21A) for COVID-19 vaccination. No Medical History information was reported. On 03-Jan-2022, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 10-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced INTRACRANIAL ANEURYSM (medical workers called it a rupture of a brain aneurysm, and it happened exactly 7 days after the 2nd dose of the Moderna vaccine was administered.) (seriousness criterion death). The reported cause of death was Aneurysm cerebral. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 27-Jul-2021, Blood cholesterol (0-190): 255 255 milligram. On 27-Jul-2021, Low density lipoprotein: negative (Negative) Negative. On 27-Jul-2021, Red blood cell sedimentation rate (0-15): 16 16 percent. Concomitant medications were not reported. Treatment information was not provided. The patient did not suffer from any illness, did not take medication, was in excellent health and a few months before patient had also done blood tests and dopplers who certified patient's good state of health. Company Comment: This regulatory authority case concerns a 71-year-old old, female patient with no medical history reported who experienced the fatal, unexpected event of Intracranial aneurysm which occurred seven days after receiving the second dose of mRNA-1273 vaccine. There was no information regarding the first dose of COVID-19 immunization. The event was further described as ruptured brain aneurysm. Death occurred on the same day as the event started. The cause of death was reported as cerebral aneurysm. It is unknown if an autopsy was performed. Although patient was reported to be in excellent health with normal blood tests and doppler findings few months prior to the event, body mass index and total cholesterol

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	values were noted to be elevated. Patient´s advanced age is a risk factor for intracranial aneurysm and a confounder for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 16-Jun-2022: Updated lab data result for LDL cholesterol from inconclusive to negative and updated result unit for erythrocyte sedimentation rate.
4.1(b) [redacted]	This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (Intracerebral haemorrhage) in a 71-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch nos. 3002917/ 3003606 and 3002917/ 3003606) for COVID-19 vaccination. The patient's past medical history included Non ST segment elevation myocardial infarction on 31-May-2018. Concurrent medical conditions included Arterial hypertension, Coronary heart disease, Peripheral arterial occlusive disease, Apnea syndrome, Hypercholesteraemia and Gout. Concomitant products included TAMSULOSIN HYDROCHLORIDE (TAMSULOSIN MEPHA), CANDESARTAN, ACETYLSALICYLIC ACID (ASPIRIN CARDIO), ROSUVASTATIN CALCIUM (ROSUVASTATIN MEPHA LACTAB) and PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTOPRAZOL SANDOZ) for an unknown indication. On 23-Jun-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 28-Jul-2021, received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On 12-Aug-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced CEREBRAL HAEMORRHAGE (Intracerebral haemorrhage) (seriousness criteria death, hospitalization, disability and life threatening). The patient died on 20-Aug-2021. It is unknown if an autopsy was performed. Patient was brought to the hospital via ambulance in case of aphaisa, vigilance reduction (GCS 10, over course 6) and hypertensive derailment. Patient had his second vaccine, lot number 3003606, was carried out on 28.07.21. On 12.08.21 Relevant findings: Skull CT: Extensive hypertensive mass hemorrhage in basal ganglia and frontal lobe on the left with ventricle slump in all three ventricles and midline displacement. none demarked infarction areas, no aneurysm, no AVM. On 15.08.21 EEG: none epilepsy potentials, no status epilepticus. On 17.08.21 MRI: ICB left, demarked ischemia, mostly uncal hernia on the left. Diagnosis was Hypertensive basal ganglia hemorrhage in arterial hypertension. Patient was transfer to intensive care unit and single shot of mannitol was administrated, to stabilize Blood pressure and intracranial pressure with drug therapy. In case of persistent. On 17.08.2021 In case of persistently poor neurological status (GCS 7, none sedation), a treatment withdrawal occurred after a detailed consultation of relatives with the aim of organ donation after circulatory arrest in accordance with the suspected patient request. CC: This case concerns a 71-year-old male patient with relevant medical history of non-STEMI, hypertension, coronary artery disease, peripheral arterial occlusive disease and hypercholesterolemia, who experienced serious due to hospitalization, disability and life-threatening, unexpected AESI of cerebral haemorrhage. The event occurred approximately 15 days after the 2nd dose of the mRNA-1273. The patient was hospitalized due to aphasia, vigilance reduction with GCS 10 and hypertensive derailment. The CT showed hypertensive basal ganglia hemorrhage in arterial hypertension. Due to poor neurological status, treatment withdrawal was done and the patient passed away due to the event. The patient's relevant medical history aare possible confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (cause of death unknown) and CARDIAC ARREST (cardiac arrest) in an 83-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216046) for COVID-19 vaccination. Patients pre-existing diseases include heart failure, several myocardial infarctions progressive dementia/patient has been suffering from severe heart failure after multiple myocardial infarctions for years. Progressive dementia was also known. She cared for herself at home with support from nursing staff and was mobile in and around the house. The patient's past medical history included Infarct myocardial. Concurrent medical conditions included Dementia and Cardiac insufficiency. On 28-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 29-Jan-2022, the patient experienced DEATH (cause of death unknown) (seriousness criterion death) and CARDIAC ARREST (cardiac arrest) (seriousness criterion death). The patient died on 29-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. The family doctor performed the vaccination during a home visit and the patient died the following day while walking stairs in the garden because of cardiac arrest. Treatment information was not provided. Company comment: This regulatory authority case concerns a 83-year-old male patient with a relevant medical history of multiple Myocardial infarctions, Cardiac failure and Dementia, who experienced the fatal unexpected events of Cardiac arrest and Death (reported as unknown cause of death), approximately 1 day after receiving a dose mRNA- 1273 vaccine (reported as 3 dosage form) and had a fatal outcome on the same day. The patient died while walking stairs in the garden, as a result of cardiac arrest. Cause of death not further specified. It is unknown if an autopsy was performed. Patient´s age and the mentioned medical history remain a confounder. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report.
4.1(b) [redacted]	This spontaneous case was reported by a physician and describes the occurrence of CARDIO-RESPIRATORY ARREST (State of CPA (cardiopulmonary arrest) (After the third vaccination)) and ACUTE MYOCARDIAL INFARCTION (Suspected acute myocardial infarction (After the third vaccination)) in a 9-decade-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 000009A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Hypertension.

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	On 14-Feb-2022, the patient received third dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) .25 milliliter. On 14-Feb-2022, after starting mRNA-1273 (COVID 19 Vaccine Moderna), the patient experienced PRODUCT STORAGE ERROR (Administration with temperature excursion (After the third vaccination)). On 16-Feb-2022, the patient experienced CARDIO-RESPIRATORY ARREST (State of CPA (cardiopulmonary arrest) (After the third vaccination)) (seriousness criteria death and medically significant). 16-Feb-2022, the patient experienced ACUTE MYOCARDIAL INFARCTION (Suspected acute myocardial infarction (After the third vaccination)) (seriousness criteria death and medically significant). On an unknown date, the patient experienced ANGIOPATHY (Some kind of vascular event (After the third vaccination)). The patient died on 16-Feb-2022. The reported cause of death was state of cpa (cardiopulmonary arrest) and suspected acute myocardial infarction. An autopsy was not performed. At the time of death, ANGIOPATHY (Some kind of vascular event (After the third vaccination)) and PRODUCT STORAGE ERROR (Administration with temperature excursion (After the third vaccination)) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Body temperature: 35.3 degree celsius 35.3 degree Celsius. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered CARDIO-RESPIRATORY ARREST (State of CPA (cardiopulmonary arrest) (After the third vaccination)), ACUTE MYOCARDIAL INFARCTION (Suspected acute myocardial infarction (After the third vaccination)), ANGIOPATHY (Some kind of vascular event (After the third vaccination)) and PRODUCT STORAGE ERROR (Administration with temperature excursion (After the third vaccination)) to be possibly related. Company comment: This is a fatal spontaneous case that concerns an elderly 9-decades-old female patient, with medical history of hypertension, who experienced the serious (due to medically significant and death) unexpected events of cardio-respiratory arrest and acute myocardial infarction, among other non-serious events. She died two days after the third dose of mRNA-1273 vaccine. Details of primary doses was not provided. The cause was suspected as acute myocardial infarction, highly likely that vascular event developed between vaccination and the moment she was found at home in a state of cardiopulmonary arrest. Autopsy was not performed. The history of hypertension remains as a confounder. The reporter stated that there is a temporal relationship with the vaccine. The benefit-risk relationship of the mRNA-1273 is not affected by this report. Reporter's comments: Not reported Most recent FOLLOW-UP information incorporated above includes: On 22-Mar-2022: follow up contains cause of death added, event added.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 21-Feb-2022. The most recent information was received on 06-Apr-2022 and was forwarded to Moderna on 14-Apr-2022. This case was reported by a pharmacist via a medical representative. On 28-Feb-2022, follow-up information was received from a physician. On 06-Apr-2022, follow-up information was received from a physician. On 21-May-2021, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On 11-Jun-2021, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius. On 13-Feb-2022, at 11:00, the patient received the 3rd vaccination with this vaccine. On 16-Feb-2022, around 01:00, dyspnea developed. The patient became unable to move and thus was transported by ambulance. On arrival at the hospital, blood pressure was 142/96 with pulse of 150/min, and SaO2 of 93% (5 L of oxygen via a mask), and the patients consciousness was clear. Based on the results of the lung CT and blood test, exacerbation of interstitial pneumonia and complication of bacterial pneumonia were considered. For aggravation of respiratory status, steroid pulse therapy (methylprednisolone sodium succinate 500 mg) was concomitantly performed in addition to administration of antibiotics (meropenem hydrate). Oxygen was administered at 6 L via a mask. On 17-Feb-2022, the respiratory status gradually improved. Antibiotics (meropenem hydrate) and steroid therapy were continued. Around 20:00, the respiratory status was aggravated. Although 10 L of oxygen was administered via a reservoir mask, there was no improvement in SaO2, which was in the range of 70%. On 18-Feb-2022, the respiratory status gradually worsened. At 08:44, the patient died. The cause of death was pneumonia. No autopsy was performed. The outcome of dyspnea, bacterial pneumonia, and exacerbation of interstitial pneumonia was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: Since exacerbation of interstitial pneumonia is possible, the occurrence of adverse events is associated with pathological factors of interstitial pneumonia and cardiac failure. Since interstitial pneumonia may have been aggravated by administration of this vaccine, there was a relationship between the cause of death and adverse events. Since dyspnea occurred within 3 days after vaccination with this vaccine, it is possible that the vaccine contributed to the exacerbation of interstitial pneumonia. Follow-up received on 28-FEB-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative Follow-up received on 06-APR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Interstitial lung disease developed after administration of ELASOMERAN, but it may also be affected by concurrent condition. Also, pneumonia bacterial developed after administration of ELASOMERAN, but it is possible that it was an incidental occurrence. Also, dyspnoea developed after administration of ELASOMERAN, but it may also be affected by intercurrent event.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 21-Feb-2022. The most recent information was received on 15-Mar-2022 and was forwarded to Moderna on 23-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a (physician), was received via the PMDA (Ref, 4.1(b)). On 15-Mar-2022, follow-up information was received from a physician. Arteriosclerosis of the base of the brain and hyperkalaemia was assessed as serious by the MAH. The vaccine recipient had a history of treatment for left brain infarction two years ago. The patient was under treatment with edoxaban tosilate hydrate as anticoagulant agent, but no cardiac disease had been found. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (unknown product name). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (unknown product name). On 18-Feb-2022, around 15:00, the patient received the 3rd vaccination with this vaccine. The patient had no symptoms on the day of the vaccination. On 19-Feb-2022, during the day, the patient complained of mild malaise. Around 17:00, the family member confirmed that the patient was alive. Around 18:30, the patient took a bath. The patient experienced thrombosis with thrombocytopenia. Around 19:25, the family member found the patient in a cardio-respiratory arrest state in the bathtub. An ambulance call was made, and cardiopulmonary resuscitation was performed by the family member. Around 19:40, an ambulance team confirmed that the patient was in asystole. Resuscitative measures were taken. Around 20:30, the patient arrived at a hospital. At 21:01, the patient continued to be in asystole status. Blood sampling and other tests revealed thrombocytopenia, elevated D-dimer, hepatic function disorder, hyperkalaemia, and acidosis. Resuscitation was judged to be difficult, and the patient was confirmed dead. The cause of death was near drowning. Autopsy imaging did not show cerebral hemorrhage and new-onset cerebral infarction. No appreciable findings were obtained except for the findings which could be considered as changes after death or cardiopulmonary resuscitation including gases in the hepatic portal. It cannot be ruled out that the patient experienced ischemic cerebral infarction or brain-stem infarction caused by disseminated intravascular coagulation syndrome or thrombus. On an unknown date, an autopsy was performed. The left lung weighed 320 g and the right lung weighed 506 g. Intrabronchial foam, pleural effusions, and arteriosclerosis of the base of the brain were seen. The outcome of thrombosis with thrombocytopenia, cardio-respiratory arrest, possibility of disseminated intravascular coagulation syndrome, possibility of ischemic cerebral infarction, possibility of brain-stem infarction, and near drowning

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	was reported as fatal. The outcome of malaise, hepatic function disorder, hyperkalaemia, acidosis, pleural effusions, and arteriosclerosis of the base of the brain was unknown. No follow-up investigation will be made. Reporter's comment: At present, the cause of death is unknown, and a judicial autopsy was conducted to consider the possibility of abnormal death while taking a bath. Acute cardiac death and choking death due to aspiration may be other possible factorsThe relationship between the cause of death and the adverse events is under forensic investigation. Looking back over the interview with the family members, it is difficult to believe that the patient had chronic thrombocytopenia of up to 57,000, even though the patient was seen by the nearby primary physician for underlying diseases. Although platelet decrease can be caused by a variety of factors, it was too soon to cause drug-induced platelet decrease. There was no bleeding, and unless the patient originally had idiopathic thrombocytopenic purpura, it is reasonable to consider that disseminated intravascular coagulation syndrome would have occurred. It is unclear whether a sudden decrease in platelet count may occur as a postmortem change; however, if blood clots were formed in association with immune response following administration of this vaccine on the previous day, the occurrence of adverse events may be temporally related to and the timing of administration of this vaccine. Since concomitant drugs have been used without change in the past and are unlikely to be associated with acute diseases such as platelet decrease, thrombus formation, and cerebral infarction, the occurrence of adverse events is not associated with concomitant drugs. Atherosclerosis can be considered as one of the factors of the development of cerebral infarction. Narrowing of the vessel lumen due to the atherosclerosis increases the risk of occlusion when a thrombus is produced; therefore, it is difficult to consider that the events in this case were not related to the pathological factors of the underlying old cerebral infarction. This case is currently being analyzed by the forensic medicine course of a medical institution after the autopsy was performed, and the causal relationship between vaccination with this vaccine and death is under investigation with forensic medicine. Therefore, nothing definitive can be said at this time. At the time of the initial diagnosis, cerebral hemorrhage or cerebral infarction was considered based on the patient's history, but autopsy imaging revealed no cerebral hemorrhage. In addition, because the changes were noted about three hours after the patient was found in cardio-respiratory arrest, no CT imaging changes suggesting cerebral infarction were observed. It is notable that no increase in the shadow of asymptomatic cerebral infarction was observed compared to the CT image at the time of previous cerebral infarction several years earlier. Anticoagulants were taken, and the daily life was considered to have been appropriately controlled. Thus, if a cerebral infarction accidentally occurred near the brain stem on the day after the vaccination, it must have been a rather unfortunate situation. In addition, platelet decrease, elevated D-dimer, and hepatic function disorder may occur even as changes after death, but the time for the changes were too brief. It seemed more reasonable to assume that the onset had begun several hours before the time of near drowning based on the test values. It is regrettable that treatments could not have been given when the patient complained of malaise. However, at the daytime of the day following the administration, thrombosis was caused by a mechanism similar to disseminated intravascular coagulation syndrome, and ischaemic enterocolitis and hepatic function disorder due to intrahepatic vascular occlusion developed gradually. Eventually, thrombosis developed within the basilar arteriosclerosis when the patient was taking a bath, resulting in cerebral infarction. The possibility that the patient had difficulty moving and experienced near drowning cannot be ruled out. Although there is no clue of examination that would raise the possibility of this hypothesis, it is desirable, in this case, to avoid concluding easily that a coincidental event developed. It is hoped that investigation with forensic medicine will clarify whether or not there was a causal relationship. Follow-up received on 15-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments LP Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship. Company comment: This spontaneous case report concerns a 77-year-old female patient with relevant medical history of previous cerebral infarction, who experienced serious unexpected events of Thrombosis with thrombocytopenia syndrome, Cardiorespiratory arrest, Disseminated intravascular coagulation, Ischaemic cerebral infarction, Brain stem infarction and Near drowning which ended with fatal outcome. In addition, the patient also experienced serious unexpected events of Hyperkalaemia and Cerebral arteriosclerosis, as well as non-serious unex
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b)) on 21-Feb-2022 and was forwarded to Moderna on 24-Feb-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by (a vaccination venue manager), was received via the PMDA (Ref, 4.1(b)). The patient was under treatment with oral medication for diabetes mellitus, hypertension, and prostatism, with concomitant use of insulin self-injection for diabetes mellitus. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On an unknown date, body temperature before vaccination: 36.4 degrees Celsius. On 10-Feb-2022, at 14:25, the patient received the 3rd vaccination with this vaccine. After the vaccination, there were no complaints from the patient. At the end of the observation of the patient's condition after vaccination, the vaccination staff watched the condition of the patient just in case, and it was found and reported to the physician that the patient had an ill complexion with a pulse oximeter reading of 90%. Since signs of cardiac failure were noted, the primary physician got contacted, and the patient was instructed to take a cab for a visit to the hospital. The patient was hospitalized. On 18-Feb-2022, the patient died. The outcome of suspected cardiac failure and ill complexion was unknown. Follow-up investigation will be made. Reporter comments continuation: There were no complaints from the patients in the post-vaccination observation. At the end of the 15-minute observation, the observer noticed that the patient's facial color was not good, so Sp02 was measured just in case, which showed 90%, and it was reported to the physician. The physician suspected worsening of cardiac failure and made a request to the hospital for medical examination after confirming the patient's primary physician, and the patient was ordered to take a cab to the hospital. Based on this series of events, it is unlikely that this incident was caused by vaccination with this vaccine. Congestive cardiac failure was suspected as another factor. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 22-Feb-2022 and was forwarded to Moderna on 22-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 PNEUMONIA (COVID-19 pneumonia) in an 85-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Hypertension and COVID-19 pneumonia on 14-Apr-2021. On 06-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 20-Apr-2021, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death and hospitalization). The patient died on 20-Apr-2021. The reported cause of death was COVID-19 pneumonia. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Apr-2021, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments.

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	Concomitant medications were not provided. It was reported that the patient died due to COVID-19 pneumonia 14 days after vaccination with Spikevax. Treatment information was not provided. Company comment: This case concerns an 85-year-old female patient who developed serious, unexpected COVID-19 PNEUMONIA approximately 14 days after the first dose of mRNA-1273. It was reported that the patient died due to COVID-19 pneumonia 14 days after vaccination. The reported cause of death was COVID-19 pneumonia. An autopsy was not performed. Based on the current available information, the mRNA-1273 vaccine does not contain a virus capable of causing COVID-19 infection after vaccination, therefore, the causality for COVID-19 is not applicable. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.
4.1(b) [redacted]	This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Death) and CHEST PAIN (Chest pain aggravated) in an 84-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005704) for COVID-19 vaccination. Co-suspect product included non-company product DARBEPOETIN ALFA (ARANESP) for an unknown indication. Concurrent medical conditions included Cardiomyopathy and Myelodysplastic syndrome. Concomitant products included ACETYLSALICYLIC ACID (ASPIRIN CARDIO), CANDESARTAN (CANDESARTANUM), METOPROLOL SUCCINATE (BELOC ZOK), LERCANIDIPINE HYDROCHLORIDE (ZANIDIP), TORASEMIDE, AMIODARONE HYDROCHLORIDE (CORDARONE), LEVOTHYROXINE SODIUM (EUTHYROX), PANTOPRAZOLE and LACIDIPINE (SINOPIL) for an unknown indication. On 06-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form and DARBEPOETIN ALFA (ARANESP) (unknown route) at an unspecified dose. On 07-Jan-2022, the patient experienced CHEST PAIN (Chest pain aggravated) (seriousness criteria death and hospitalization). The patient died on 14-Jan-2022. It is unknown if an autopsy was performed. The medical history included Heart surgery 2018. Report to a patient who died at the age of 84 on 14.01.22. In advance, the 1st Covid-19 mRNA vaccination with Spikevax (formerly COVID-19 Vaccine Moderna) took place on 06.01.22. According to information given by daughter data related to the result arose one day after vaccination, from 07.01.22, burning chest pain which intensified with light exertion or excitement. This pain was progressively worsening and led to emergency hospitalization via ambulance on 14.01.22. Arrived at the center hospital, the patient died a short time later. Due to a myelodysplastic syndrome, he was under therapy with the epoetin darbepoetin alfa, the last administration was at the same time as the vaccination on 06.01.22. Co-medication also included Nopil Forte and Sinopil with the ingredients Sulfamethoxazole of 800mg and Trimethoprim 160 mg. This patient experienced progressive burning chest pain one day after the first vaccination with Spikevax which was severely aggravated during physical exertion. The patient died 8 days after COVID-19 vaccination. As far as it can be determined, none autoptic determination of the cause of death was made in this case. There was none further information regarding possible clinical causes or diagnostic investigations of the exitus lethal. Company comment- This regulatory authority case concerns an 84-year-old male patient with relevant medical history of Cardiomyopathy and Myelodysplastic syndrome and concurrent use of darbepoetin alfa, who experienced serious unexpected events of chest pain and death. The chest pain occurred 1 day after the 1st dose of the mRNA-1273 whereas the patient passed away 7 days post-vaccination. Reportedly, the patient was hospitalized due to burning chest pain that intensified on light exertion or excitement. The patient progressively worsened and the patient was hospitalized. Following hospitalization, the patient passed away. The patient's advanced age and relevant medical history are possible confounders. The use of darbepoetin alfa is an additional confounder due to known increased risk for death in patients treated with this medication. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 17-Feb-2022 and was forwarded to Moderna on 17-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CORONARY ARTERY DISEASE (multiple blockage of coronary arteries) in a 68-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 18-Aug-2021, the patient experienced CORONARY ARTERY DISEASE (multiple blockage of coronary arteries) (seriousness criteria death, hospitalization and life threatening). On an unknown date, the patient experienced DYSPNOEA (shortness of breath) and VISUAL IMPAIRMENT (vision deterioration). The patient died on 23-Aug-2021. It is unknown if an autopsy was performed. At the time of death, DYSPNOEA (shortness of breath) and VISUAL IMPAIRMENT (vision deterioration) outcome was unknown. Concomitant medications were not provided by the reporter. Treatment information was not provided. Company comment: This regulatory case concerns a 68-year-old, elderly female patient with no medical history reported who experienced fatal unexpected event of Coronary artery disease, 3 weeks after receiving second dose of mRNA-1273 Vaccine. It is unknown whether an autopsy was performed. Elderly age of the patient could be a risk factor for the event and the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 23-Feb-2022 and was forwarded to Moderna on 23-Feb-2022.

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	This regulatory authority case was reported by a physician and describes the occurrence of CONDITION AGGRAVATED (Condition worsened), DECREASED APPETITE (Appetite lost), WEIGHT DECREASED (Weight loss) and VOMITING (Vomiting) in an 81-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004235) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Prophylactic vaccination. Previously administered products included for COVID-19 vaccination: COMIRNATY on 29-Apr-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY. On 10-Jun-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (unknown route) 2 dosage form. On 06-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In August 2021, the patient experienced DECREASED APPETITE (Appetite lost) (seriousness criterion death), WEIGHT DECREASED (Weight loss) (seriousness criterion death) and VOMITING (Vomiting) (seriousness criterion death). In October 2021, the patient experienced CONDITION AGGRAVATED (Condition worsened) (seriousness criterion death). The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. Comirnaty strength was 0.3 millilitre. The patient received Spikevax booster vaccination. Date of death was not reported. No treatment information was reported.
4.1(b) [redacted]	This spontaneous case was reported by a consumer and describes the occurrence of DEATH (he passed away) and DYSPNOEA (he passed away on Dec 17 2021 with continued symptoms of breathing difficulties/not be able to breath) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 029A21A and 007M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Low pulse rate in 2015, Hospitalization from 24-Feb-2021 to 02-Mar-2021, Thrombosis leg, Thrombosis pulmonary, Lung opacity, Dyspnoea and Pacemaker insertion (cardiac) (pacemaker prior to vaccination). Previously administered products included for Drug use for unknown indication: Flu shot (Flu shot in 2020 (Sept/Oct)) in 2020. Past adverse reactions to the above products included No adverse event with Flu shot. Concurrent medical conditions included Seasonal allergy. Concomitant products included ACETYLSALICYLIC ACID (BABY ASPIRIN), PREDNISONE, APIXABAN (ELIQUIS) and OMEPRAZOLE for an unknown indication. On 28-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 05-Mar-2021, the patient experienced INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Received first Modena vaccine on Jan 28, 2021 and second COVID vaccine on March 05, 2021). On an unknown date, the patient experienced DYSPNOEA (he passed away on Dec 17 2021 with continued symptoms of breathing difficulties/not be able to breath) (seriousness criterion medically significant) and GAIT DISTURBANCE (He could not walk the distance of the halls of the house). The patient died on 17-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, DYSPNOEA (he passed away on Dec 17 2021 with continued symptoms of breathing difficulties/not be able to breath) had not resolved and GAIT DISTURBANCE (He could not walk the distance of the halls of the house) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Received first Modena vaccine on Jan 28, 2021 and second COVID vaccine on March 05, 2021) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No history of blood clots and no consistent medical problems until the vaccination. He was able to do most anything that he wanted to do and no history of COVID.Concomitants medications includes water pill. For concomitant medication Eliquis reporter was unsure if taking at the time.It was reported that at the encouragement of his family doctor he received a second COVID vaccine. He did not get a booster and a third one. Patient placed on a blood thinner in Feb- 2021 and remained on it until time of death.Received Modena vaccine on Jan 28, 2021.Went to PCP on Feb 24, 2021 first for breathing difficulties, they sent him to the hospital.Admitted to hospital on Feb 24 2021. They found blood clots in legs and lungs. Caller states hospital said patients lungs looked like chards of glass. Caller states her husband had no history of blood clots. He continued to have problems with breathing that they(HCPs) felt could have been a clot interfering with his breathing. Dischar March 02, 2021. CC This spontaneous fatal case concerns a 75-year-old male patient, with medical history of hospitalization because of blood clots in legs and lungs, dyspnea and lung opacity approximately 9 months prior to death (and 28 days after receiving the first dose of mRNA-1273 vaccine), dyspnea remaining after hospitalization, and Pacemaker insertion prior to vaccination, who experienced the unexpected serious events of DEATH and dyspnoea. Death occurred approximately 9 months and 12 days after receiving second dose of mRNA-1273 vaccine. Patient passed away on Dec 17 2021 with continued symptoms of breathing difficulties. He could not walk the distance of the halls of the house and be able to breath. The cause of death was not reported. It is unknown if an autopsy was performed. The mentioned medical history remains as a confounder. INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION was considered as an additional event. The benefit-risk relationship of mRNA-1273 is not affected by this report. This case was linked to 4.1(b) [redacted] (Patient Link).
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 23-Feb-2022 and was forwarded to Moderna on 23-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (cause of death unknown) in an 87-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004494) for COVID-19 vaccination. Concurrent medical conditions included Arterial hypertension. On 03-Feb-2022, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 06-Feb-2022 The patient died on 06-Feb-2022. The cause of death was not reported. It is unknown if an autopsy was performed.

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	For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided. No information on risk factors or pre-existing illnesses art. It was reported that Hypertorus/Pat found dead in bed in the morning. No treatment information was provided. This is a regulatory authority case concerning a 87-year-old, female patient with concurrent medical condition of Arterial hypertension, who experienced the unexpected fatal event of Death. The event occurred 3 days after the first dose of mRNA-1273 COVID 19 Vaccine. The cause of death was not reported. Autopsy was unknown if it was performed. The concurrent medical condition of Arterial hypertension remains a confounder for the event of Death. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number 4.1(b)) on 23-Feb-2022 and was forwarded to Moderna on 23-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of FALL (Falls), PAIN (Generalized pain), BACK PAIN (Back pain), CARDIAC DEATH (Cardiac death), DYSPNOEA (Dyspnoe) and SYNCOPE (Syncope) in a 73-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Alzheimer's disease (incipient dementia), COPD, Cachexia and Hypertension. Concomitant products included POTASSIUM CHLORIDE (KALNORMIN), BISOPROLOL FUMARATE (CONCOR), CALCIUM CARBONATE, COLECALCIFEROL, COPPER SULFATE, MAGNESIUM OXIDE, MANGANESE SULFATE, ZINC OXIDE (CALTRATE MINI CALS), AMLODIPINE BESILATE (AGEN), PERINDOPRIL ARGININE (PRESTARIUM A) and PANTOPRAZOLE SODIUM SESQUIHYDRATE (CONTROLOC) for an unknown indication. On 27-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Subcutaneous) 1 dosage form. On 17-Jan-2022, the patient experienced FALL (Falls) (seriousness criterion medically significant), PAIN (Generalized pain) (seriousness criterion medically significant), BACK PAIN (Back pain) (seriousness criterion medically significant), CARDIAC DEATH (Cardiac death) (seriousness criteria death and medically significant), DYSPNOEA (Dyspnoe) (seriousness criterion medically significant), SYNCOPE (Syncope) (seriousness criteria medically significant and life threatening) and ASTHENIA (Weakness). The patient died on 17-Jan-2022. The reported cause of death was Cardiac failure. An autopsy was not performed. At the time of death, FALL (Falls) and BACK PAIN (Back pain) outcome was unknown and PAIN (Generalized pain), DYSPNOEA (Dyspnoe), SYNCOPE (Syncope) and ASTHENIA (Weakness) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 17-Jan-2022, Chest X-ray: no signs of pneumothorax. pulmonary parenchyma is (normal) No signs of pneumothorax. pulmonary parenchyma is without focal changes. Heart contour is of normal size, mediastinum slim, without deviation. The diaphragm is segmented, the aorta is of normal shape. Conclusion - no signs of skeletal trauma or intrathoracic trauma.. For mRNA-1273 (Spikevax) (Subcutaneous), the reporter did not provide any causality assessments. No treatment information was reported. This is a fatal case concerning a 73-year-old female patient with medical conditions of Alzheimer's disease, COPD, Cachexia and Hypertension, who experienced the unexpected serious events of Fall, Pain, Back Pain, Cardiac Death, Dyspnea, and Syncope. The events were medically significant, life-threatening, and led to the eventual demise of the patient as reported by the regulatory authority. The events occurred in 21 days after receiving an unspecified dose of mRNA-1273 Vaccine. Chest X-ray results showed no signs of skeletal trauma or intrathoracic trauma, no other clinical or treatment details were given. The patient died on the onset date of events. The reported cause of death was Cardiac failure. An autopsy was not performed. The medical history of Alzheimer's disease, COPD, Cachexia and Hypertension remains a confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 23-Feb-2022. The most recent information was received on 05-May-2022 and was forwarded to Moderna on 05-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and DRUG INEFFECTIVE (Drug ineffective) in a 66-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214022) for COVID-19 vaccination. Co-suspect products included non-company products CASIRIVIMAB, IMDEVIMAB (RONAPREVE) for COVID-19 prophylaxis, TOZINAMERAN (COMIRNATY) for COVID-19 vaccination, OBINUTUZUMAB (GAZYVARO) for Non-Hodgkin's lymphoma and LENALIDOMIDE (REVLIMID) for Non-Hodgkin's lymphoma. Concurrent medical conditions included Linea alba hernia in 1986, Non-Hodgkin's lymphoma in March 2017, Psoriasis, Hypercholesterolaemia, Cyst, Carpal tunnel syndrome, Maxillary sinusitis, Aortic incompetence in May 2021 and Tendinopathy. On 16-Feb-2021, the patient started OBINUTUZUMAB (GAZYVARO) (Oral) 1000 milligram. On 10-Mar-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 07-Apr-2021, received second dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to 1 dosage form. On 13-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 27-Sep-2021, the patient started LENALIDOMIDE (REVLIMID) (Oral) 20 milligram. On 25-Oct-2021, the patient started CASIRIVIMAB, IMDEVIMAB (RONAPREVE) (Intravenous) 600 milligram. On an unknown date, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). an unknown date, the patient experienced DRUG INEFFECTIVE (Drug ineffective) (seriousness criterion death). The reported cause of death was Drug ineffective and Vaccination failure. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive.

Case ID	Narrative (Complete)
	For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Treatment information was not provided. Dosage text given as R1. Company comment: This is a Vaccination failure Regulatory Authority case concerning a 66-year-old male patient, with relevant medical history of non-Hodgkin´s lymphoma and aortic incompetence. Patient died 106 days after a dose of mRNA-1273 vaccine. The reported cause of death was Drug ineffective and Vaccination failure. It is unknown if an autopsy was performed. SARS-CoV-2 test with positive result was reported approximately 3 months and 20 days after mRNA-1273 vaccine. Medical history of non-Hodgkin´s lymphoma and aortic incompetence could be confounders for the fatal outcome. Co-suspect products included non-company products: Casirivimab, Imdevimab, Obinutuzumab and Lenalidomide. Primary vaccination completed with Pfizer vaccine, which remains as a co-suspect product. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 05-May-2022: Follow Up received with significant information as Co-suspect drug added.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 22-Feb-2022. The most recent information was received on 15-Mar-2022 and was forwarded to Moderna on 23-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by an anatomist, was received via the PMDA (Ref, 4.1(b)). On 04-Mar-2022, follow-up information reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by an anatomist, was received via the PMDA (Ref, 4.1(b)). On 15-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.1 degrees Celsius. On 17-Feb-2022, at 13:30, the patient received the 3rd vaccination with this vaccine. The patient returned home after the vaccination, and there were no complaints of physical deconditioning or others. On 18-Feb-2022, around 17:00, the patient ate dinner. Around 17:45, the patient talked on the telephone. The living situation of the patient thereafter was unknown. Around 18:00, the patient experienced near drowning while taking a bath. It was presumed that she died. On 19-Feb-2022, at 07:30, a family member found the patient submerged in the bathtub. On 21-Feb-2022, the patient died. At an autopsy, there were swelling and pleural effusion retention in the right and left lungs and a large amount of fluid in the stomach, which were consistent with near drowning. On the other hand, there was no organic disease leading to near drowning. The cause of death was near drowning. The outcome of near drowning during bathing was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: There was no temporal relationship between the occurrence of the adverse event and the time of administration of this vaccine. The occurrence of the adverse event is not associated with concomitant drugs. There is no relationship between the occurrence of the adverse event and pathological factors such as underlying diseases and complications. Organic disease leading to drowning was absent. Abnormal deaths occurred other than this case, and therefore this case cannot be evaluated alone. The relationship between cause of death and the adverse event is unknown. Follow-up received on 04-MAR-2022 Updated: Event Information, Narrative Follow-up received on 15-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Drowning can be also considered as an accidental disease although it developed after the administration of ELASOMERAN.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b)) on 21-Feb-2022. The most recent information was received on 25-Mar-2022 and was forwarded to Moderna on 30-Mar-2022. This case was presented in "The 673rd Kanto Regional Meeting of the Japanese Society of Internal Medicine". Since the proprietary name of the suspect drug was not specified, the drug is handled as a Takeda product in this case report. Pancytopenia, bilateral pneumonia, function kidney decreased, septic shock, multi-organ failure, and acute circulatory failure were assessed as serious by the MAH. Follow-up information revealed that ELASOMERAN (product name: "COMIRNATY intramuscular injection") was not a Takeda product. A 79-year-old female patient. [History of present illness] The patient visited with chief complaint of difficulty retention sitting to our reporting hospital. Since subcutaneous haemorrhage in right occipital lobe and bilateral subdural haemorrhage were noted, the patient was admitted to the brain surgery department of the hospital. [Clinical courses] Covid-19 vaccine (proprietary name unknown) was vaccinated 14 days after the hospitalization following the states were stabilized. The patient experienced pyrexia in the night of the same day. The patient had been on the treatments for urinary tract infection, but general condition was aggravated. Therefore, the patient was transferred to this department. Bilateral pneumonia on the imaging, decreased kidney and hepatic functions, pancytopenia, new cerebral haemorrhage were noted. Fourth day of the onset, the patient was monitored on ventilator. Although the patient had been on the treatments for multi-organ failure, acute circulatory failure caused by septic shock, she died on the same day. After obtaining the family's agreement, pathologic autopsy was performed. Direct cause of the death was cerebral haemorrhage, but pancytopenia caused by covid-19 vaccination adverse reaction was suggested in pathological findings. Follow-up investigation will be made. Follow-up received on 25-MAR-2022 Updated: Narrative Company Comment: The events developed after the administration of elasomeran and there is temporal relationship.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 22-Feb-2022. The most recent information was received on 17-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 17-Mar-2022, follow-up information was received from a physician. The vaccine recipient had a history of cerebral infarction and was being followed up for hypertension at the time of the medical examination. The patient did not receive any medical treatment such as oral medication. On 14-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 05-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 35.7 degrees Celsius. On 21-Feb-2022, around 11:00, the patient received the 3rd vaccination with this vaccine. On 22-Feb-2022, at 00:30, the patient was found lying face down at home. AED was used, but the patient had no response. The patient was transported by ambulance. At 01:10, the patient was in a state of cardio-respiratory arrest. At 02:29, the patient was confirmed dead at the same hospital. Bruise on the head and epistaxis were noted. Autopsy was not performed. The outcome of cardio-respiratory arrest was reported as fatal. The outcome of bruise on the head and epistaxis was unknown. No follow-up investigation will be made. Follow-up received on 17-MAR-2022 Updated: Reporter Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 22-Feb-2022. The most recent information was received on 11-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician was received via the PMDA (Ref, 4.1(b)). On 11-Mar-2022, additional information was received from a physician. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On 18-Feb-2022, the patient received the 3rd vaccination with this vaccine. On 19-Feb-2022, in the daytime, pyrexia of 38s degrees Celsius developed. After returning home, the patient took acetaminophen orally. Subsequently, the fever subsided. On an unknown date, anorexia was noted. On 20-Feb-

Case ID	Narrative (Complete)
	2022, pyrexia of 37s degrees Celsius was observed, and the patient took acetaminophen orally. The patient only drank water and had a light meal. On 21-Feb-2022, around 07:00, the patient defecated. At 07:15, the patient was encouraged to drink water. Around 08:00, it was found that the patient was unconscious when being moved to a wheelchair. Therefore, an ambulance call was made. When the ambulance team arrived, cardiopulmonary resuscitation was performed with cardio-pulmonary arrest. The patient was transported to a hospital. Although cardiopulmonary resuscitation was conducted about an hour, the patient remained to be in a state of cardiopulmonary arrest. The patient was already dead at the time of arrival at the hospital. Around 09:10, the patient was confirmed dead. No autopsy was performed. There was a possibility of the recurrence of myocardial infarction. The outcome of pyrexia, anorexia, unconsciousness, and possibility of the recurrence of myocardial infarction was unknown. The outcome of cardio-pulmonary arrest was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The association between the cause of death and the adverse events is unknown, but the possibility cannot be ruled out. Since the possibility cannot be ruled out, the occurrence of adverse events is temporally related to the timing of administration of this vaccine. The occurrence of adverse events is not associated with concomitant drugs because the drugs were regular medication for the patient and were unlikely to be related. It cannot be ruled out that the occurrence of adverse events may have been related to the pathophysiological factors of myocardial infarction and cardiac failure After the vaccination, the patient experienced pyrexia, anorexia, and dehydration; therefore, the possibility of hypercoagulability cannot be ruled out and the possibility of the recurrence of myocardial infarction can be considered. However, blood tests were not performed, and thus the details are unknown. Follow-up received on 11-MAR-2022 Updated: Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Although the event of myocardial infarction developed after the administration of ELASOMERAN, preexisting conditions are also considered to have affected the event. Although the event of cardio-respiratory arrest developed after the administration of ELASOMERAN, it is possible that a concurrent event may have affected the event.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 24-Feb-2022. The most recent information was received on 14-Mar-2022 and was forwarded to Moderna on 22-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a pharmacist, was received via the PMDA (Ref, 4.1(b)). On 14-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 17-Feb-2022, the patient received the 3rd dose of this vaccine. On 18-Feb-2022, at 18:30, it was the last time when the patient was confirmed healthy. Around 19:00, lethal arrythmia developed. A family member found the patient taking a bath and called an ambulance. When the ambulance team made contact, the patient was in a state of cardio-respiratory arrest. The initial waveform was asystole. At 19:40, the patient entered the emergency outpatient department of the reporting hospital. At 19:48, adrenaline 1 mg/mL was injected intravenously. At 19:52, adrenaline 1 mg/mL was injected intravenously. At 19:57, adrenaline 1 mg/mL was injected intravenously. At 20:00, adrenaline 1 mg/mL was injected intravenously. At 20:03, adrenaline 1 mg/mL was injected intravenously. At 20:06, adrenaline 1 mg/mL was injected intravenously. At 20:10, adrenaline 1 mg/mL was injected intravenously. Though intravenous injections were carried out seven times in total, the spontaneous circulation was not returned. At 20:11, death was pronounced. At 20:24, the obvious cause of death could not be indicated in diagnostic imaging CT at the time of death. At 20:41, an autopsy was performed. According to the postmortem certificate, the cause of death was lethal arrhythmia, and the time from onset to death was short. No autopsy was performed. The outcome of lethal arrythmia and cardio-respiratory arrest (CPA) was reported as fatal. No follow-up investigation will be made. Follow-up received on 14-MAR-2022 Updated: Other Relevant History, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of DEATH (death, slow death) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEATH (death, slow death) (seriousness criteria death and medically significant), TREMOR (tremors in his hands), NEUROLOGICAL SYMPTOM (neurological symptoms) and SPEECH DISORDER (could barely get the words out). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, TREMOR (tremors in his hands), NEUROLOGICAL SYMPTOM (neurological symptoms) and SPEECH DISORDER (could barely get the words out) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant medication was not provided. Treatment medication information was not provided by the reporter. It was mentioned that they kept sedating him and prevent her from seeing him, she watched him dying and mentioned it was traumatic something was up. Because of the symptoms HCPs didn't recognized it was related to the vaccine, slow death, happened in few months Company comment This spontaneous fatal case concerns a 75-year-old male patient, with no reported medical history, who experienced the unexpected serious fatal event of DEATH, and the non-serious events of TREMOR, NEUROLOGICAL SYMPTOM and SPEECH DISORDER. Onset date of the events were not provided nor vaccination date or schedule; hence, latency cannot be assessed. The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. Reporter stated that her father died because of the vaccine, he had tremors in his hands, neurological symptoms and then it went down hill, that they kept sedating him and prevent her from seeing him, she watched him dying and mentioned it was traumatic something was up. Because of the symptoms HCPs didn't recognize it was related to the vaccine, slow death, happened in few months. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 24-Feb-2022: Non Significant follow up (No new information received) On 25-Feb-2022: Follow up information included no new information
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 25-Feb-2022 and was forwarded to Moderna on 25-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (Lung embolism), RESUSCITATION (Resuscitation) and THROMBOPHLEBITIS (Thrombophlebitis) in a 67-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Smoker and Infection NOS.

Case ID	Narrative (Complete)
	On 28-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Feb-2022, the patient experienced PULMONARY EMBOLISM (Lung embolism) (seriousness criterion death), RESUSCITATION (Resuscitation) (seriousness criterion death) and THROMBOPHLEBITIS (Thrombophlebitis) (seriousness criterion death). The patient died on 09-Feb-2022. The reported cause of death was Lung embolism. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Patient had no previous history of cardiopulmonary diseases. No concomitant medications were reported. No treatment drug details were reported. COMPANY COMMENT : This regulatory authority case concerns a 67-years-old, male patient with concurrent medical history of smoking, who had fatal outcome with unexpected serious AESI event of pulmonary embolism, resuscitation, thrombophlebitis (seriousness criterion death), which occurred 1 month 12 days after third dose of mRNA-1273 vaccine administration. The patient died on 09-Feb-2022. The reported cause of death was Lung embolism. It is unknown if an autopsy was performed. Patients concurrent medical condition of smoking remains as confounding. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events were assessed as serious as per Regulatory Authority´s report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 24-Feb-2022. The most recent information was received on 17-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 17-Mar-2022, follow-up information was received from a physician. The patient made regular visits to another hospital for diabetes mellitus, hypertension, and late effects of cerebral infarction. On 27-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 18-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 15-Feb-2022, the patient made a regular visit to a hospital. There were no particular abnormalities. On 17-Feb-2022, the patient did not have dinner due to physical deconditioning. There were no symptoms such as pyrexia. On 18-Feb-2022, the patient had a light meal. On 20-Feb-2022, the patient received the 3rd vaccination with this vaccine. At night, the patient had poriomania. On 21-Feb-2022, in the morning, the family member confirmed traumatic injury on the head and right lower leg. The patient had no particular symptoms until around noon. After 18:00, the patient was sitting leaning against the bed and did not respond to calls. At 18:31, an ambulance was called. At 18:44, the ambulance team arrived and confirmed the patient's cardio-respiratory arrest. Cardiopulmonary resuscitation was started for asystole, and the patient was transported to the reporting hospital. Administration of adrenaline 2A was performed. At 19:03, the patient was race to the reporting hospital. The patient made an initial visit to the reporting hospital. The patient remained in the asystole state. A total of 8A of adrenaline was used every three minutes, and cardiopulmonary resuscitation was performed, but waveforms did not change. There was no return of spontaneous circulation. At 19:39, the patient was confirmed dead. Postmortem diagnostic imaging was performed by CT. There were no obvious causes in the head or thoracoabdominal region. Blood sampling failed to identify the cause of death, and as a result of autopsy by the police, it was determined that there was no extrinsic factor, and the cause of death was determined as intrinsic cardiac death. There was a possibility of thrombosis or myocardial infarction due to high D-dimer levels. The outcome of poriomania and traumatic injury on the head and right lower leg was unknown. The outcome of asystole, possibility of thrombosis, and possibility of myocardial infarction was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The causality with this vaccine cannot be ruled out. The possibility of thrombosis or myocardial infarction from high D-dimer levels and other factors and the influence of diabetes mellitus from hyperglycaemia are considered. The relationship between cause of death and adverse events is unknown. Follow-up received on 17-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Although the event of thrombosis and myocardial infarction developed after the administration of ELASOMERAN, preexisting conditions are also considered to have affected the event.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 24-Feb-2022. The most recent information was received on 27-Mar-2022 and was forwarded to Moderna on 04-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 27-Mar-2022, follow-up information, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b)) . On 28-Mar-2022, follow-up information, reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 16-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 07-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.1 degrees Celsius. On 07-Feb-2022, at 16:30, the patient received the 3rd vaccination with this vaccine. On 08-Feb-2022, at 08:00, myocarditis developed. The patient had shortness of breath and difficulty moving the body. On 09-Feb-2022, the patient visited an outpatient department. Blood pressure was 112/62 with body temperature of 37.0 degrees Celsius, SpO2 of 96% (RA). Blood tests revealed elevations in CK 9,572 U/L, CK-MB 78.5 U/L, troponin T 0.1 ng/mL, CRP 7.16 mg/dL, and D-dimer 3.2 mcg/mL. Electrocardiogram showed flat T waves in V4-6. The patient was hospitalized. On 12-Feb-2022, worsening of respiratory status was noted. Shortness of breath and polypnea were observed. Electrocardiogram showed ST depressions in V2-6, negative T waves, which were findings of myocarditis. Echocardiography showed left ventricular ejection fraction of 30%, local or diffuse dysfunction in the right or left ventricle, and decreased contraction of the anterior wall. The patient went into a shock state. The patient had no response to diuretic, vasopressor, and cardiac stimulant. At 15:44, the patient died. The outcome of myocarditis and shock state was reported as fatal. No follow-up investigation will be made. Follow-up received on 27-MAR-2022 Updated: Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 24-Feb-2022 and was forwarded to Moderna on 24-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DIARRHOEA (diarrhea, vomiting, inappetite, extreme weakness, Saturday evening. on Sunday without eating or getting out of bed. Monday morning death from cardiac arrest.), ASTHENIA (diarrhea, vomiting, inappetite, extreme weakness, Saturday evening. on Sunday without eating or getting out of bed. Monday morning death from cardiac arrest.), DECREASED APPETITE (Diarrhea, vomiting, inappetite, extreme weakness, Saturday evening. on Sunday without eating or getting out of bed. Monday morning death from cardiac arrest.), CARDIAC ARREST (diarrhea, vomiting, inappetite, extreme weakness, Saturday evening. on Sunday without eating or getting out of bed. Monday morning death from cardiac arrest.) and VOMITING (diarrhea, vomiting, inappetite, extreme weakness, Saturday evening. on Sunday without eating or getting out of bed. Monday morning death from cardiac arrest.) in a 67-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 007G21A) for COVID-19 vaccination. Healthy patient with mild hypertension.

Case ID	Narrative (Complete)
	On 20-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 29-Jan-2022, the patient experienced DIARRHOEA (diarrhea, vomiting, inappetite, extreme weakness, Saturday evening. on Sunday without eating or getting out of bed. Monday morning death from cardiac arrest.) (seriousness criterion death), ASTHENIA (diarrhea, vomiting, inappetite, extreme weakness, Saturday evening. on Sunday without eating or getting out of bed. Monday morning death from cardiac arrest.) (seriousness criterion death), DECREASED APPETITE (Diarrhea, vomiting, inappetite, extreme weakness, Saturday evening. on Sunday without eating or getting out of bed. Monday morning death from cardiac arrest.) (seriousness criterion death), CARDIAC ARREST (diarrhea, vomiting, inappetite, extreme weakness, Saturday evening. on Sunday without eating or getting out of bed. Monday morning death from cardiac arrest.) (seriousness criterion death) and VOMITING (diarrhea, vomiting, inappetite, extreme weakness, Saturday evening. on Sunday without eating or getting out of bed. Monday morning death from cardiac arrest.) (seriousness criterion death). It is unknown if an autopsy was performed. No concomitant medications were mentioned. No treatment details were reported. Company comment: This regulatory authority case concerns a 67-year-old male patient with relevant medical history of mild hypertension, who experienced serious, fatal unexpected events of cardiac arrest, vomiting, diarrhoea, asthenia, decreased appetite, that occurred approximately 40 days after the dose of the mRNA-1273. Reportedly, the patient had diarrhea, vomiting, inappetence, extreme weakness on Saturday evening. On Sunday, the patient did not eat and could not get out of the bed. On Monday morning, the patient passed away due to cardiac arrest. The patient's relevant medical history is a possible confounder for cardiac arrest. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events reported and seriousness assessment retained as per regulatory authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non Significant Follow up appended
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 25-Feb-2022. The most recent information was received on 17-Mar-2022 and was forwarded to Moderna on 17-Mar-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of OFF LABEL USE (dose 1 and 2 comirnaty, dose 3 Moderna), INTERCHANGE OF VACCINE PRODUCTS (Moderna vaccine during autumn 2021) and DEATH (died on 18Jan2022) in a 95-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 016G21A) for COVID-19 immunisation. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 immunisation. No Medical History information was reported. On 04-Jun-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 21-Jul-2021, received second dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. On 28-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 28-Dec-2021, the patient experienced OFF LABEL USE (dose 1 and 2 comirnaty, dose 3 Moderna) (seriousness criteria death and medically significant). 28-Dec-2021, the patient experienced INTERCHANGE OF VACCINE PRODUCTS (Moderna vaccine during autumn 2021) (seriousness criteria death and medically significant). The patient died on 18-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided. Dosage text for suspect product Spikevax was reported as DOSE 3 (BOOSTER), SINGLE and for co-suspect product Dosage text was reported as DOSE 1, SINGLE and DOSE 2, SINGLE. No treatment medication was reported. Company comment: This regulatory case concerns a 95-year-old, female patient with history of interchange of vaccine products (two doses of Pfizer BioNTech covid19 vaccine), who experienced unexpected fatal event of Death approximately 7 months after receiving third dose (booster) of mRNA-1273 vaccine. Interchange of vaccine products and Off label use are also reported in the case with a fatal outcome. It is unknown if an autopsy was done, and the cause of death was reported as unknown. Advanced age of the patient could be a risk factor. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting. This case was linked to 4.1(b) [redacted] (E2B Linked Report). Most recent FOLLOW-UP information incorporated above includes: On 17-Mar-2022: Significant Follow Up: Spikevax start date and batch number updated, Comirnaty start date of two doses updated. Interchange of vaccine products and off label use start date was updated as 28-Dec-2021. Narrative updated.
4.1(b) [redacted]	This case was received via United Kingdom MHRA (Reference number: 4.1(b) [redacted]) on 27-Feb-2022 and was forwarded to Moderna on 27-Feb-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (Heart attack) and THROMBOSIS (Blood clot) in a 66-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. No Medical History information was reported. On 17-Sep-2021, the patient received third dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 22-Jan-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced THROMBOSIS (Blood clot) (seriousness criterion death). On 24-Jan-2022, the patient experienced MYOCARDIAL INFARCTION (Heart attack) (seriousness criterion death). The patient died on 24-Jan-2022. The reported cause of death was Clot blood and Heart attack. It is unknown if an autopsy was performed.

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	Concomitant medications were not provided. It was reported that this reaction was not occurred as a result of a mistake made in the administration of the vaccine that was Covid-19 Vaccine Moderna and the reason was not applicable. Treatment information was not provided. Company Comment: This is a regulatory case concerning a 66-year-old male patient with no medical history reported, who experienced the fatal unexpected AESIs of myocardial infarction and thrombosis (both reported as causes of death), approximately 4 months and 8 days after a dose of mRNA-1273 vaccine, received as the third dose for COVID-19 Vaccination (no information disclosed on previous doses). It is unknown if an autopsy was done. Patient´s age and gender remain as confounders for myocardial infarction. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events´ seriousness assessed as reported.
4.1(b) [redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of COVID-19 (Death after Moderna mRNA vaccines) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Liew J, Gianfrancesco M, Harrison C, Izadi Z, Rush S, Jacobsohn L, et al.. SARS-CoV-2 infections among vaccinated individuals with rheumatic disease: results from the COVID-19 global rheumatology alliance provider registry. Arthritis Rheumatol. 2021;73(9):4090-3 Liew J ,Gianfrancesco M, Harrison C, Izadi Z, Rush S, Lawson-Tovey S, et al.. SARS-CoV-2 breakthrough infections among vaccinated individuals with rheumatic disease: results from the COVID-19 Global Rheumatology Alliance provider registry. RMD open. 2022;8(1) The patient's past medical history included B-cell depletion therapy (B cell-depleting therapy was reported for medications at the time of vaccination, and at the time of COVID-19 diagnosis). Concurrent medical conditions included Lung disease and Rheumatoid arthritis. Concomitant products included LEFLUNOMIDE for Rheumatoid arthritis. In 2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In 2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced COVID-19 (Death after Moderna mRNA vaccines) (seriousness criteria death and hospitalization). The reported cause of death was SARS-CoV-2 infection. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered COVID-19 (Death after Moderna mRNA vaccines) to be related. The patient was on invasive ventilation. Also, it was reported that COVID-19 diagnosis was made via PCR, antigen or antibody test. Unspecified glucocorticoid was reported for medications at the time of vaccination, held for vaccination and at the time of COVID-19 diagnosis. The majority were not on glucocorticoids among those taking some of them were taking prednisone 1–9 mg/ day and some of them were on ≥10 mg/day. The impact on vaccine immunogenicity from medications used for rheumatic disease has been studied using surrogates for protection for humoral and T cell mediated responses. In the general population, antibody neutralization titers have correlated well with clinical protection against COVID-19. The precise clinical implications of these lower antibody responses in conjunction with maintained T cell responses are still unclear. Company Comment: This literature non-study case concerns a 66-year-old, female patient with pre-existing lung disease, rheumatoid arthritis and with concomitant treatment of B cell depletion therapy and Leflunomide, who experienced the unexpected, fatal AESI of COVID-19 (laboratory confirmed). The event occurred after receiving mRNA-1273 as second dose of COVID-19 vaccine. The patient was hospitalized due to the event and required invasive mechanical ventilation. She subsequently died on an unknown date. Clinical course leading to demise were not reported in the case. It is unknown if autopsy was performed. The patient's pre-existing conditions and concomitant medications remain as confounders for contracting the COVID-19 and for the fatal outcome. The ongoing Covid-19 pandemic is also a contributory factor. The benefit-risk relationship of mRNA-1273 is not affected by this report. This case was linked to 4.1(b) [redacted] 4.1(b) [redacted] (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 19-Apr-2022: Follow up received by safety on 20-Apr-2022 has Email with abstract received from SARA team and contains significant information, New citation details added. On 20-Apr-2022: Follow up received by safety on 21-Apr-2022 has Email with FTA received from SARA team and contains significant information Literature citation, medical history. Also, occupation of primary reporter was changed.
4.1(b) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] on 24-Feb-2022. The most recent information was received on 14-Mar-2022 and was forwarded to Moderna on 22-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b) [redacted]). On 14-Mar-2022, follow-up information was received from a physician. On 03-Aug-2021, the patient experienced fracture of shaft of right femur. Conservation treatment was performed instead of surgery because the patient was elderly and had dementia. On 19-Aug-2021, the patient experienced aspiration pneumonia concurrently and was diagnosed with inability to take anything by mouth. On 02-Sep-2021, central intravenous catheter was placed. On 21-Sep-2021, the patient hospitalized in the reporting hospital for the purpose of continued care. Right femur fracture was avulsed, and bone fusion was inadequate. The previous physician pointed out transverse colon tumor, but the details were unknown. The patient had been in a relatively stable condition although pyrexia developed occasionally. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On 01-Feb-2022, the patient experienced pyrexia, which was treated as aspiration pneumonia. Antibiotics were administered. On 06-Feb-2022, pyrexia resolved. On 09-Feb-2022, the patient underwent blood test before the vaccination with this vaccine, but there were no findings of infection. At 14:30, the patient received the 3rd vaccination with this vaccine. On 11-Feb-2022, in the early evening, the patient experienced a single episode of pyrexia of 37.4 degrees Celsius. On 12-Feb-2022, the patient had recurrent low-grade fever until the early evening. On 15-Feb-2022, thereafter, there was no pyrexia. Vital signs and level of

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	consciousness were unchanged. On 23-Feb-2022, in the early evening, body temperature was 36.6 degrees Celsius, PR was 82, and SpO2 was 98%. On 24-Feb-2022, at 00:00, the patient was asleep. At 05:00, the patient was checked on and found in a state of respiratory arrest. The patient died. The cause of death was geromarasmus. No autopsy was performed. The outcome of pyrexia was resolved. The outcome of cardio-respiratory arrest was unknown. No follow-up investigation will be made. Reporter comments continuation: The occurrence of adverse events is not related to concomitant drugs. The possibility of sudden pathological changes is considered because of incomplete fusion after femur fracture, central venous nutrition management, dementia, and decreased cardiopulmonary function due to advanced age. The relationship to this vaccine is unknown. The relationship between the cause of death and adverse events is unknown. Follow-up received on 14-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments The temporal relationship between the occurrence of adverse events and timing of administration of this vaccine is unknown. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 24-Feb-2022. The most recent information was received on 21-Mar-2022 and was forwarded to Moderna on 21-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration), PNEUMONITIS (Lung inflammation), PYREXIA (Pyrexia), INFECTION (Infection), IDIOPATHIC PULMONARY FIBROSIS (Exacerbation of idiopathic pulmonary fibrosis) and DYSPNOEA (Breath shortness) in a 77-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Dyslipidaemia, Hypertension arterial, Prostate cancer, Arthritis rheumatoid, AFib, Fibrosis lung, Infarct myocardial, Cancer of lung and Lung lobectomy. Concomitant products included APIXABAN (ELIQUIS), AMIODARONE, PREDNISONE (CORTANCYL), FOLIC ACID (SPECIAFOLDINE), PANTOPRAZOLE SODIUM SESQUIHYDRATE (EUPANTOL), TIEMONIUM METHYLSULPHATE (TIMETH) and BISOPROLOL FUMARATE (BISOPROLOL EG) for an unknown indication. On 08-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 22-Dec-2021, the patient experienced GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration) (seriousness criterion death), PNEUMONITIS (Lung inflammation) (seriousness criterion death), PYREXIA (Pyrexia) (seriousness criterion death), INFECTION (Infection) (seriousness criterion death), IDIOPATHIC PULMONARY FIBROSIS (Exacerbation of idiopathic pulmonary fibrosis) (seriousness criterion death) and DYSPNOEA (Breath shortness) (seriousness criterion death). The patient died on 27-Jan-2022. The reported cause of death was exacerbation of pulmonary fibrosis. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 19-Jan-2022, SARS-CoV-2 test: negative (Negative) Negative. mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 08-Dec-2021. Date of last administration of Spikevax was 8-DEC-2021. No treatment medication was provided. Company comment. This fatal regulatory authority case concerns a 77 year old, male patient with relevant medical history of dyslipidemia, hypertension, myocardial infarction, prostate cancer, rheumatoid arthritis, atrial fibrillation, lung fibrosis and lung cancer, who experienced unexpected, serious fatal events of general physical health deterioration, pneumonitis, pyrexia, infection, idiopathic pulmonary fibrosis and dyspnoea, 14 days after receiving a dose of mRNA-1273. SARS-Cov-2 test was performed with negative results. Clinical course and treatment details were not reported. The cause of death was reported as exacerbation of pulmonary fibrosis. The patient died on 27-Jan-2022, approximately 7 weeks after vaccination. It is unknown if an autopsy was performed. The age and medical history of the patient remain as confounders for the events and fatal outcome. The benefit risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Mar-2022: Significant Follow-up received : Patient's date of death , cause of death, medical history, new event and concomitant product updated
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 25-Feb-2022 and was forwarded to Moderna on 25-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (fatalities) in a 65-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 091F21A) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: COMIRNATY (Dose 1: Adult Comirnaty-30 Pfizer Vaccine, 10/05/2021, Left Arm, Intramuscular Injection, Lot number: FA5831) on 10-May-2021, COMIRNATY (Dose 2: Adult Pfizer Comirnaty-30 Vaccine, 18/06/2021, Right Arm, Intramuscular Injection and Lot number: FD0168) on 18-Jun-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY. Concurrent medical conditions included Hypertension arterial, Benign prostatic hyperplasia and Osteoarthritis generalised. Concomitant products included TOZINAMERAN (COMIRNATY) from 10-May-2021 to an unknown date for COVID-19 vaccination. On 11-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on 12-Jan-2022 It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Dose number for Spikevax was reported as R1. No treatment information was provided.

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	Company comment: This regulatory authority case concerns a 65-year-old male patient with relevant medical history of Hypertension arterial, who died (serious unexpected event of Death) one day after the administration of the mRNA-1273 vaccine (as booster vaccination, since the patient previously had received two doses of the Tozinameran COVID-19 vaccine). The cause of death remained unknown and there was no any information regarding autopsy results (if it was performed). Limited information precludes a meaningful medical assessment at this point. The rechallenge is not applicable having in mind that the patient died. The underlying medical history of Hypertension arterial remains a confounder for the reported event. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Having in mind that this patient received Tozinameran COVID-19 vaccine prior to vaccination with the company product, Interchange of vaccine products should have been considered in this specific case.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b)) on 22-Feb-2022 and was forwarded to Moderna on 28-Feb-2022. This case, reported to the Pharmaceuticals and medical devices agency by a person in charge of the vaccination, was received via the PMDA (Ref, 4.1(b)). The patient was taking limaprost alfadex 5 mcg and sarpogrelate hydrochloride 100 mg. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (unknown product name). On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (unknown product name). On an unknown date, body temperature before the vaccination: 36.0 degrees Celsius. On 14-Feb-2022, at 14:01, the patient received the 3rd vaccination with this vaccine. On an unspecified date in Feb-2022, the patient died. On 15-Feb-2022, at 12:30, there was an inquiry from the police that the patient was found dead and the police wanted to confirm the vaccination, and the situation was known. On an unknown date, according to the police, the cause of the death and causality with this vaccine were unknown. It was reported that there were no complaints or signs of physical deconditioning. No follow-up investigation was possible because the report was received from a non-healthcare worker. Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 25-Feb-2022. The most recent information was received on 24-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of ASTHENIA (Loss of strength, arm (s) first, then body), COUGH (Cough (flu symptoms?)), NASOPHARYNGITIS (Have a cold(flu symptoms?)) and PERIPHERAL COLDNESS (ice-cold hands) in a 72-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Pneumonia (He also had pneumonia exactly 3 years ago. That's when that prednisone cure helped him on top of it. After that previous pneumonia, his lungs were completely checked and I was anxious that a spot would be found on his lungs, but they were clean!! He's recovered from that pneumonia and no longer bothered it.) in January 2019, Abdominal aneurysm in 2019 and Renal cancer (He had pneumonia 3 years ago and completely recovered from prednisone treatment. Then his lungs were checked and were clean but there was a spot (cancer) on his kidney. The tumour was in his kidney and was removed about 2.5 years ago, received 'free letter' after examination pathologist and again came out of the top fit, did not need a chemo cure (rinsing in the beginning).) in 2019. Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccine (Comirnaty) COVID-19 VACCINE PFIZER SUSPENSION FOR INJECTION 0.3 ML on 31-May-2021 and BioNTech/Pfizer vaccine (Comirnaty) COVID-19 VACCINE PFIZER SUSPENSION FOR INJECTION 0.3 ML on 15-Jul-2021. Past adverse reactions to the above products included Injection site pain with BioNTech/Pfizer vaccine (Comirnaty) COVID-19 VACCINE PFIZER SUSPENSION FOR INJECTION 0.3 ML and BioNTech/Pfizer vaccine (Comirnaty) COVID-19 VACCINE PFIZER SUSPENSION FOR INJECTION 0.3 ML. Concurrent medical conditions included Smoker (I don't have any numbers. My dad smoked. Even when he was here, he went outside regularly.) and COPD. On 03-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Jan-2022, the patient experienced ASTHENIA (Loss of strength, arm (s) first, then body) (seriousness criteria death and life threatening). On 10-Jan-2022, the patient experienced VOMITING (vomiting, productive in the beginning, later more prone to vomit, walked around with a bucket, but bucket remained empty.), MYALGIA (Muscle Pain), NAUSEA (nausea) and MALAISE (Don't feel good). On 17-Jan-2022, the patient experienced CHILLS (Cold shivers) and PERIPHERAL COLDNESS (ice-cold hands) (seriousness criteria death and life threatening). On 20-Jan-2022, the patient experienced COUGH (Cough (flu symptoms?)) (seriousness criteria death and life threatening) and NASOPHARYNGITIS (Have a cold(flu symptoms?)) (seriousness criteria death and life threatening). On 22-Jan-2022, the patient experienced INSOMNIA (Haven't slept in 72 hours. I still thought that was strange, I said to my father "if you feel sick or bad, then you would prefer to sleep, wouldn't you?", but he couldn't do that. Or very restless.). The patient died on 25-Jan-2022. The reported cause of death was copd. It is unknown if an autopsy was performed. At the time of death, INSOMNIA (Haven't slept in 72 hours. I still thought that was strange, I said to my father "if you feel sick or bad, then you would prefer to sleep, wouldn't you?", but he couldn't do that. Or very restless.) had not resolved and VOMITING (vomiting, productive in the beginning, later more prone to vomit, walked around with a bucket, but bucket remained empty.), CHILLS (Cold shivers), MYALGIA (Muscle Pain), NAUSEA (nausea) and MALAISE (Don't feel good) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In December 2019, Physical examination: not alarming Measurement aneurysm: the measurement was not alarming, actually not to worry about but came back after half a year to see if there was any growth. In June 2020, Physical examination: no need for concern Aneurysm measurement: The second measurement was about half a year later. When it turned out that no growth had been detected, there was no need for concern, a half-yearly measurement was not necessary.. On 17-Jan-2021, SARS-CoV-2 test: negative (Negative) negatively. Concomitant medications were not reported . Treatment information was not provided. Company Comment: This is a regulatory, fatal case concerning a 72-year-old male patient with reported medical history of COPD, Smoker, Abdominal aneurysm, Renal cancer, and previous COVID-19 Vaccination history with BioNTech/Pfizer vaccine (Comirnaty), who experienced the unexpected serious events of Nasopharyngitis, Cough, Peripheral Coldness and Asthenia. The events were life-threatening and led to the eventual demise of the patient as reported by the regulatory authority. The event Asthenia 6 days after receiving a dose (3rd dose of the COVID-19 Vaccination) of mRNA-1273 Vaccine. Peripheral Coldness occurred 14 days later while Cough and Nasopharyngitis occurred 17 days later. The patient died approximately 22 days after a dose of mRNA-1273 vaccine was received. It is unknown if autopsy was performed. The reported cause of death was COPD. The medical history

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	of COPD, Smoker, Abdominal aneurysm, and Renal cancer remains a confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 24-Mar-2022: Significant follow up appended: Relevant medical history details updated, Event and lab test added. On 24-Mar-2022: Translation received on 29-MAR-2022 contains translated event verbatim with no new information.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 23-Feb-2022 and was forwarded to Moderna on 23-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of RESPIRATORY ACIDOSIS (respiratory acidosis) and CEREBROVASCULAR ACCIDENT (Patient has become suddenly reduced admissible 1 day after booster vaccination, presumably due to cerebral cause such as cerebral hemorrhage/infarction) in an 82-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216036) for COVID-19 vaccination. The patient's past medical history included Resuscitation (2011 abdominal aortic aneurysm wv tubular prosthesis, hereby resuscitation) in 2011, Abdominal aortic aneurysm in 2011, Ex-smoker in 1973, Coronary artery bypass graft in 2019, Percutaneous coronary intervention (2007 PTCA ramus descendens anterior) in 2007 and Aortic aneurysm repair (bioprosthesis) in 2011. Previously administered products included for Product used for unknown indication: COMIRNATY on 24-Mar-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 01-Jun-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 01-Jun-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 01-Jun-2021. Past adverse reactions to the above products included Balance difficulty with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; Dizziness with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; Dyspnoea with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST; and No adverse reaction with COMIRNATY. Concurrent medical conditions included Hypertension, Atrial fibrillation (arrhythmias-atrial fibrillation. due to high risk of bleeding, no oral anticoagulation started, only acetylsalicylic acid), Implantable defibrillator user (not mentioned by reporter, but described in autopsy journal), Wheelchair user, Penicillin allergy and Plasmacytoma (From history as noted in autopsy report: Isolated plasmacytoma Th5/Th6. No Kahler at follow-up). Concomitant products included METOPROLOL TARTRATE (METOPROLOL-BC), SALBUTAMOL (SALBUTAMOL A), TIOTROPIUM and ACETYLSALICYLZUUR for an unknown indication. On 30-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 31-Dec-2021, the patient experienced RESPIRATORY ACIDOSIS (respiratory acidosis) (seriousness criterion death) and CEREBROVASCULAR ACCIDENT (Patient has become suddenly reduced admissible 1 day after booster vaccination, presumably due to cerebral cause such as cerebral hemorrhage/infarction) (seriousness criterion death). The patient died on 02-Jan-2022. The reported cause of death was respiratory acidosis suspected in cerebral hypoventilation (skull obduction follows) and hypoventilation by cerebral cause. An autopsy was performed. The autopsy-determined cause of death was no abnormalities seen to organs. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Jan-2021, Autopsy: no particularities ABDOMEN: The liver weighs 1086 g. No particularities at cut. The spleen weighs 182 g. No specifics at cut. Due to the presence of a trouser prosthesis in the abdominal aorta. Both kidneys weigh 300 g. No specifics at cut. Gastrointestinal tract and pancreas: no particularities. Bladder and prostate: no particularities., no abnormalities externally BRAIN: A skull production was performed. The brain weigh 1680 g. No abnormalities externally. These will be investigated in university center, hypereosinophilia and contraction band necrosis MICROSCOPY: Bone marrow: reactive changes. Adrenal glands: no specifics. Liver and spleen: low centrilobular congestion of the liver. Slight expansion of the red pulp. No splenitis. Pancreas: Advanced Autolysis. Left kidney: no specifics. Right kidney: no specifics. Left lung: no details. Right lung no specifics. Myocardial: picture of chronic ischemic cardiomyopathy. Under the form of multiple spotted old fibrous fireplaces. Microscopically no features of recent ischemia. Local some hypereosinophilia and contraction band necrosis. However, no infiltration of inflammation cells. There was extensive sampled. and no particularities. The left lung weighs 333 g, the right lung 372 g. No specifics at cut. No embolisms. The heart shows extensive adhesions to previous coronary surgery where it is technically impossible to properly assess the internal status of the coronaries. Presence of a pacemaker. The aortic thoracic aorta exhibits moderately pronounced atherosclerosis. However, the carotid arteries are easily accessible. The left ventricular wall has a thickness of 3 cm with image matching a concentric left ventricular hypertrophy. In the LDH test, there is a fairly pronounced decolouration of the left ventricular wall. Recent ischemia? Infrared? Agonal? Throat skeleton, trachea, esophagus and thyroid: no particularities.. In January 2021, Autopsy: obduction has occurred Obduction has occurred, in which the organs were not diagnosed with any pathology that could explain death.. In December 2021, SARS-CoV-2 test: negative (Negative) negative. On 31-Dec-2021, Laboratory test: no notable abnormalities (Inconclusive) platelet 130x10^9 (platelets have been slightly lowered since 2019), CRP 14, pH 7.24, pCO2 94, bicarbonate 30.5, Po2 111, coagulation values have not been determined. No notable abnormalities. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment information were given. Company comment: This is a regulatory authority case concerning a 82-year-old, male patient with relevant medical history of hypertension, abdominal aortic aneurysm in 2011, resuscitation (2011, abdominal aortic aneurysm with tubular prosthesis, hereby resuscitation), aortic aneurysm repair (2011, bioprosthesis) atrial fibrillation (due to high risk of bleeding, no oral anticoagulation started, only acetylsalicylic acid), coronary artery bypass graft in 2019, implantable defibrillator user, percutaneous coronary intervention (2007 PTCA ramus descendens anterior), wheelchair user, former smoker in 1973 and Plasmacytoma and with vaccine history of receiving 2 doses of another brand of Covid-19 vaccine (Covid-19 vaccine Comirnaty) as previous doses, who experienced the unexpected serious (fatal according to regulatory authority) AESI event of presumably cerebrovascular accident and unexpected serious (fatal according to regulatory authority) event of respiratory acidosis. The events occurred approximately 1 day after the unknown dose number of mRNA-1273 vaccine administration. The reported cause of death was respiratory acidosis suspected in cerebral hypoventilation (skull obduction follows) and hypoventilation by cerebral cause. An autopsy was performed with autopsy findings of, obduction has occurred, in which the organs were not diagnosed with any pathology that could explain death. The autopsy-determined cause of death was no abnormalities seen to organs. The reported medical history remains confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 25-Feb-2022. The most recent information was received on 07-Apr-2022 and was forwarded to Moderna on 15-Apr-2022.

Case ID	Narrative (Complete)
	This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by an anatomist, was received via the PMDA (Ref, 4.1(b)). On 07-Apr-2022, follow-up information was received from an anatomist. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 19-Feb-2022, around 10:00, the patient received the 3rd vaccination with this vaccine. On 20-Feb-2022, around 11:00, the patient took a walk with the dog near the home. Around 20:00, acute cardiac insufficiency developed. The patient was presumed dead. On 21-Feb-2022, in the early evening, the family member made several calls but did not get through the patient. Around 21:40, the family member visited the patient. The patient was found dead as if sitting on the floor holding the knees in the bathtub of the home. The set temperature of the bath water was 43 degrees Celsius. On 23-Feb-2022, a judicial autopsy was performed, and the cause of death was determined as acute cardiac insufficiency. An autopsy revealed high atherosclerosis in the aorta. In the heart, micro-fibrogenesis was observed around the small coronary arteries on the intimal side of the left ventricular outflow tract and on the intimal side of the left ventricular posterior wall. The degree was not serious. In the brain, mild lacunar was noted in the basal ganglia. In the right kidney, slight lymphocytic infiltration under the bulbar conjunctiva and a few glomerular sclerosis images in the cortex were revealed. Alcohol test revealed only alcohol due to postmortem production, not antemortem ingestion. The qualitative test for toxin was negative. Two days and 15 hours had passed since the patients death, and postmortem changes were noted. There was no other possible cause of death. The outcome of acute cardiac insufficiency was reported as fatal. The outcome of atherosclerosis of the aorta and lacunar was unknown. No follow-up investigation will be made. Reporter comments continuation: The relationship between the occurrence of adverse events and concomitant drugs is unknown. The cause of death is related to adverse events because there is a possibility that there was some influence. An autopsy revealed high atherosclerosis in the aorta. In the heart, micro- fibrogenesis was observed around the small coronary arteries on the intimal side of the left ventricular outflow tract and on the intimal side of the left ventricular posterior wall. The degree was not serious. In the brain, mild lacunar was noted in the basal ganglia. In the right kidney, slight lymphocytic infiltration under the bulbar conjunctiva and a few glomerular sclerosis images in the cortex were revealed. Postmortem changes were slightly advanced, with some changes associated with decomposition. The cause of death was determined as acute cardiac dysfunction because there was no disease that could be the cause of death, there was no damage, and no abnormality was found in toxicological test. Although the patient had a history of stomach cancer, she ate 3 meals every day, took a daily walk, and made daily farm work as usual. The patient took a bath every day. What is unusual is that the patient received the vaccination with this vaccine on the previous day. Looking at the time course, it was thought to be more appropriate to think that there was some influence. Follow-up received on 07-APR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments Company Comment: Cardiac failure acute, aortic arteriosclerosis, and lacunar infarction can be also considered as an accidental disease although it developed after the administration of ELASOMERAN.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 25-Feb-2022. The most recent information was received on 09-Mar-2022 and was forwarded to Moderna on 16-Mar-2022. This case was reported by a physician via the Drug Information Center. On 09-Mar-2022, follow-up information, reported by a physician, was received by Takeda via Moderna's adverse reaction reporting site (4.1(b) , and reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 13-Jun-2021, at 11:00, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 04-Jul-2021, at 11:00, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 35.8 degrees Celsius. On 23-Feb-2022, around 10:00, the patient received the 3rd vaccination with this vaccine. After vaccination, the patient experienced mild headache but walked back to the room alone and ingested meals. At 17:45, the patient fell and lost consciousness in cardio-respiratory arrest. After confirming that the patient was unconscious, cardiopulmonary resuscitation was started. As an ambulance call was made, intravenous injection of adrenaline was performed since electrocardiogram showed cardiac arrest. The waveform then became pulseless electrical activity, but spontaneous circulation was not returned. At 18:57, the patient was confirmed dead in a hospital where the patient was transported. Diagnostic imaging at the time of death was performed. There were findings of aortic dissection. Pleural effusion and blood were mixed in the aorta. The outcome of headache, fall, and loss of consciousness was unknown. The outcome of cardio-respiratory arrest and aortic dissection was reported as fatal. No follow-up investigation will be made. Follow-up received on 09-MAR-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 28-Feb-2022. The most recent information was received on 22-Mar-2022 and was forwarded to Moderna on 29-Mar-2022. This case was reported by a physician via a medical representative. On 22-Mar-2022, follow-up information was received by a physician. On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, the patient received the 2nd dose of this vaccine. On 21-Feb-2022, the patient received the 3rd dose of this vaccine. There were no abnormalities during follow-up. On 24-Feb-2022, the patient was found in a state of cardio-respiratory arrest at home. The patient was confirmed dead. On an unknown date, an autopsy was performed. The cause of death was unknown. The outcome of cardio-respiratory arrest was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: Since the patient had not made an outpatient visit for two years, it is unknown whether the occurrence of adverse event is related to pathologic factors of underlying diseases and complications. The patient had visited the reporting hospital until 17-Jun-2020 and had taken amlodipine besilate 5 mg and rosuvastatin calcium 2.5 mg (alternate-day) orally. Thereafter, the patient was withdrawn and did not visit other medical institutions. Follow-up received on 22-MAR-2022 Updated: Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: As for cardio-respiratory arrest, the event developed after administration of ELASOMERAN, but it may also be affected by the patient factors such as advanced age.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Feb-2022 and was forwarded to Moderna on 28-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of HAEMORRHAGIC STROKE (Hemorrhagic stroke) in a 72-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect products included non-company products RIVAROXABAN (XARELTO) for Thromboembolism prophylaxis and ACETYLSALICYLATE LYSINE (KARDEGIC) for Thromboembolism prophylaxis. The patient's past medical history included Lower limb ischemia, Hypertension arterial, Dyslipidaemia and Stroke. In 2019, the patient started RIVAROXABAN (XARELTO) (Oral) 20 milligram once a day and ACETYLSALICYLATE LYSINE (KARDEGIC) (Oral) 75 milligram once a day. On 05-Jan-2022, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced HAEMORRHAGIC STROKE (Hemorrhagic stroke) (seriousness criterion death). The patient died on 07-Jan-2022. The reported cause of death was cerebral hemorrhage. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Relevant concomitant medications were not reported.

Case ID	Narrative (Complete)
	Treatment information was not provided. Dosage text of suspect product reported as D1. Company comment: This regulatory authority case concerns a 72-year-old female patient with a relevant medical history of Hypertension, Stroke and co-suspect use of Rivaroxaban and Acetylsalicylate lysine, who experienced the fatal unexpected AESI of Haemorrhagic stroke, approximately 1 day after receiving the first dose mRNA- 1273 vaccine, with death occurring on the following day. Cause of death was reported as Cerebral haemorrhage. No further clinical information is available. It is unknown if an autopsy was performed. The use of Rivaroxaban and Acetylsalicylate lysine remain as co-suspect. Additionally, patient´s age, underlying hypertension and previous stroke might be confounders. The benefit-risk relationship of mRNA- 1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Feb-2022 and was forwarded to Moderna on 28-Feb-2022. This regulatory authority case was reported by a physician and describes the occurrence of MENINGITIS (Meningitis) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure) in a 69-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Date of death not given. First result of the autopsy with proof unspec. Coatings on the meninges in the sense of meningitis. Previously administered products included for COVID-19 vaccination: COMIRNATY and COVID-19 VACCINE ASTRAZENECA (Vaxzevria). Past adverse reactions to the above products included No adverse event with COMIRNATY and COVID-19 VACCINE ASTRAZENECA. On 16-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 16-Jan-2022, the patient experienced MENINGITIS (Meningitis) (seriousness criteria death, hospitalization and life threatening) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiple organ failure) (seriousness criteria death, hospitalization and life threatening). The reported cause of death was Multiple organ failure. An autopsy was performed. The autopsy-determined cause of death was Meningitis. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medications were not provided. Treatment information was not provided. Company comment: This is a regulatory case concerning a 69 year-old, male patient with no reported medical history, who experienced the fatal serious unexpected, events of meningitis (AESI) and Multiple organ dysfunction syndrome, the same day after the mRNA-1273 vaccine, received as the booster dose of the COVID-19 vaccination schedule. Patient´s death date was not provided but the duration of both events was reported as 2 days. The autopsy determined cause of death was meningitis and an additional cause of death reported in the case was Multiple organ dysfunction syndrome. Additionally, Interchange of vaccine products was noted in the case, vaccination with a dose of COVID-19 vaccine Tozinameran and a dose of NRVV AD (CHADOX1 NCOV-19) no dates provided. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Feb-2022 and was forwarded to Moderna on 28-Feb-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) in a 74-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 006G21A) for COVID-19 vaccination. No Medical History information was reported. On 17-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 03-Jan-2022, the patient experienced CARDIO-RESPIRATORY ARREST (Cardio-respiratory arrest) (seriousness criterion death). The patient died on 03-Jan-2022. The reported cause of death was heart failure. An autopsy was not performed. No concomitant medications were provided. No treatment information was provided. Company comment: This is a fatal regulatory case concerning a 74-year-old male patient with no reported medical history, who experienced the serious unexpected event cardio-respiratory arrest, approximately 17 days after an unspecified dose of mRNA-1273. The patient died the same day the event occurred. The reported cause of death was heart failure. An autopsy was not performed. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 02-Mar-2022 and was forwarded to Moderna on 02-Mar-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of DISORIENTATION (Orientation disturbed), SEPSIS (sepsis), CARDIAC FAILURE (heart failure), APATHY (apathy), COMMUNICATION DISORDER (Communication disorder), GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration) and MOBILITY DECREASED (Mobility decreased) in a 90-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Culture wound (swab from ulcer, therapy with antibiotics) in February 2021. Concurrent medical conditions included Bacterial infection (klebsiella pneumoniae, proteus mirabilis), Breast carcinoma (treatment with Letrozole) since 2018, Peripheral arterial occlusive disease Fontaine stage IV, Ulcus cruris (led to repeated hospitalizations, massive extent of the ulcer, managed to cure only once and only for a short time, treatment with systemic antibiotics was necessary several times a year, the treatment was very painful, therefore, in 2018, the patient was registered with a pain clinic and opiates and antidepressants were used) since 2015, Multimorbidity and Depression. Concomitant products included CITALOPRAM HYDROBROMIDE (CITALEC) and FENTANYL (DOLFORIN) for an unknown indication.

Case ID	Narrative (Complete)
	On 22-Feb-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 24-Feb-2021, the patient experienced DISORIENTATION (Orientation disturbed) (seriousness criterion medically significant), SEPSIS (sepsis) (seriousness criterion medically significant), APATHY (apathy) (seriousness criterion medically significant), COMMUNICATION DISORDER (Communication disorder) (seriousness criterion medically significant), GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration) (seriousness criteria death and medically significant) and MOBILITY DECREASED (Mobility decreased) (seriousness criterion medically significant). On 03-Apr-2021, the patient experienced CARDIAC FAILURE (heart failure) (seriousness criteria death and medically significant). The patient died on 03-Apr-2021. The reported cause of death was General physical health deterioration and Failure heart. An autopsy was not performed. At the time of death, DISORIENTATION (Orientation disturbed), SEPSIS (sepsis), APATHY (apathy), COMMUNICATION DISORDER (Communication disorder) and MOBILITY DECREASED (Mobility decreased) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Mar-2021, Body temperature: 37.1 (normal) 37.1 Cel (degree Celsius). On 03-Mar-2021, Physical examination: abnormal (abnormal) adynamic, tachypneic, communicates in one word, painful, food and fluid intake limited, auscultation - alveolar breathing, numerous expiratory whistles diffusely, dorsobasally quieter.. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided. Information on concomitant therapies was reported as false. Company Comment: This regulatory case concerns a 90-year-old, female patient with relevant medical history of breast carcinoma being treated with Letrozole, peripheral arterial occlusive disease Fontaine stage IV and chronic case of ulcus cruris infected with Klebsiella pneumoniae and Proteus mirabilis and with concomitant medications use of Citalopram hydrobromide and Fentanyl, who experienced the unexpected, fatal and medically significant AESI of Cardiac failure and the unexpected, serious (medically significant) events of Sepsis, Mobility decreased, Disorientation, Communication disorder and Apathy. General physical health deterioration was reported as an additional event with fatal outcome. The non-fatal events occurred 2 days after receiving the second dose of mRNA-1273 vaccine while the fatal events occurred more than a month after the vaccination. The patient was seen 9 days after vaccination and was noted to be adynamic, tachypneic, with minimal verbal communication, in constant pain and had limited food and fluid intake. On auscultation, vesicular breath sounds were heard with persistent expiratory wheezing mainly on upper to middle sections of lungs. Clinical course leading to demise and treatment details were not reported in the case. The patient died 5 weeks and 5 days after the second dose of mRNA-1273 vaccine. Autopsy was not performed. The advanced age of the patient and multiple comorbidities remain as confounders for the events and for the fatal outcome. Additionally, therapy with Letrozole and the concomitant medications could be confounders for the Cardiac failure. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 28-Feb-2022. The most recent information was received on 23-Mar-2022 and was forwarded to Moderna on 29-Mar-2022. This case was reported by a physician via a medical representative. On 23-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On 25-Dec-2021, the patient visited a hospital as a routine. There were no abnormalities in particular. On 24-Feb-2022, the patient received the 3rd vaccination with this vaccine. There were no particular problems. On 25-Feb-2022, around 21:00, the patient died in the bathroom. This case was informed by the police. The cause and details were unknown. No follow-up investigation will be made. Reporter comments continuation: The occurrence of adverse events is not associated with concomitant drugs. The occurrence of the adverse event is related to the pathophysiological factors of atrial fibrillation because it may cause myocardial infarction and cerebral infarction. The event is not considered to have been caused by this vaccine. Follow-up received on 23-MAR-2022 Updated: Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter comments Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 01-Mar-2022. The most recent information was received on 26-May-2022 and was forwarded to Moderna on 26-May-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of INTESTINAL INFARCTION (bowel infarction), MESENTERIC ARTERIAL OCCLUSION (Occlusion mesenteric artery), INTESTINAL HAEMORRHAGE (Enterorrhagia) and ILEUS (ileus) in a 77-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included False aneurysm (in the groin, resection), Femoropopliteal artery bypass occlusion, Teetotaller since an unknown date, Smoker (20 cigarettes a day) since an unknown date, Arterial hypertension since an unknown date, Femoropopliteal artery bypass since 2000, Femoral-popliteal shunt since 2000 and Prosthetic vessel implantation since an unknown date. Concurrent medical conditions included Ischemic heart disease, Arterial stenosis (60-70%, the left internal carotid artery) and Hypertension. Concomitant products included INDAPAMIDE, PERINDOPRIL ARGININE (PRESTARIUM NEO COMBI), URAPIDIL (EBRANTIL KAKEN), VERAPAMIL HYDROCHLORIDE (ISOPTINO) and ACETYLSALICYLIC ACID (STACYL) for an unknown indication. On 07-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In January 2022, the patient experienced MESENTERIC ARTERIAL OCCLUSION (Occlusion mesenteric artery) (seriousness criteria death, hospitalization, medically significant and life threatening) and ILEUS (ileus) (seriousness criteria hospitalization, medically significant and life threatening). On 18-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced INTESTINAL INFARCTION (bowel infarction) (seriousness criteria death, hospitalization, medically significant and life threatening). On 20-Jan-2022, the patient experienced INTESTINAL HAEMORRHAGE (Enterorrhagia) (seriousness criteria hospitalization and medically significant), DIARRHOEA (diarrhea), DECREASED APPETITE (Appetite lost) and NAUSEA (Nausea). The patient died on 23-Jan-2022. The reported cause of death was Bowel infarction. An autopsy was not performed. At the time of death, INTESTINAL HAEMORRHAGE (Enterorrhagia), DIARRHOEA (diarrhea), DECREASED APPETITE (Appetite lost), NAUSEA (Nausea) and ILEUS (ileus) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Jan-2022, Blood pressure measurement: 144/88 144/88 mmHg. On 14-Jan-2022, Body mass index: 25.82 25.82. On 14-Jan-2022, Ejection fraction: 65 65 percent.

Case ID	Narrative (Complete)
	On 14-Jan-2022, Physical examination: abdomen soft, palpable, palpably painless, hepar n abdomen soft, palpable, palpably painless, hepar not enlarged, lien does not bump, tapottement bilaterally negative, Israeli negative, pathological resistance not palpable, per rectum painless, no resistance, stool normal consistency, no blood. On 20-Jan-2022, Activated partial thromboplastin time: 29.4 29.4 Siemens. On 20-Jan-2022, Activated partial thromboplastin time ratio: 1 1 Siemens. On 20-Jan-2022, Blood pressure measurement: 129/83 129/83 mmHg. On 20-Jan-2022, Body height: 175 175 centimetre. On 20-Jan-2022, Body mass index: 28,41 28,41. On 20-Jan-2022, C-reactive protein: 326 326 mg/L. On 20-Jan-2022, Electrocardiogram: tachycardia, atrial fibrillation, horizontal axis, (abnormal) tachycardia, atrial fibrillation, horizontal axis, QRS 106 ms, T-wave positive, ST isoelectric. On 20-Jan-2022, Heart rate: 121 121/min. On 20-Jan-2022, Mean platelet volume: 11 11 fL. On 20-Jan-2022, Platelet count: 212 212 billion per litre. On 20-Jan-2022, Platelet distribution width: 13.5 13.5 fL. On 20-Jan-2022, Prothrombin time: 15.7 15.7 Siemens and 1.31 1.31 Siemens. On 20-Jan-2022, Red blood cell count: 5.18 5.18 trillion per litre. On 20-Jan-2022, Weight: 87 87 kilogram. On 20-Jan-2022, White blood cell count: 16.7 16.7 billion per litre. On 21-Jan-2022, Angiogram: occlusion of the superior mesenteric artery trunk, occlusion of the superior mesenteric artery trunk, defective saturation of most of the tenue (except the proximal jejunum and duodenum) and right colon. Tenue is slightly opacified from the collateral circulation only in the portovenous phase. Illusions, discreet effusion in the pelvis. Diverticles of sigma and descendens, cysts of the left kidney.. On 21-Jan-2022, C-reactive protein: 344 344 mg/L. On 21-Jan-2022, Chest X-ray: atherosclerosis of the aorta, otherwise a normal f (abnormal) atherosclerosis of the aorta, otherwise a normal finding on the intrathoracic organs. On 21-Jan-2022, Platelet count: 152 152 billion per litre. On 21-Jan-2022, White blood cell count: 8.6 8.6 billion per litre. Treatment information was not provided. Company comment: This regulatory authority case concerns a 77-year-old, male patient with relevant medical history of Femoropopliteal Artery Occlusion status post Femoropopliteal Artery Bypass Occlusion, Hypertension, Arterial Stenosis, Ischemic Heart Disease; Overweight (BMI: 25.82) and Smoking (20 cigarettes/day for unknown number of years), who experienced the unexpected, serious (fatal, life-threatening, hospitalization and medically significant) AESI of intestinal infarction; the unexpected, serious (fatal, life-threatening, hospitalization and medically significant) event of mesenteric arterial occlusion; the unexpected, serious (life-threatening, hospitalization and medically significant) event of ileus; the unexpected, serious (hospitalization and medically significant) event of intestinal haemorrhage; and other associated unexpected and expected, non-serious events. The events intestinal infarction, intestinal haemorrhage, and the non-serious events occurred approximately 1 month after receiving the third dose of the mRNA-1273 vaccine. The events mesenteric arterial occlusion and ileus occurred on unspecified dates in Jan2022 after receiving the third dose of the mRNA-1273 vaccine. Approximately 1 month (38 days) after vaccination (4 to 6 days before the onset of the events), physical examination findings and laboratory tests done were unremarkable except for the elevated blood pressure (BP) of 144/88 mmHg and Body mass index (BMI) of 25.82. After 6 days, the patient's heart rate was increased (121 beats/minute) but the BP was lower (129/83 mmHg). The BMI was noted to be higher (28.41) and the patient's weight had also increased (from 80 kg to 87 kg, unspecified time interval). The Electrocardiogram (ECG) showed 'tachycardia, atrial fibrillation, horizontal axis, QRS 106 ms, T-wave positive, ST isoelectric'. Blood tests showed elevated C-reactive protein (CRP) of 326 mg/L and Leukocyte count of 16.7 x 10^9/L. The following day, the Leukocyte count was normal (8.6 x 10^9/L) but the CRP was still elevated (344 mg/L). The Computerized Tomography Angiogram of the Abdomen and Pelvis (two-phase post-contrast) showed 'occlusion of the superior mesenteric artery trunk, defective saturation of most of the tenue (except the proximal jejunum and duodenum) and right colon. Tenue is slightly opacified from the collateral circulation only in the portovenous phase. Illusions, discreet effusion in the pelvis. Diverticles of sigma and descendens, cysts of the left kidney'. The Chest X-ray was unremarkable except for 'atherosclerosis of the aorta'. No further clinical information (including details about hospitalization) was available for medical review. Treatment information was also not provided. The patient expired on 23Jan2022 (1 month, 16 days after vaccination). The reported cause of death was Bowel infarction. An autopsy was not performed. The medical history of Femoropopliteal Artery Occlusion, Hypertension, Arterial Stenosis and Ischemic Heart Disease, which contributes to arterial vasoconstriction, remain as confounders for the events mesenteric arterial occlusion and intestinal infarction. The medical history of being Overweight and Smoking, which are risk factors for thromboembol
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 01-Mar-2022 and was forwarded to Moderna on 01-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of UROSEPSIS (Ataxia, confusion, disorientation, urosepsis), ATAXIA (Ataxia, confusion, disorientation, urosepsis) and CONFUSIONAL STATE (Ataxia, confusion, disorientation, urosepsis) in a 79-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216045) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Asthma bronchial (CHILD A), Macrocytic hyperchromic anemia (CHILD A), Type 2 diabetes mellitus (CHILD A), Cardiac insufficiency (CHILD A) and Hepatic cirrhosis (CHILD A). On 20-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Jan-2022, the patient experienced PYREXIA (Ataxia, confusion, disorientation, urosepsis), ATAXIA (Ataxia, confusion, disorientation, urosepsis) (seriousness criterion hospitalization) and CONFUSIONAL STATE (Ataxia, confusion, disorientation, urosepsis) (seriousness criterion hospitalization). On 25-Jan-2022, the patient experienced UROSEPSIS (Ataxia, confusion, disorientation, urosepsis) (seriousness criteria death and hospitalization). The patient died on 25-Jan-2022. The reported cause of death was 10048709. It is unknown if an autopsy was performed. At the time of death, PYREXIA (Ataxia, confusion, disorientation, urosepsis), ATAXIA (Ataxia, confusion, disorientation, urosepsis) and CONFUSIONAL STATE (Ataxia, confusion, disorientation, urosepsis) had not resolved.

Case ID	Narrative (Complete)
	Patients' medical history included hay fever, chronic heart failure NYHA I. Booster vaccination Spikevax, after previous primary immunization with Comirnaty. Development of confusion 5 hours after vaccination. During the night restlessness, ataxia. By Emergency Medical Order from Tavor. Further neurological deterioration the following day. Arrival of the family doctor in the afternoon. 40.1°C, pronounced state of confusion, ataxia, lack of trunk stability. There was antibiotic treatment for urosepsis, without ultimate stabilization. Patient died after five days. Previously stable general condition. Asthma, type 2 diabetes, and CHILD A liver cirrhosis were known but did not result in any restrictions. The rapid deterioration is at least partly attributable to the high probability of boosting. The internal medicine colleagues confirm the same in the final report. Most recent FOLLOW-UP information incorporated above includes: On 10-Mar-2022: Follow up received included no new information.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 01-Mar-2022 and was forwarded to Moderna on 01-Mar-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of VACCINATION FAILURE (Vaccination failure) in a 71-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3002616 and 214004) for COVID-19 vaccination. The patient's past medical history included Dyslipidaemia and Diffuse large B-cell lymphoma. Concurrent medical conditions included Hypertension arterial. On 08-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 20-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On 03-Jan-2022, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). The patient died on 18-Jan-2022. The reported cause of death was sars-cov2 pneumonia. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Jan-2022, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication of the patient was not reported. No treatment information was provided by the reporter. Company Comment: This regulatory case concerns a 71-year-old, female patient with relevant medical history of Hypertension and Diffuse Large B-Cell Lymphoma, who experienced vaccination failure. The event occurred 5 months, 14 days after administration of the second dose of the Moderna mRNA-1273 vaccine. The patient tested positive for SARS-CoV-2 on 03Jan2022. No further details were provided. The report stated that the patient expired on 18Jan2022 which was 15 days after she tested positive for SARS-CoV-2. It is unknown if an autopsy was performed. However, the reported cause of death was SARS-CoV2 pneumonia. The patient's advanced age (high risk for infections) and medical history of Hypertension and Diffuse Large B-Cell Lymphoma, which are risk factors for COVID-19, remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 02-Mar-2022 and was forwarded to Moderna on 02-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of VENTRICULAR FIBRILLATION (Terminal disease that directly caused death: ventricular fibrillation.) in a 78-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3001941) for COVID-19 vaccination. The patient's past medical history included Acute coronary syndrome (Intermediate Disease: Acute Coronary Syndrome) and Arteriosclerosis (Initial disease: trivasal coronary atherosclerosis.). On 24-Apr-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced VENTRICULAR FIBRILLATION (Terminal disease that directly caused death: ventricular fibrillation.) (seriousness criterion death). The patient died on 26-Apr-2021. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided. Company Comment: This regulatory authority report concerns a 78-year-old, female patient with a medical history of trivasal coronary atherosclerosis and acute coronary syndrome, who experienced the unexpected serious (Results in death) AESI of Ventricular fibrillation. The event occurred unknown number of days after a dose of mRNA-1273 VACCINE, dose number unknown. The event was reported as the "terminal disease that directly caused death", had a fatal outcome. It is unknown whether an autopsy was performed. The patient's age and medical history of trivasal coronary atherosclerosis and acute coronary syndrome, remain as confounders. The benefit-risk relationship of m mRNA-1273 VACCINE is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 16-Jun-2022: Follow up received included no new information.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DECREASED APPETITE (Loss of appetite), INCONTINENCE (Incontinence) and MUSCULAR WEAKNESS (Limb weakness) in an 84-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient had past medical history of HTN,DM, gout, and heart disease. The patient received the 1st and 2nd doses of the AZ vaccine on 16-Jun-2021 and on 16-Sep-2021 respectively.

Case ID	Narrative (Complete)
	On 17-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 22-Jan-2022, the patient experienced DECREASED APPETITE (Loss of appetite) (seriousness criterion death), INCONTINENCE (Incontinence) (seriousness criterion death) and MUSCULAR WEAKNESS (Limb weakness) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. The Worldwide UID was reported as 4.1(b) [redacted]. Concomitant product use was not provided by the reporter. On 17-Jan-2022, the patient received the 3rd dose of Moderna vaccine as booster at Clinic, 4-5 days after vaccination, he developed limb weakness and had difficulty walking. On 22-Jan-2022, he went to the emergency department. Chest X-ray showed suspected tuberculosis. Sputum test was performed and he was prescribed antibiotics and returned home. On 05-Feb, he was sent to the emergency department, due to symptoms did not improved, inappetence and incontinence. Later he was transferred to negative pressure ward for isolation due to definite diagnosis of TB. Subsequently, he died on 09-Feb-2022, due to tuberculosis an acute respiratory failure. As per FU received on 22-Feb-2022 stated that, patient's daughter-in-law wanted to apply for VICP, and the process was explained. The daughter-in-law stated she understood and paragnosis had been uploaded. The case was closed. Company comment: This Fatal Regulatory Authority case concerns a 84-year-old, male patient, with medical history of diabetes, who experienced the unexpected, serious(death) events of decreased appetite, incontinence and muscular weakness. The patient developed 4-5 days after receiving a dose of mRNA-1273 vaccine, considered as the third, booster dose of the patient's COVID-19 vaccination schedule, limb weakness and had difficulty walking for what he went to the emergency department and chest radiography showed suspected pulmonary tuberculosis. The next day a sputum test was performed, he was prescribed antibiotics and returned home, however, his symptoms did not improve, evolved with poor appetite and incontinence and he was sent to the emergency department again 19 days after vaccination. A definite diagnosis of Tuberculosis was obtained. The patient died 23 days after vaccination due to pulmonary tuberculosis and acute respiratory failure. Autopsy report is not available. It was reported that the patient received as first and second dose AstraZeneca's COVID-19 vaccine. The medical history of diabetes remains as a confounder for pulmonary tuberculosis. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received includes non significant information.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of NEUROLEPTIC MALIGNANT SYNDROME (Neuroleptic malignant syndrome) in an 86-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent conditions included diabetes, hypertension, hyperlipidemia, Parkison's disease, OA and dementia for many years with regular medical control at hospital and clinic. On 19-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Jan-2022, the patient experienced NEUROLEPTIC MALIGNANT SYNDROME (Neuroleptic malignant syndrome) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication was not reported. On 22-Jan-2022, She suffered from short of breath since last night. So visited emergency room where laboratory data showed elevated troponon-I, CPK, CK-MB and ProBNP, CXR showed no active lung lesion. In ER, DAPT with clexane and millisrol were treatment. Under impression of NSTEMI, she admitted to ICU for treatment. After admission, kept intensive care for her. millisrol pump and antiplatelet therapy were used. According to her family, she had hallucination situation at home. However, her conscious showed confuse since 23-Jan-2022 night (GCSE4M6V4). Accompanied by irritable, self-talking and whole-body trembling. Added her parkison's disease medication use and anxicam 1amp iv st also given. Fever was found on 24-Jan-2022 midnight. Infection work up was done and added antibiotic with cefuroxime was used. But she still high fever, so antibiotic shift to cefin on 24-Jan-2022. Arrange brain CT showed low densities at midbrain and pons, R/O ischemic change. Arrange abdominal echo showed chronic parenchymal liver disease and fatty liver, mild. Consulted neurology reply was treat ACS and infection, arrange brain MRI, EEG and check renal function, liver function, CPK 5. Kept Parkinson disease medication. However, hypotension was found on 24-Jan-2022 night, so stopped millisrol pump use. Suddenly, bradycardia was found, and desaturation was also noted, so bosmin, atropin and gipamin injection used. Intubation also done. ABG showed metabolic acidosis, so rolikan injection was prn used for correct acidosis. Hyperkalemia was noted, so D50W+RI and calglon injection was given. EKG showed PEA on 25-Jan-2022 noon, so did CPCR with thumper used, and bosmin injection kept used. ROSC was found at 12:33.Explained of her condition to her family, the DNR (except drug) was signed by her family. Asystole was noted in same day night, so we keep bosmin 1amp/3min iv used, but in vain. The physician suspected Neuroleptic malignant syndrome. Company Comment: This is a regulatory case concerning 86-year-old female patient with relevant medical history of Parkison's disease and dementia on regular medications, who experienced the serious fatal unexpected event of Neuroleptic malignant syndrome approximately 3 days after third dose of mRNA-1273 vaccine. To begin with she developed shortness of breath, hospitalized in ICU diagnosed with NSTEMI and treatment started accordingly. She developed confusion, was irritable, self-talking and whole body trembling was noted. Parkison's disease medication was restarted. Later she developed fever, infection work up was done and antibiotic started. Due to persistent fever and elevated serum CK, physician suspected Neuroleptic malignant syndrome. Antibiotics were changed, brain CT shows low densities at midbrain and pons.. Neuro physician consultation was taken and was advised to stabilize the ACS and control infection followed by an MRI brain. Later that night she desaturated with hypotension and bradycardia, metabolic acidosis and hyperkalemia was corrected, intubated. EKG showed PEA, CPCR was done, condition explained to patient relatives DNR was signed by them. Asystole was noted on the same day night and patient was declared dead. The patient´s age and relevant medical history of Parkison's disease and dementia on regular medications remains as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.

Case ID	Narrative (Complete)
	Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up information included no new information.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of ABDOMINAL PAIN (Abdominal pain), DYSPNOEA (Dyspnea) and MUSCULAR WEAKNESS (Limb weakness) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006K21A_1110210-CDC) for COVID-19 vaccination. Patient had a history of hypertension, which was controlled through regular medication and Patient was regularly followed for LMD he suffered from. On 09-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Feb-2022, the patient experienced ABDOMINAL PAIN (Abdominal pain) (seriousness criterion death), DYSPNOEA (Dyspnea) (seriousness criterion death) and MUSCULAR WEAKNESS (Limb weakness) (seriousness criterion death). The patient died on 19-Feb-2022. It is unknown if an autopsy was performed. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Patient presented with abdominal fullness and dull pain after COVID-19 vaccination (Moderna) on 02/09. Therefore, he visited ER on 16-Feb for progressive general weakness, dizzy and nausea now decreased urine also noted. At ER, he was clear and alert. Physical examination Splenomegaly. Hemogram showed leukocytosis (37318000/cumm) (neutrophil 1.1 percent and Lym 0.0, Blast 27%), anemia (5.5 g/dl), and thrombocytopenia (120000/cumm). Laboratory test showed elevated serum BUN/creatinine (30.1/2.46mg/dl) and Uric Acid 28.3mg/dl, CRP (6.20 mg/dl) was also noted. CT scan of abdomen revealed 1. Newly developed splenomegaly with multisegmental infarction, etiology to be determined. 2. No obvious hydronephrosis or nephrolithiasis noted. 3. Enlarged prostate gland with nondistended UB. 4. Others as above descriptions. We thus transfused him with leukoreduced packed RBC/platelet apheresis 4 units, and there was no transfusion reaction. Patient thus given empirical antibiotic. Therefore, Under the impression of Hyperleukocytosis. He was admitted to the ward for further evaluation and treatment. Patient follow up care was reported as sought medical attention at the urology division due to suspected bilateral hydronephrosis. The Worldwide UID was reported as 4.1(b) Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up received with no new information.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (Fever) in an 86-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 24-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 01-Feb-2022, the patient experienced PYREXIA (Fever) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. The patient had a fever and went to the Emergency Department on 01-Feb-2022. On 03-Feb-2022, The patient had a fever and shortness of breath and was admitted to the ICU. On 09-Feb-2022, Patient died. The follow-up care was as follows, 21-Feb-2022 Family members wanted to apply for VICP, and the dead diagnosis was uploaded. No treatment medications were reported. WWID was reported as 4.1(b) . Company Comment: This regulatory case concerns an 86-year-old, male patient with no reported medical history, who experienced the unexpected, fatal event of Pyrexia. The event occurred 8 days after receiving mRNA-1273 as a third dose of COVID-19 vaccine. The patient initially presented with fever which prompted consult to the emergency room. After 2 days he developed shortness of breath and was later admitted in the ICU. The patient died 16 days after vaccination. Clinical course leading to demise and treatment details were not provided in the case. It is unknown if autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non-significant information received.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DIZZINESS (dizziness with general weakness and consciousness drowsy since this afternoon, chest tightness, no dyspnea, fever or chillnessness), ASTHENIA (dizziness with general weakness and consciousness drowsy since this afternoon, chest tightness, no dyspnea, fever or chillnessness), DEPRESSED LEVEL OF CONSCIOUSNESS (dizziness with general weakness and consciousness drowsy since this afternoon, chest tightness, no dyspnea, fever or chillnessness) and CHEST DISCOMFORT (dizziness with general weakness and consciousness drowsy since this afternoon, chest tightness, no dyspnea, fever or chillnessness) in an 85-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported.

Case ID	Narrative (Complete)
	On 27-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 09-Feb-2022, the patient experienced DIZZINESS (dizziness with general weakness and consciousness drowsy since this afternoon, chest tightness, no dyspnea, fever or chillnessness) (seriousness criterion death), ASTHENIA (dizziness with general weakness and consciousness drowsy since this afternoon, chest tightness, no dyspnea, fever or chillnessness) (seriousness criterion death), DEPRESSED LEVEL OF CONSCIOUSNESS (dizziness with general weakness and consciousness drowsy since this afternoon, chest tightness, no dyspnea, fever or chillnessness) (seriousness criterion death) and CHEST DISCOMFORT (dizziness with general weakness and consciousness drowsy since this afternoon, chest tightness, no dyspnea, fever or chillnessness) (seriousness criterion death). The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant products were not provided. On 27-Jan-2022, the patient went to ping'an clinic of Xitun district, received Moderna COVID-19 Vaccine third dose. On 09-Feb-2022, the patient was admitted to the hospital for treatment because of dizziness with general weakness and consciousness drowsy since this afternoon, chest tightness, no dyspnea, fever or chillness. On 17-Feb-2022, the patient died. Treatment medications were not reported. The Worldwide UID number was reported as 4.1(b) [redacted] Company comment: This is a fatal regulatory case concerning a 85-year-old female patient with no reported medical history, who experienced the serious unexpected events dizziness, asthenia, depressed level of consciousness and chest discomfort, approximately 13 days after the third dose of mRNA-1273 and was admitted to the hospital for treatment. Eight days later patient died. Cause of death was not reported. It is unknown if an autopsy was performed. Patient´s advanced age remains a confounder for the events and the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up contains non significant information.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of ALTERED STATE OF CONSCIOUSNESS (Change of consciousness) in a 95-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 050F21A_1110124-CDC) for an unknown indication. Patient had a history of hypertension, heart disease and stroke. On 17-Jan-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .05 milliliter. On 19-Jan-2022, the patient experienced ALTERED STATE OF CONSCIOUSNESS (Change of consciousness) (seriousness criterion death). The reported cause of death was changes in consciousness. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication were reported Patient was admitted to hospital because he did feel like eating on November 18, 2021 and was discharged on December 7, 2021. On January 19, 2022, the staff of Fraternity Long-Term Care Center found that the patient was unconscious and sent him to the Emergency Room, when the patient had no heartbeat and breathing. The family members were assisted in applying for VICP. The Worldwide UID was reported as 4.1(b) [redacted] Company Comment: This is a regulatory authority case concerning a 95-year-old, female patient with medical history of hypertension, heart disease and stroke, who experienced the unexpected serious event of Altered state of consciousness which resulted in death. The event occurred 2 days after the first dose of mRNA-1273 COVID 19 Vaccine. Patient was found unconscious and rushed to the Emergency Room, when it was found that patient had no heartbeat and breathing. It was unknown if an autopsy was performed. The medical history of hypertension, heart disease and stroke are risk factors. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 01-Mar-2022: Upon internal Review on 09-Mar-2022, significant correction was made to update seriousness of the event Altered state of consciousness to death only. On 25-Apr-2022: Follow-up received includes non significant information.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache) in a 65-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006K21A_1110214-CDC) for COVID-19 vaccination. Concurrent medical conditions included Diabetes. On 27-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to .25 milliliter. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 27-Jan-2022, the patient experienced HEADACHE (Headache) (seriousness criterion death). The patient died in February 2022. The reported cause of death was Headache and psychogenic shock. An autopsy was performed, but no results were provided.

Case ID	Narrative (Complete)
	DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Autopsy: psychogenic shock (abnormal) psychogenic shock. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication information was provided. It was reported that patient was received two doses of Moderna vaccine and received a dose of Moderna booster at on 27-Jan-2022. After vaccination, patient had severe headache and went to a Neurology Department of clinic. He was scheduled to have further examination in the hospital on 9-Feb-2022, but on 8-Feb-2022, he had shock at the workplace. After forensic examination, it was judged to be psychogenic shock, but patient had only diabetes and did not have heart related diseases. WWID was reported as 4.1(b) . No treatment medication information was provided. Company Comment: This regulatory case concerns a 65-year-old, male patient with no reported relevant medical history, who experienced the unexpected, fatal event of Headache. The patient was reported to have complained of severe headache on the same day after receiving booster dose of mRNA-1273. He then sought medical consult at a neurology clinic where he was given unspecified medication and was scheduled at a later date for further examination. Twelve days after vaccination, the patient suddenly collapsed while at work, experienced shock and died. The clinical course leading to demise were not provided in the case. Post-mortem examination reportedly identified psychogenic shock as cause of death. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Significant follow up received updated lab details and narrative.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of RESPIRATORY FAILURE (Respiratory failure, heart failure) and CARDIAC FAILURE (Respiratory failure, heart failure) in a 93-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient has a history of chronic diseases such as hypertension, Parkinson's disease, and Alzheimer's disease; history of tobacco and alcohol: the patient quit smoking more than 10 years ago. On 15-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 22-Jan-2022, the patient experienced RESPIRATORY FAILURE (Respiratory failure, heart failure) (seriousness criteria death and medically significant) and CARDIAC FAILURE (Respiratory failure, heart failure) (seriousness criteria death and medically significant). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication details were provided. No treatment medication details were provided. The patient was diagnosed as positive pulmonary tuberculosis and renal failure. On 18-Feb-2022, the patient's son came to the Health Center to inquire about the reporting of vaccine adverse events. After consultation, he was provided with an application for victim relief to fill in. After he prepares the documents. The patient received the additional dose of Moderna vaccine on 15-Jan-2022, had insomnia at night on 22-Jan-2022, developed general weakness, drowsiness and fatigue on January 23, had cough and blood phlegm and visited General Hospital to receive chest X-ray and sputum examinations on January 24, and received computed tomography on January 25. On January 26, the patient paid a return visit, and the report indicated suspected cancer, inflammation and tuberculosis. The doctor did not prescribe any medicines, and the patient was transferred to other hospital. After reading the CT report, the doctor prescribed antibiotics for the patient to take orally, 18-Feb-2022, causes of death: respiratory failure, heart failure, pulmonary tuberculosis, renal failure. WWID was reported as 4.1(b) . Company comment: This regulatory authority case concerns an 93-year-old male patient, with history of hypertension, Parkinson's disease, and Alzheimer's disease, who experienced the unexpected fatal events of respiratory failure and cardiac failure that occurred 8 days after receiving a third dose of mRNA-1273. The patient had developed shortness of breath and breathlessness,1 week later was diagnosed as positive pulmonary tuberculosis and renal failure. Patient's computed tomography indicated suspected cancer, inflammation and tuberculosis, he was prescribed antibiotic.18-Feb-2022,causes of death: respiratory failure, heart failure, pulmonary tuberculosis, renal failure. Patient's medical history and advanced age remains as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: No new information was updated
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE KIDNEY INJURY (acute kidney injury) and HEPATITIS (acute hepatitis) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. The patient's past medical history included Chronic viral hepatitis, Chemoembolization (multiple TACE), Radiofrequency ablation (s/p Sorafenib since December 29, 2021.) on 21-Dec-2021 and Percutaneous ethanol injection therapy on 21-Dec-2021. Concurrent medical conditions included Liver cell carcinoma recurrent (CLIP 1,TNM IIIb, BCLC C, s/p resection). Concomitant products included SORAFENIB from 29-Dec-2021 to an unknown date for Liver cell carcinoma recurrent. On 12-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Feb-2022, the patient experienced ACUTE KIDNEY INJURY (acute kidney injury) (seriousness criterion death) and HEPATITIS (acute hepatitis) (seriousness criterion death). The patient died on 15-Feb-2022. The reported cause of death was Acute kidney injury and acute hepatitis. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments.

Case ID	Narrative (Complete)
	Additional details: The patient had Status post resection. On 12 Jan 2022, it was reported that patient received AZ vaccine on 28 Jun 2021, and 17 Sep 2021. Patient received Moderna vaccine on 12 Jan 2022. According to the patient, his family and previous medical record, general malaise was noted for 3 days (February 8). Accompanied symptoms included dysuria, urinary frequency and urgency. Decreased urine was also noted. Bladder pill was brought for the symptoms. However, symptoms got worsen. He was transferred from LMD due to elevated liver function. At emergency department, his consciousness was clear and vital signs showed BP: 113/72 mmHg; HR: 96/Min; RR:25; BT:34. Laboratory data revealed leukocytosis with elevation of CRP and acute kidney injury. Urinalysis showed pyuria. Elevation of AST: 1880 and ALT: 460 were also noted. Bedside echo: preserved LV contractility, pericardial effusion around 1.2-1.5cm, posterior, no tamponade sign. Chest Xray: bilateral pleural effusion. Abdominal computed tomography: pericardial effusion, normal bowel wall enhancement over small/large bowel. Under the impression of acute kidney injury with severe metabolic acidosis, acute liver failure and urinary tract infection, he was admitted to intensive care unit for planning continuous venous venous hemofiltration since 12 Feb. On 12 Feb 2022 After admitted, he received continuous renal replacement therapy for acute kidney injury and ongoing lactate acidosis, empirical antibiotics with Tazocin (12 Feb to 14 feb) then changed to Meropenem (Feb 14-) + doxycycline (Feb 12-) + teicoplanin (Feb 14-) for severe shock, BiPAP support for dyspnea, deep and shallow but family refused intubation. It was also consulted infection for suspecting atypical infection related renal and liver failure, could not rule out leptospirosis with J-H reaction, multi-organ failure, DIC and refractory lactate acidosis, suspected ongoing hemophagolymphohistiocytosis; also needed to rule out occult autoimmune disease triggered by COVID-19 vaccine, which suggested to keep meropenem + doxycycline, check stool E.coli O157:H7, Campylobactor and vibrio culture due to stool routine found dysentery appearance, check ANA, C3, C4, RF, IgG/A/Mfor basic autoimmune disease survey; if positive on ANA, consult rheumatologist for complete autoimmune profile survey. Consulted GI for acute liver failure, and abdomen CT suspected liver abscess or tumor necrosis, then bedside sono was done showed hyperechoic lesion, suspected tumor. CV men also consulted for pericardial effusion, who prefer chronic, not acute episode. Progressive metabolic acidosis, change to CVVH-DF since 12 Feb, septic shock progress with ongoing lactate acidosis, high dose inotropic agent was given, the family had been informed about his current condition again on 14 Feb, they preferred DNR (refused intubation) and palliative care. The patient had found ventricular fibrillation then asystole at 08:55 on 15 Feb 2022, critical AAD (against advise discharge) was arranged on 15 Feb 2022. On 17 Feb 2022 the family said the patient died on 15 Feb possibly of renal injury. The patient had no history of chronic diseases. The family was told about VICP, and the family wanted to apply for it. On 24, Feb 2022 is the date that public health workers tried to contact the patient and found that he had died. Cause of death: Urinary tract infection with septic shock, acute kidney injury, liver cancer, acute hepatitis. Company comment: This regulatory authority case concerns a 75 year old male with relevant medical history of Chronic viral hepatitis, Chemoembolization (multiple TACE), Radiofrequency ablation (s/p Sorafenib since December 29, 2021.) on 21-Dec-2021 and Percutaneous ethanol injection therapy on 21-Dec-2021, Liver cell carcinoma recurrent (CLIP 1,TNM IIIb, BCLC C, s/p resection).and also initially vaccinated with two dose of Covid 19 vaccine Astra Zeneca , who experienced Serious (fatal) , unexpected, AESI events of Acute Kidney injury and hepatitis which occurred 27 days post vaccination with the 3rd dose of mRNA-1273 vaccine. This patient initialy had general malaise accompanied by dysuria, urinary frequency and urgency, decrease in urine output was also noted. An unknown medication was given however symptoms worsen. He was brought to the ER due to elevated liver function. and at the emergency department, he was conscious with the following vital signs BP: 113/72 mmHg; HR: 96/Min; RR:25; BT:34. Laboratories and diagnostic procedures were performed with the results. CBC : revealed leukocytosis, elevated CRP and acute kidney injury. Urinalysis showed pyuria. Elevation of AST: 1880 and ALT: 460 were also noted. Bedside echo: preserved LV contractility, pericardial effusion around 1.2-1.5cm, posterior, no tamponade sign. Chest Xray: bilateral pleural effusion. Abdominal computed tomography:pericardial effusion, normal bowel wall enhancement over small/large bowel. Under the impression of acute kidney injury with severe metabolic acidosis, acute liver failure and urinary tract infection, he was admitted to the intensive care unit underwent continuous venous venous hemofiltration. During his admission he received continuous renal replacement therapy for acute kidney injury and ongoing lactate acidosis. He was started on empirical antibiotics with tazocin then change to meropenem + doxycycline + teicoplanin under the impression of severe shock, BiPAP support for dyspnea since family refused intubation. An infectious disease service was consulted for suspecting atypical infection related to renal and liver failure, cannot rule out leptospirosis with J-H reaction, multi-organ failure, DIC and refractory lactate acidosis, An ongoing hemophagolymphohistiocytosis; also needs to be ruled out occult autoimmune disease triggered by COVID-19 vaccine,. The infectious disease service continued meropenem + doxycycline, check stool E.coli O157:H7, Campylobactor and vibrio culture due to stool routine found dysentery appearance,. Also ANA, C3, C4, RF, IgG/A/Mfor basic autoimmune disease survey; was requested if it turns out positive need to be seen by rheumatologist for complete autoimmune profile survey. Consult to GI service for his acute liver failure, and abdomen CT suspect liver abscess or tumor necrosis. A bedside ultrasound was done which showed hyperechoic lesion, suspect tumor. Cardiovascular service also consulted for pericardial effusion, who said it is a chronic, not acute episode. Progressive metabolic acidosis, change to CVVH-DF renal treatment and septic shock progress with ongoing lactate acidosis High dose inotropic agent was given. Due to the deteriorating situation of the patient the family was informed of the prognosis and DNR was signed and refusal for intubation , They just opted palliative care .The patient was found to have ventric
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDITIS (Myocarditis) in an 84-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 11-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Subcutaneous) 1 dosage form. On 18-Jan-2022, the patient experienced MYOCARDITIS (Myocarditis) (seriousness criteria death and life threatening). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Subcutaneous), the reporter considered MYOCARDITIS (Myocarditis) to be related. Worldwide UID was reported as 4.1(b) [redacted]. No concomitant and treatment medication was reported by patient. It was reported on 18Jan2022, patient developed shortness of breath after 3 dose of Moderna vaccination. On 17Jan2022, patient had cough, decreased urine output and bil legs edema and was sent to MER for help then admission. On 17Feb2022, In the morning a phone call was made to care the family member that was the daughter-in-law of the patient. The family member reported that dyspnea and swollen hands and feet began about one week after the vaccine was administered. The patient went to the emergency room of Cardinal Tien Hospital for first aid on 24Jan2022 and was transferred to the general ward after the conditions was stable and the patient was hospitalized. On 24Feb2022, in the morning the wife of the patient called to informed that the patient died on February 19, 2022. They intended to apply for (VICP), and the required documents was told and it was agreed to send the documents around 3:00 pm on March 2. On February 25,2022, the subsequent adverse event consequence death was maintained. Company Comment: This regulatory case concerns an 84-year-old, female patient with no medical history reported, who experienced the unexpected, serious (fatal and life-threatening) AESI of myocarditis. The event occurred 1 week after administration of the third dose of the Moderna mRNA-1273 vaccine. The patient experienced shortness of breath, cough, decreased urine output and bilateral leg edema. The patient was brought to the Emergency room on 24Jan2022 for first aid treatment. She was then transferred to the general ward after stabilization. Laboratory test/s done and treatment

Case ID	Narrative (Complete)
	information were not provided. The patient expired on 19Feb2022 which was 1 month, 8 days after vaccination. The cause of death was not provided. It is unknown if an autopsy was performed. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this r Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non significant follow up appended on 25-APR-2022, contains no new information.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of CONSCIOUSNESS FLUCTUATING (Changes of consciousness) in a 79-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient with a history of diabetes and hypertension and long term neurology outpatient visit (suspected dementia). On 12-Feb-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Feb-2022, the patient experienced CONSCIOUSNESS FLUCTUATING (Changes of consciousness) (seriousness criterion death). It is unknown if an autopsy was performed. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Company Comment: This regulatory authority case concerns a 79-year-old female patient, with medical history of diabetes, and hypertension, who experienced the serious (fatal), unexpected event of changes in consciousness. Patient initially experienced vomiting and dyspnea on the same day after receiving first dose of mRNA 1273 COVID-19 vaccine. She was then found unconscious by dependents and was sent to the hospital. At arrival to the hospital, patient was comatose, pupil dilated without light reflex. Endotracheal intubation was done and patient received Adrenalin 10 times until CPR was stopped. Patient was diagnosed to have Cardiac arrest (heartbeat stopped) due to unknown cause. Preliminary forensic analysis report showed that Cause of Death was massive pulmonary thromboembolism and Cardiomegaly, judicial autopsy was performed. The patient's age and history of diabetes and hypertension remain as confounders to the patient's death. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non-significant follow-up appended: Event verbatim updated.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache) and FEELING COLD (Chillness) in a 93-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 2100685_1110308-CDC) for an unknown indication. No Medical History information was reported. On 15-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Feb-2022, the patient experienced HEADACHE (Headache) (seriousness criterion death) and FEELING COLD (Chillness) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. February 17, 2022 The patient developed tiredness, weakness and fever on the morning of February 16 after receiving the booster vaccine on February 15. The patient's family called an ambulance and sent the patient to Zuoying Branch of Kaohsiung Armed Forces General Hospital for general weakness. The patient died on the way to the hospital. The family said the patient had cardiovascular, blood glucose and blood pressure problems and had been controlling them well with long-term medication. They suspected that the sudden death was caused by the vaccine, so they wanted to apply for VICP (we sent them the application form), and reported to the District Office. No treatment information was reported. The Worldwide UID was reported as 4.1(b) [redacted]. Company comment: This fatal regulatory authority case concerns a 93-year-old male patient, with relevant medical conditions of cardiovascular disorder, and unspecified blood glucose and blood pressure problems. Reported fatal events of headache and feeling cold occurred the day after receiving a booster dose of mRNA-1273. According to source document narrative, patient was fatigued and weak the day after vaccination and died on an ambulance on his way to the Hospital. No cause of death was provided. It is unknown if an autopsy was performed. Patient's advanced age and relevant medical conditions remain as confounders. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up contains no new information.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death before arriving at hospital) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 06-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on 23-Aug-2021 The patient died on 23-Aug-2021. The reported cause of death was Cardiogenic shock. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Regulatory Authority number-4.1(b) [redacted] Concomitant information was not provided by reporter.

Case ID	Narrative (Complete)
	The family member complained that the patient had asthma and fatigue symptoms about a week after the vaccination. On 29-July-2021: the patient came to the emergency department for consultations and treatments due to epigastric pain, cold sweat, extreme discomfort and was diagnosed with acute myocardial infarction. After being diagnosed by the doctor, the patient had NSTEMI and was recommended to receive cardiac catheterization. The patient family refused and requested, so the patient was discharged. Later, the symptoms were not improved. The patient went to the cardiology department, attending physician told that the cardiac discomfort of the patient was suspected to be adverse reactions induced by vaccination. On 23-August-2021, the patient was unwell again and was sent to hospital, and the patient died before arriving at the hospital, and the first aid was ineffective. The cause of death was cardiogenic shock. No treatment medication information was provided by reporter. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up included cause of death, event stop date added and I-narrative updated. Company Comment: This regulatory case concerns a 72-year-old female patient with no medical history reported, who died 48 days after receiving the first dose of mRNA-1273 vaccine. The patient experienced asthma and fatigue symptoms one week after vaccination, and two weeks later, Epigastric pain and cold sweats. She was taken to emergency department and diagnosed as having Non-ST elevation myocardial infarction, was recommended cardiac catheterization. The patient's family refused and decided to shift the patient to another hospital and cardiac stent placed there. Post procedure, the symptoms did not improve, and she was on follow-up every 2 days. Subsequently, she was unwell again and while shifting to hospital died on the way. First aid was ineffective. She was declared dead due to cardiogenic shock. There was no information if an autopsy was done. Elderly age of the patient could be a risk factor. Details of concurrent conditions, concomitant medications, clinical course, Investigation reports and treatment details were not provided. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 01-Mar-2022 and was forwarded to Moderna on 01-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (tired and listless) in a 67-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004951) for COVID-19 vaccination. Patient had current conditions of mild asthma,type 2 diabetes. On 05-MAR-2016 a small stroke without permanent damage. The patient's past medical history included Apoplectic fit in 2016. Previously administered products included for Prophylactic vaccination: COVID-19 Vaccine Janssen Injektionssuspension COVID-19 Vaccine JanssenCOVID-19-Impfstoff Ad26.COV2-S on 16-Jun-2021. Past adverse reactions to the above products included No adverse event with COVID-19 Vaccine Janssen Injektionssuspension COVID-19 Vaccine JanssenCOVID-19-Impfstoff Ad26.COV2-S. On 01-Dec-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 02-Dec-2021, the patient experienced CEREBROVASCULAR ACCIDENT (tired and listless) (seriousness criterion death). The patient died on 09-Dec-2021. The reported cause of death was Apoplectic fit. It is unknown if an autopsy was performed. Concomitant medications were not reported. It was reported that person was alone and felt unwell and weak one day after the vaccination and lay down around noon. Patient was diagnosed in the night with severe stroke. Patient was in coma for a week and died on 09Dec2021. Treatment medications were not reported. Company Comment: This regulatory case concerns a 67-year-old, male patient with relevant medical history of Stroke (Apoplectic fit) without permanent damage (2016) and Type 2 Diabetes Mellitus (T2DM), and past drug history of administration of a dose of the Janssen COVID-19 vaccine, who experienced the unexpected, serious (fatal) AESI of cerebrovascular accident. The event occurred 1 day after administration of the second dose of the Moderna mRNA-1273 vaccine. The patient felt unwell and weak, and lay down around noon. On the same evening, the patient did not answer calls and did not answer when the doorbell rang. He was brought to the clinic and was diagnosed with 'severe stroke'. Laboratory test/s and treatment information were not provided. The report stated that the patient was in a coma for a week and expired on 09Dec2021 (8 days after vaccination). It is unknown if an autopsy was performed. However, the reported cause of death was 'Apoplectic fit'. The patient's medical history of Stroke (Apoplectic fit) and T2DM, and past drug history of administration of a dose of the Janssen COVID-19 vaccine remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 03-Mar-2022 and was forwarded to Moderna on 03-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of PYREXIA (Fever), HYPOXIA (Hypoxia) and DYSPNOEA (Dyspnea) in an 83-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 017G21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Coagulation disorder, Stroke in 2021, Transient ischaemic attack in 2019, Thyroidectomy total in 2019 and Transfusion in December 2021. Previously administered products included for COVID-19 immunisation: Comirnaty from 09-Mar-2021 to 06-Apr-2021. Past adverse reactions to the above products included No adverse event with Comirnaty. Concurrent medical conditions included Lymphoma (medullary lymphoma). On 26-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 dosage form. On 26-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). On 29-Jan-2022, the patient experienced PYREXIA (Fever) (seriousness criterion death). On 30-Jan-2022, the patient experienced HYPOXIA (Hypoxia) (seriousness criteria death and medically significant) and DYSPNOEA (Dyspnea) (seriousness criterion death). On 26-Jan-2022, COVID-19 IMMUNISATION (Revaccination

Case ID	Narrative (Complete)
	with different COVID-19 vaccine) had resolved. The patient died on 30-Jan-2022. The reported cause of death was Transfusion, Chemotherapy, Fever, COVID-19 immunisation and medullary lymphoma. An autopsy was not performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. Dosage text given as R1. Company Comment: This is an RA case concerning a -83year-old, female patient with a history of medullary lymphoma, coagulation disorder, total thyroidectomy (2019), TIA (2019), stroke (2021) and transfusion in Dec/2021. After completing primary vaccination with Pfizer vaccine in April 2021, patient received the third dose of mRNA1273 on 22JAN2022 and 3 days later starts presenting fever. The day after she experienced dyspnea with hypoxia. All the events were reported as fatal and causes of death were transfusion, chemotherapy, lymphoma, COVID-19 vaccination and fever. Date of death was not reported. Patient's medical history is a cofounder as not only she had several comorbidities which lead to a frail state, but also it appears that the Lymphoma was still ongoing and being treated with chemotherapy. Cancer and chemotherapy are immunosupressors potentializing the frail state and increasing the risk of death due to other causes. Event seriousness captured according RA assessment. No treatment medications were reported. Reporter mentioned Causality as Method of assessment includes FRENCH IMPUTABILITY METHOD and Result of Assessment includes C2 S1 (I1 dubious) B2.
4.1(b) [redacted]	This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Death), EXTENSIVE SWELLING OF VACCINATED LIMB (Extensive swelling of vaccinated limb) and PNEUMONITIS (Pneumonitis) in a 95-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. The patient's past medical history included Femur fracture on 15-Nov-2021. Concurrent medical conditions included Diabetes, Dementia Alzheimer's type, Normochromic normocytic anaemia, Chronic renal failure, Cardiomyopathy (Rhythmogenic and hypertensive cardiopathy in sinus arrest with ventricular escape rhythm) in 2015, Arterial hypertension and Dyslipidaemia. Concomitant products included METAMIZOLE SODIUM (NOVALGINA), ENOXAPARIN SODIUM (CLEXANE), QUETIAPINE FUMARATE (SEQUASE), CANDESARTAN CILEXETIL (CANDESARTAN TAKEDA), BISOPROLOL FUMARATE (CONCOR), DULOXETINE HYDROCHLORIDE (DULOXETIN MEPHA), METFORMIN HYDROCHLORIDE (METFORMIN-MEPHA), RISPERIDONE (RISPERIDON MEPHA), LINAGLIPTIN (TRAJENTA) and INSULIN ASPART, INSULIN DEGLUDEC (RYZODEG) for an unknown indication. On 19-Nov-2021, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form once a day. On 19-Nov-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced EXTENSIVE SWELLING OF VACCINATED LIMB (Extensive swelling of vaccinated limb) (seriousness criterion death). On 01-Dec-2021, the patient experienced PNEUMONITIS (Pneumonitis) (seriousness criterion death). The patient died on 02-Dec-2021. It is unknown if an autopsy was performed. The patient had chronic renal failure (KDIGO G3Ax), hypertensive (in sinus arrest with ventricular escape rhythm, 2015). Patient known for recent femoral fracture (Displaced, multi-fragmentary periprosthetic spiral fracture in the distal third of the femoral shaft on the left, Vancouver type C) on 15.11.21 for which it was hospitalized (15-23.11.21) and operated. The course was favorable. Received the recall of the vaccination with Spikevax on 19.11.2021, batch number not known. There is no known information on previous dosages (probably always Spikevax). In the spring of 2021 patient first showed swelling at the neck with subsequent extension of swelling to his left arm. The patient was asymptomatic. At the will of the patient, further investigations were given up. However, the patient's niece reports that swelling in neck (and later left arm) occurred a few days after the first dose of the covid-19 vaccine, and then regress and reappear is after the second dose (with subsequent regression) and after the booster (with subsequent regression). On 01.12.21 the patient experienced a rapid and sharp deterioration in clinical status with predominantly respiratory symptomatology. As a possible cause, an infectious aspiration pneumonitis is predominantly suspected, in differential diagnosis, an extension of the suspected thyroid tumour also to the trachea. We undertake antibiotic treatment with Doxycyclin and supportive measures. However, there was a rapid clinical deterioration leading to the death of the patient on 02.12.21. Not known if an autopsy is performed. Sender's Comment:Patient had swelling in the neck, later extended to the left arm, appeared a few days after the booster dose of Spikevax vaccine and then regressed. The problem had already occurred after the first two doses of vaccine (positive rechallenge). "senders comment continued in reporter comment for inarrative". A sonography showed the suspicion of possible tumour starting from the thyroid gland and extension in the mediastinal direction, however not further investigated, for which the definitive diagnosis was not known. As the Swiss monograph describes, Spikevax is known to both swollen at the vaccination site and swollen lymph nodes, which usually occur in the axillary cord homolateral at the site of vaccination but lymphadenopathies were also reported at the neck [1,2]. Since we cannot be completely sure of the tumor diagnosis, we believe we cannot exclude a role of the vaccine in the swelling manifested by the patient, given also the suggestive time correlation and the swinging trend (symptom appear/disappearance) at each administration of the vaccine, so we consider the causal link possible. After 12 days after the booster dose, the patient also experiences a deterioration in the clinical state, with predominantly respiratory symptoms that make people think of aspiration pneumonitis and so antibiotic treatment was undertaken. In differential diagnosis, a role of suspected thyroid tumour with tracheal extension (however not investigated). The clinical situation worsens rapidly and we see the patient's death the next day. Pneumonitis was not an adverse reaction described for Spikevax either in a Swiss, European or American monograph as well as in the Upto Date database. Research in Pubmed does not show cases of pneumonia/lung infections following COVID-19 vaccines. Aspiration pneumonitis has an infectious (bacterial) or mechanical origin (obstruction): in this case we have no indications about the infectious agent but the symptomatology was treated with doxycyclin. Despite plausible time correlation, in the absence of data to support and sight, a likely infectious cause (or in tumor differential diagnosis) as well as the patient's advanced age and multiple co-morbidity, the causal link between Spikevax and the death of the patient is unlikely.

Case ID	Narrative (Complete)
	Company comment: This fatal regulatory authority case concerns a 95-year-old female patient with relevant medical history of diabetes, dementia Alzheimer's type, anaemia, chronic renal failure, rhythmogenic and hypertensive cardiopathy, arterial hypertension and dyslipidaemia, who experienced serious due to death, unexpected events of death, extensive swelling of vaccinated limb and pneumonitis. The events occurred after the 3rd dose of the mRNA-1273. Reportedly, the patient experienced neck and left arm swelling after every dose of vaccine administered, suggesting positive rechallenge for the event of extensive swelling of the vaccinated limb. Reportedly, 12 days after the 3rd dose, the patient developed a rapid and sharp deterioration of his health with predominantly respiratory symptomatology. Differential diagnosis included infectious aspiration pneumonitis and suspected thyroid tumor progression to trachea. The patient was treated with antibiotics and supportive measures however, there was rapid clinical deterioration and the patient passed away a day later. It was not known whether autopsy was performed. The patient's advanced age and relevant medical history is a possible confounder for the events. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events reported and seriousness assessment retained as per regulatory authority reporting. This case was linked to 4.1(b) (E2B Linked Report). Most recent FOLLOW-UP information incorporated above includes: On 29-Mar-2022: Follow-up document received, updated patient demographics, added medical history, updated event verbatim, start date, stop date and coding for the event of (Extensive swelling of vaccinated limb), added new event of pneumonitis, concomitant medications, removed events of (headache and dyspnea) updated suspect drug details (dose description and rechallenge result), reporter causality for the events and narrative was updated.
4.1(b)	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 03-Mar-2022 and was forwarded to Moderna on 03-Mar-2022. This spontaneous case was reported by a nurse and describes the occurrence of DEATH (Passed away) in an 87-year-old patient of an unknown gender who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 050E21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Atrial fibrillation and Acute kidney failure. In November 2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced DEATH (Passed away) (seriousness criteria death and medically significant) and EXPIRED PRODUCT ADMINISTERED (34 patients were administered from an expired vaccine\16 staff members were administered from the expired vaccine). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, EXPIRED PRODUCT ADMINISTERED (34 patients were administered from an expired vaccine\16 staff members were administered from the expired vaccine) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. 50 expired vaccine doses were administered to patients and staff. Date the vial was initially stored in the refrigerator: 04-Nov-2021. Date(s) of administration of vaccine was reported as some 05-Nov-2021 and the other doses on 12-Nov-2021. Vial did not undergo any temperature excursions. No any adverse event as a result of this misadministration, patients were monitored. Company Comment: This spontaneous case concerns a 87 year old patient with unknown gender with relevant medical history of atrial fibrillation and Acute kidney injury , who experienced Serious (fatal) unexpected event of Death which occurred on an unknown date after vaccination with an unknown dose number of mRNA-1273. Non-serious , unexpected event of expired product administered was reported for this case. I t was reported that 50 expired vaccine doses were administered to patients and staff. The vial was initially stored in the refrigerator and the next day it was administered and other doses 7 days after. The vial did not undergo any temperature excursions. No adverse event as a result of this misadministration was reported and the patients were monitored. This patient being reported was included in the list of the patients who received the expired product. The date and the cause of death of this patient was not reported and it is unknown if an autopsy was done. The details surrounding the event of death were not reported. The medical history of atrial fibrillation , age and acute kidney failure are considered confounders for the event of death (ageing and these medical conditions can lead to this death) . The administration of expired vaccine may also be considered a confounder however as mentioned above the patients were closely monitored and no report of adverse events noted after the incident. The benefit -risk relationship of mRNA -1273 is not affected by report. This case was linked to 4.1(b) (Patient Link).
4.1(b)	This spontaneous case was reported by a nurse and describes the occurrence of DEATH (patient passed away) in a 77-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 050E21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. In November 2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. In November 2021, the patient experienced EXPIRED PRODUCT ADMINISTERED (patient was administered from an expired vaccine /misadministration). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, EXPIRED PRODUCT ADMINISTERED (patient was administered from an expired vaccine /misadministration) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. it was reported that the dose administered was after 30-day use by date or after manufacturer date of expiry.

Case ID	Narrative (Complete)
	50 expired vaccine doses were administered to patients and staff. Date the vial was initially stored in the refrigerator: 04-Nov-2021. Date(s) of administration of vaccine was reported as some 05-Nov-2021 and the other doses on 12-Nov-2021. Vial did not undergo any temperature excursions. No adverse event was reported as a result of this misadministration, patients were monitored. Company comment: This is a case of Expired product administered for this 77-year-old male patient, with no medical history reported, who died after the administration of a dose of mRNA-1273 vaccine. It was reported that vaccine was administered after 30-day Use By Date or after manufacturer date of expiry. The patient received a dose in November 2021, he died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. Very limited information regarding this event has been provided at this time, further information has been requested. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) (Patient Link).
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of 4.1(b)) in a 65-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 061621A) for an unknown indication. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for an unknown indication. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form and dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On an unknown date, received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to 1 dosage form. On 30-Jan-2022, the patient experienced 4.1(b) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. ATC code for Tozinameran and Elasomeran were J07BX. Vaccine was administered on 20 Aug 2021 and 10 Sep 2021. No treatment information was provided. Company comment: This is a regulatory case concerning a 65-year-old male patient with no reported medical history, who experienced the fatal event 4.1(b) , more than 4 months after receiving dose of mRNA-1273. Death date and cause of death were not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of PYREXIA (Fever 38 C) in a 65-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 15-Dec-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 20-Jan-2022, received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 04-Feb-2022, the patient experienced PYREXIA (Fever 38 C) (seriousness criterion death). It is unknown if an autopsy was performed. No concomitant medication provided. No treatment information mentioned. Company comment: This is a fatal regulatory authority case of inappropriate schedule of product administration (36-days interval) concerning a 65-year-old male patient with no medical history reported who experienced the unexpected and serious (death) event of pyrexia 15 days after a second dose of mRNA-1273 vaccine was administered. It is not known if an autopsy was performed. The date of death is unknown. No further details were provided for medical reviewing. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 03-Mar-2022. The most recent information was received on 19-Apr-2022 and was forwarded to Moderna on 25-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by an anatomist, was received via the PMDA (Ref, 4.1(b)). On 19-Apr-2022, follow-up information was received from a medical examiner. The vaccine recipient was taking oral medication for Parkinson's disease and epilepsy. Adherence was in good condition, and no epileptic seizure developed. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.3 degrees Celsius. On 23-Feb-2022, at 17:20, the patient received the 3rd vaccination with this vaccine. The patient went home after the vaccination. After that, there was nothing unusual. Around 19:00, the patient had no appetite at dinner. Around 23:00, the patient was nodding off sitting in a legless chair. On 24-Feb-2022, around 02:00, the patient took a bath. Around 02:30, lethal arrythmia developed, and it was presumed that the patient died at this time. Around 07:00, when a family member went to the bathroom, the lights were on, and the patient was found to be in a state of cardiopulmonary arrest sitting with the knees drawn up to the chest in the bathtub. An emergency call was made immediately, but the patient was confirmed dead. On an unknown date, autopsy showed findings of acute death and Parkinson's disease. Acidophilic changes of the myocardium and mild to moderate fat infiltration in the right ventricle were found while there were no fibrosing myocardium and findings of aspiration of water by near-drowning. The cause of death was lethal arrythmia. On 25-Feb-2022, sodium valproate and ropinirole hydrochloride were detected in analysis of drugs and toxic substances in the blood by LC/MS and GC/MS. The blood concentration of sodium valproate was 3.48 mcg/mL. The results of alcohol testing were negative both in urine and blood. The outcome of inappetence was unknown. The outcome of state of cardiopulmonary arrest and lethal arrhythmia was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: Therefore, the patient is considered to have experienced lethal arrythmia rather than near-drowning due to loss of consciousness caused by epileptic seizure or the like. It is known that patients with epilepsy may die suddenly (SUDEP), and involvement of SUDEP cannot also be ruled out. The patient reportedly had inappetence after the vaccination with this vaccine, and subsequently she died while taking a bath. In addition, the patient had a history of epilepsy. Some elderly people may die while taking a bath and some patients with epilepsy may die suddenly, and these possibilities cannot also be ruled out. However, the patient died after the vaccination with this vaccine, and considering the time sequence, it may be reasonable to consider that this vaccine may have affected the death to some extent. At least, it is considered impossible to conclude that there was no causal relationship at all.

Case ID	Narrative (Complete)
	Follow-up received on 19-APR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 03-Mar-2022. The most recent information was received on 29-Mar-2022 and was forwarded to Moderna on 06-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 19-Mar-2022, follow-up information, reported to Takeda by a physician, was received via the Moderna's adverse reaction reporting site (4.1(b)). On 29-Mar-2022, follow-up information was received from a physician. On 22-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 13-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 19-Feb-2022, the patient received a regular exam. The patient's condition was stable. On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius. On 26-Feb-2022, around 11:10, the patient received the 3rd vaccination with this vaccine. The patient returned home without any particular problems. Around 27-Feb-2022, the patient died suddenly. On 01-Mar-2022, in the morning, the patient was found lying dead on the hallway at home. On an unknown date, after postmortem inspection, it was determined that the patient died of natural causes and that she died between 27-Feb-2022 and the morning of 28-Feb-2022. No necropsy was performed. The cause of death was cardiac valvulopathy. The outcome of cardiac valvulopathy was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: Although sudden death may occur naturally considering that the patient was at an old age with underlying diseases, it is likely that the patient died on the next day of the vaccination, and the causality to this vaccine cannot be ruled out. The patient originally lived alone, and the patients condition since returning home after the vaccination is unknown. Other possible causes include advanced age, cardiac valvulopathy, and cerebrovascular disorder. Since the patient died on the next day or two days after administration of the vaccine, the occurrence of the adverse event is temporally related to the timing of administration of the vaccine. Some drugs were started on 19-Feb-2022, but there were no particular problems for a week, so the occurrence of the adverse event is not related to concomitant drugs. Since there is no information on symptoms leading to the death, the relationship between the occurrence of adverse events and pathological factors of underlying diseases and complications is unknown. There is no relationship between the cause of death and the adverse event. Since the patient died on the next day or two days after vaccination with this vaccine, it is considered that an adverse event cannot be ruled out. Follow-up received on 19-MAR-2022 Updated: Patient Information, Other Relevant History, Narrative Follow-up received on 29-MAR-2022 Updated: Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Sudden death can be also considered as an accidental disease although it developed after the administration of ELASOMERAN.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-Mar-2022 and was forwarded to Moderna on 04-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of STATUS EPILEPTICUS (on 14.12.2021 she was hospitalized: diagnosis of encephalitis & status epilepticus.), ENCEPHALITIS (on 14.12.2021 she was hospitalized: diagnosis of encephalitis & status epilepticus.) and BRAIN INJURY (on 14.12.2021 she was hospitalized: diagnosis of encephalitis & status epilepticus.) in a 69-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent condition includes obesity, high blood pressure and depression. On 06-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Dec-2021, the patient experienced STATUS EPILEPTICUS (on 14.12.2021 she was hospitalized: diagnosis of encephalitis & status epilepticus.) (seriousness criterion hospitalization), ENCEPHALITIS (on 14.12.2021 she was hospitalized: diagnosis of encephalitis & status epilepticus.) (seriousness criterion hospitalization) and BRAIN INJURY (on 14.12.2021 she was hospitalized: diagnosis of encephalitis & status epilepticus.) (seriousness criteria death and hospitalization). The patient was hospitalized on 14-Dec-2021 due to BRAIN INJURY, ENCEPHALITIS and STATUS EPILEPTICUS. The patient died on 04-Jan-2022. The reported cause of death was Brain injury. It is unknown if an autopsy was performed. At the time of death, STATUS EPILEPTICUS (on 14.12.2021 she was hospitalized: diagnosis of encephalitis & status epilepticus.) and ENCEPHALITIS (on 14.12.2021 she was hospitalized: diagnosis of encephalitis & status epilepticus.) had not resolved. Concomitant product use was not provided by the reporter. Reporter stated that 8 days after vaccination, the patient experienced loss of speech, slight confusion. Hospitalization, diagnosis: encephalitis, status epilepticus. Patient died on 04Jan2022, as epilepticus status could not be broken and massive brain damage had to be assumed. Dosage text: 3 No treatment information was provided. Company Comment: This regulatory case concerns a 69-year-old, female patient with no relevant medical history, who experienced the unexpected, serious (fatal and hospitalization) event of brain injury, and the unexpected, serious (hospitalization) AESI of status epilepticus and encephalitis. The events occurred 8 days after administration of the third dose of the Moderna mRNA-1273 vaccine. The patient experienced loss of speech and slight confusion. She was hospitalized and the diagnosis was Encephalitis and Status epilepticus. Laboratory test/s and treatment information were not provided. The patient expired on 04Jan2022 (29 days after vaccination) since the status epilepticus could not be controlled and massive brain damage had to be assumed. The reported cause of death was Brain injury. It is unknown if an autopsy was performed. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 04-Mar-2022. The most recent information was received on 04-Mar-2022 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) and PULMONARY EMBOLISM (LUNG EMBOLISM) in a 74-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 023F21A) for COVID-19 vaccination. The patient's past medical history included COVID-19 immunisation (Vaxzevria dose 1) on 12-Apr-2021 and COVID-19 immunisation (Vaxzevria dose 2) on 21-Jun-2021. Concurrent medical conditions included Hypertension. Concomitant products included HYDROCHLOROTHIAZIDE, LOSARTAN POTASSIUM (LOSARTAN/HYDROCHLOROTHIAZIDE), AMLODIPINE and METOPROLOL for an unknown indication.

Case ID	Narrative (Complete)
	In December 2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In December 2021, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) (seriousness criterion death). In January 2022, the patient experienced PULMONARY EMBOLISM (LUNG EMBOLISM) (seriousness criterion death). The reported cause of death was Pulmonary embolism. An autopsy was performed, but no results were provided. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment drug details was reported. Company Comment: This case concerns a 74-year-old, female patient with reported relevant medical history of Hypertension, who experienced the fatal serious unexpected event of Pulmonary embolism. The event occurred in an unknown date during the next month after the administration of dose of the mRNA-1273 vaccine (third dose of COVID-19 vaccine; previous primary vaccination with Vaxveria). Cause of death was provided as Pulmonary embolism. An autopsy was performed, but no results were provided. Revaccination with different COVID-19 vaccine was also reported as an event. Reported medical history remains as a confounder for the event. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Mar-2022: Upon query received from business partner, significant correction was performed on 10-Mar-2022. The autopsy details was updated in the company comment.
4.1(b)	This case was received via Health Canada (Reference number: 4.1(b)) on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by a nurse and describes the occurrence of AGITATION (Agitation), APNOEA (Apnoea), BREATH SOUNDS ABNORMAL (Breath sounds abnormal), CHEYNE-STOKES RESPIRATION (Cheyne-Stokes respiration), ERYTHEMA (Erythema), HAEMATOMA (Haematoma), HYPOTENSION (Hypotension), JUGULAR VEIN DISTENSION (Jugular vein distension), LETHARGY (Lethargy), MOANING (Moaning), OEDEMA PERIPHERAL (Oedema peripheral), PULMONARY EMBOLISM (Pulmonary embolism), STUPOR (Stupor) and TACHYPNOEA (Tachypnoea) in an 85-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 immunisation. Co-suspect product included non-company product INFLUENZA VACCINE INACT SPLIT 4V (FLUZONE HIGH DOSE QUADRIVALENT) for an unknown indication. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) .5 milliliter and dose of INFLUENZA VACCINE INACT SPLIT 4V (FLUZONE HIGH DOSE QUADRIVALENT) (Intramuscular) .5 milliliter. On an unknown date, the patient experienced AGITATION (Agitation) (seriousness criterion death), APNOEA (Apnoea) (seriousness criterion death), BREATH SOUNDS ABNORMAL (Breath sounds abnormal) (seriousness criterion death), CHEYNE-STOKES RESPIRATION (Cheyne-Stokes respiration) (seriousness criterion death), ERYTHEMA (Erythema) (seriousness criterion death), HAEMATOMA (Haematoma) (seriousness criterion death), HYPOTENSION (Hypotension) (seriousness criterion death), JUGULAR VEIN DISTENSION (Jugular vein distension) (seriousness criterion death), LETHARGY (Lethargy) (seriousness criterion death), MOANING (Moaning) (seriousness criterion death), OEDEMA PERIPHERAL (Oedema peripheral) (seriousness criterion death), PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criterion death), STUPOR (Stupor) (seriousness criterion death) and TACHYPNOEA (Tachypnoea) (seriousness criterion death). It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided. Company comment: This regulatory authority case concerns a 85-year-old female with no reported medical history who experienced the serious (Death), unexpected events of Agitation, Apnoea, Breath sounds abnormal, Cheyne-Stokes respiration , Erythema, Haematoma, Hypotension, Jugular vein distension, Lethargy, Moaning, Oedema peripheral, Pulmonary embolism (AESI), Stupor and Tachypnoea presumably sometime time after and unknown dose of mRNA-1273. Testing and treatment are not reported. The outcome is death. The risk-benefit relationship of mRNA-1273 vaccine is not affected by this report. Very scant information is available and no more is expected.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 03-Mar-2022 and was forwarded to Moderna on 03-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of the first episode of MYOCARDIAL INFARCTION (Light myocardial infarction after a week; after 3 weeks of severe myocardial infarction) and the second episode of MYOCARDIAL INFARCTION (Light myocardial infarction after a week; after 3 weeks of severe myocardial infarction) in a 92-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000121A) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: SPIKEVAX on 16-Mar-2021, Moderna vaccin (Spikevax)COVID-19 VACCIN MODERNA INJVLST 0 and5MLCOVID-19 VACCIN MODERNA INJVLST on 18-May-2021. Past adverse reactions to the above products included No adverse reaction with Moderna vaccin (Spikevax)COVID-19 VACCIN MODERNA INJVLST 0,5MLCOVID-19 VACCIN MODERNA INJVLST and SPIKEVAX. On 10-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Jan-2022, the patient experienced the first episode of MYOCARDIAL INFARCTION (Light myocardial infarction after a week; after 3 weeks of severe myocardial infarction) (seriousness criteria death and life threatening). On an unknown date, the patient experienced the second episode of MYOCARDIAL INFARCTION (Light myocardial infarction after a week; after 3 weeks of severe myocardial infarction) (seriousness criteria death and life threatening). The patient died on 12-Feb-2022. The reported cause of death was heavy myocardial infarction. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	No concomitant medication information was mentioned by reporter No treatment medication information was mentioned by reporter Company comment: This regulatory case concerns a 92-year-old, female patient with no relevant medical history reported, who experienced Fatal, Life-threatening unexpected AESI events of Myocardial Infarction and Myocardial Infarction. One episode of Myocardial infarction occurred after 9 days and the other episode after unspecified days of receiving a dose of mRNA-1273 Vaccine. Patient reported light myocardial infarction after a week and after 3 weeks of severe myocardial infarction Patient died approximately 24 days after an episode of Myocardial infarction. The cause of death was reported as heavy myocardial infarction. It is unknown if an autopsy is performed. Elderly age of the patient could be risk factor for Myocardial infarction. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
4.1(b)	This case was received via Health Canada (Reference number: 4.1(b)) on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death) in a 72-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for an unknown indication. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications reported by reporter. No treatment medications provided by the reporter. Company Comment: This regulatory case concerns a 72-year-old, male patient with relevant medical history of having a BMI of 51.169 who experienced the unexpected, serious and fatal event of Sudden death on an unknown date after receiving a dose of mRNA-1273 vaccine on an unspecified date. Latency cannot be properly assessed. No relevant lab data were reported. The cause of death was not reported nor autopsy results provided. The relevant medical history of having a BMI of 51.169 could be a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	This case was received via Health Canada (Reference number: 4.1(b)) on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of HAEMORRHAGE (Haemorrhage), LETHARGY (Lethargy) and LOSS OF CONSCIOUSNESS (Loss of consciousness) in a 94-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 immunisation. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) .5 milliliter. On an unknown date, the patient experienced HAEMORRHAGE (Haemorrhage) (seriousness criteria death and disability), LETHARGY (Lethargy) (seriousness criteria death and disability) and LOSS OF CONSCIOUSNESS (Loss of consciousness) (seriousness criteria death and disability). It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. The suspect vaccine description was reported as Spikevax vial contains 10 Doses of 0.5ML and frequency was reported as Once. Duration for the event Lethargy was reported as 14 Days. No treatment details were reported. Company comment: This regulatory case concerns a 94-year-old, male patient with no medical history reported, who had a fatal outcome with unexpected, serious (disability, death) events of Lethargy, Haemorrhage and Loss of consciousness on an unknown date after receiving an unknown dose of mRNA-1273 vaccine. Vaccination date is unknown. The event Lethargy was reported to have lasted for 14 days. Clinical course and treatment were not reported in this case and it is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 07-Mar-2022. The most recent information was received on 06-May-2022 and was forwarded to Moderna on 06-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (Brain stroke) in a 75-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000030A) for COVID-19 vaccination. Concurrent medical conditions included Hypertension and Leukaemia. On 14-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 27-Jan-2022, after starting mRNA-1273 (Spikevax), the patient experienced CEREBROVASCULAR ACCIDENT (Brain stroke) (seriousness criterion death). The patient died on 10-Mar-2022. The reported cause of death was brain stroke. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	No concomitant medications were reported. No treatment medications were reported. Company Comment: This regulatory case concerning a 75-year-old male patient with relevant medical history of Leukemia and Hypertension, who had a fatal outcome with unexpected serious adverse event of special interest Cerebrovascular accident, which occurred 13 days after receiving a dose of mRNA-1273 vaccine. The clinical course leading to demise and the cause of death were not reported. No further details about the diagnostic procedures and treatments were provided. It is unknown whether an autopsy was performed. The medical history of Leukemia and Hypertension remain as confounders for the event. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 28-Mar-2022: Follow up received that contains no new information. On 06-May-2022: Follow-up received wherein seriousness of event was updated from life threatening to Death and date of death and outcome was updated.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 07-Mar-2022. The most recent information was received on 20-Apr-2022 and was forwarded to Moderna on 25-Apr-2022. This spontaneous case was reported by a physician and describes the occurrence of DEATH (Death (After the third vaccination)) in a 74-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. 3005786) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Comirnaty on 14-Jun-2021 and COMIRNATY on 05-Jul-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY and Comirnaty. On 02-Mar-2022, the patient received third dose of mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular) .25 milliliter. Death occurred on 03-Mar-2022 The patient died on 03-Mar-2022. The cause of death was not reported. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 02-Mar-2022, Blood pressure measurement: 155/60 Test Result:155/60 mm[Hg]. On 02-Mar-2022, Body temperature (Unknown-37): 35.7 35.7 degree Celsius. On 02-Mar-2022, Heart rate: 84 84 per minute. On 02-Mar-2022, Oxygen saturation: 96 96 percent. On an unknown date, Blood pressure measurement: 110-120/60 mm[hg] Test Result:110-120/60 mm[Hg]. On an unknown date, Body temperature (Unknown-37): 35.7 35.7 degree Celsius. For mRNA-1273 (COVID 19 Vaccine Moderna) (Intramuscular), the reporter considered DEATH (Death (After the third vaccination)) to be possibly related. Details were unknown because the physician is not a family doctor. Adverse events before the patient's death were unknown. A disease name cannot be identified. On the medical interview sheets for the 1st and 2nd vaccinations, there was a description that the patient had received permission from the attending physician. See "narrative" section BP CC: The event developed after the administration of ELASOMERAN and there is temporal relationship. . Most recent FOLLOW-UP information incorporated above includes: On 20-Apr-2022: Follow up contains significant information as the dosage text of suspect drug, lab data and patient demographics updated.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of DRUG INEFFECTIVE (LACK OF EFFICACY OF DRUG) and VACCINATION FAILURE (VACCINATION FAILURE) in a 66-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214022) for COVID-19 vaccination. Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for COVID-19 vaccination, CASIRIVIMAB, IMDEVIMAB (CASIRIVIMAB;IMDEVIMAB) for COVID-19 prophylaxis, LENALIDOMIDE (REVLIMID) for Non-Hodgkin's lymphoma and OBINUTUZUMAB (GAZYVARO) injection, solution for COVID-19. The patient's past medical history included Epigastric hernia, Carpal tunnel syndrome, Tendinopathy, Maxillary sinusitis, Psoriasis, Cyst and Aortic valve insufficiency. Concurrent medical conditions included High cholesterol. On 16-Feb-2021, the patient started OBINUTUZUMAB (GAZYVARO) (Intravenous) 1000 milligram. On 10-Mar-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 07-Apr-2021, received dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 1 dosage form. On 13-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 27-Sep-2021, the patient started LENALIDOMIDE (REVLIMID) (Oral) 20 milligram. On 25-Oct-2021, the patient started CASIRIVIMAB, IMDEVIMAB (CASIRIVIMAB;IMDEVIMAB) (Intravenous) 600 milligram. On 28-Dec-2021, the patient experienced DRUG INEFFECTIVE (LACK OF EFFICACY OF DRUG) (seriousness criterion death) and VACCINATION FAILURE (VACCINATION FAILURE) (seriousness criterion death). The patient died on 01-Feb-2022. The reported cause of death was Vaccination failure and lack of efficacy of drug. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered DRUG INEFFECTIVE (LACK OF EFFICACY OF DRUG) and VACCINATION FAILURE (VACCINATION FAILURE) to be related. Dosage text of Spikevax was reported as SPIKEVAX. No concomitant medication provided. No treatment medication reported. Company comment: This regulatory authority case concerns a 66-year-old male patient, who was under treatment with lenalidomide for non-Hodgkin´s lymphoma and had medical history of aortic valve insufficiency, reported serious fatal unexpected event of drug ineffective after a dose of mRNA-1273. Additionally, vaccination failure was also reported. Patient was vaccinated primary COVID-19 vaccine series with two doses of Comirnaty (co-suspect product), hence interchange of vaccine products could also be mentioned in this case. The patient died approximately 4 months after receiving a dose of mRNA-1273 vaccine (COVID-19 vaccine third dose according to vaccination schedule). Reported cause of death were: vaccination failure and lack of drug effect. No information if an autopsy was performed. Co-suspect products and underlying patient disease remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 07-Mar-2022 and was forwarded to Moderna on 09-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 17-Feb-2022, the patient received the 3rd vaccination with this vaccine. On 18-Feb-2022, pyrexia developed. On 21-Feb-2022, melena developed. It was assumed that acute renal failure and suspected haemorrhage of the digestive tract developed. On 22-Feb-2022, the patient went to see a nearby physician. Heart rate of 40 beats, cyanosis, and consciousness disturbed were confirmed. Thereafter, the patient went into cardiac arrest and was transported to a hospital. However, return of spontaneous circulation was not achieved, and the patient died. The outcome of pyrexia, cyanosis, and consciousness disturbed was unknown. The outcome of acute renal failure, suspected haemorrhage of digestive tract, cardiac arrest, and hyperkalaemia was reported as fatal. Follow-up investigation will be made. Reporter comments continuation: In addition, the patient was doing well prior to 17-Feb-2022, and no other medications were newly started in the past few days. No other triggers that could be explained as the cause for acute renal failure were found, so the vaccine is suspected to be related, although it cannot be concluded with certainty. The causal relationship cannot be proven, but meanwhile, no other diseases that could explain acute renal failure and cardiac arrest have been found, and the possibility of adverse events due to this vaccine is considered. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 08-Mar-2022. The most recent information was received on 23-Mar-2022 and was forwarded to Moderna on 30-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 23-Mar-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 03-Mar-2022, at 10:19, the patient received the 3rd dose of this vaccine. The patient was followed up for 30 minutes after the vaccination. At 13:30, the patient returned home. Death was presumed thereafter. On 05-Mar-2022, in the morning, the patient was found dead in the bathtub at home. At 22:30, a postmortem examination was performed. Autopsy was not performed. The death was caused by unknown internal cause, and acute myocardial infarction was suspected. The patient was already decomposed, and it was presumed that about one to two days had passed after death. Postmortem CT showed no evidence of obvious intracranial haemorrhage or drowning, although details were unknown as the body cavity was filled with decomposing gas. Blood collection drawn from the right subclavian vein was tried to perform the troponin test, but it could not be performed due to blood change caused by decomposition. The outcome of suspected acute myocardial infarction was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: However, no one confirmed the patient's condition after the patient returned home, and the time course and the situation of the patient were unknown; therefore, there is no information to judge the causality. Therefore, the date and time of death and the direct cause of death are only presumed, and the relationship with the vaccination with this vaccine cannot be evaluated at all. However, since the death is presumed to have occurred on the day of vaccination, a causal relationship between vaccination and death cannot be ruled out. The onset of the adverse event is temporally related to the timing of administration of the vaccine because the event probably occurred about 8 hours after the administration. The occurrence of the adverse event is not associated with concomitant drugs. The patient had coronary angina pectoris with coronary artery spasm, which was unlikely to be severe enough to cause myocardial infarction; therefore, the relationship between the adverse event and the pathophysiological factors of angina pectoris is unknown. The relationship between the cause of death and the adverse event is unknown because the time course from the vaccination to death is unknown. Follow-up received on 23-MAR-2022 Updated: Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Mar-2022 and was forwarded to Moderna on 07-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CREUTZFELDT-JAKOB DISEASE (Deadly and untreated degenerative neurological disease. Prion) in a 71-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3002183 and 3001532) for COVID-19 vaccination. No Medical History information was reported. On 28-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 26-May-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to .5 milliliter. On an unknown date, the patient experienced CREUTZFELDT-JAKOB DISEASE (Deadly and untreated degenerative neurological disease. Prion) (seriousness criterion death). It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. Treatment information was not provided.

Case ID	Narrative (Complete)
	Company comment- This is a fatal regulatory authority case concerning a 71-year-old male patient with no medical history reported who experienced the unexpected and serious (death) event of Creutzfeldt-Jakob disease 10 days after a second dose of mRNA-1273 vaccine was administered. It is not known if an autopsy was performed. The date of death is unknown. No further details were provided for medical reviewing. Patient´s age remains as a possible contributory risk factor for the event. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Mar-2022: Follow up contains no new information.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 09-Mar-2022 and was forwarded to Moderna on 09-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (Cerebral hemorrhage) in an 84-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 094F21ABS) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: COMIRNATY on 07-Mar-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST on 11-Apr-2021. Past adverse reactions to the above products included Dyspnoea with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST and COMIRNATY. On 14-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Feb-2022, the patient experienced CEREBRAL HAEMORRHAGE (Cerebral hemorrhage) (seriousness criterion death). The patient died on 14-Feb-2022. The reported cause of death was brain hemorrhage, with all consequences. It is unknown if an autopsy was performed. No concomitant and treatment information was provided. Company comment: This case concerns an 84-year-old male patient with medical history of interchange of COVID-19 products, who experienced the fatal event of cerebral haemorrhage 2 months after a dose of mRNA-1273. Previous vaccination with BioNTech/Pfizer vaccine, as well as patient's age, could be confounding factors. The reported cause of death was brain hemorrhage. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 09-Mar-2022: Translated document received on 14-Mar-2022 contains English translated verbatim.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 10-Mar-2022 and was forwarded to Moderna on 10-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CARDIO-RESPIRATORY ARREST (SUDDEN DEATH FROM RESPIRATORY CARDIO ARREST) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000004A) for COVID-19 vaccination. No Medical History information was reported. On 07-Feb-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 07-Feb-2022, after starting mRNA-1273 (Spikevax), the patient experienced CARDIO-RESPIRATORY ARREST (SUDDEN DEATH FROM RESPIRATORY CARDIO ARREST) (seriousness criterion death). It is unknown if an autopsy was performed. Patient had no disease, no pathology, or taking any medication. Sender stated last available report was dating back to 19-Mar-2021 for arthrosis. No treatment information were provided. Company comment:This case concerns an 80-year-old male patient, with no medical history provided in this case, who experienced the fatal unexpected adverse event of Cardio-respiratory arrest. It was reported as sudden death doe to Cardio-respiratory arrest. The event occurred the same day of the administration of a dose of the mRNA-1273 vaccine of an unknown dose, sequence, or schedule of vaccination. The event was assessed by the reporter with the seriousness criteria of Death. No further information on clinical course, treatments performed, or autopsy report was disclosed. Cause of death was not provided. Limited information was provided at this time. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event´s seriousness assessed as reported. Most recent FOLLOW-UP information incorporated above includes: On 17-Mar-2022: Follow up contains non significant information: Added Sender's comments. On 04-Apr-2022: Follow-up received included no new information.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 11-Mar-2022. The most recent information was received on 05-Apr-2022 and was forwarded to Moderna on 05-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PURULENT PERICARDITIS (Purulent pericarditis) in a 91-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported.

Case ID	Narrative (Complete)
	On 12-Oct-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 20-Oct-2021, after starting mRNA-1273 (Spikevax), the patient experienced PURULENT PERICARDITIS (Purulent pericarditis) (seriousness criterion death). The patient died on 20-Oct-2021. The reported cause of death was Purulent pericarditis. An autopsy was performed. No concomitant drug was reported. No treatment drug was reported. CC: This Regulatory Authority case concerns a 91-year-old male patient with no medical history reported, who experienced the unexpected, serious (Fatal) adverse event of special interest of Purulent Pericarditis, 8 days after administration of the third dose of Moderna mRNA-1273 vaccine for Covid 19 Vaccination. No other details were provided regarding the primary doses of vaccination, symptoms, clinical course, concomitant medications, labs and treatment. An autopsy was performed, which confirmed the reported cause of death of Purulent pericarditis. Advanced age of the subject was a confounding factor. Event seriousness assessed as per Regulatory Authority report. The benefit-risk relationship of COVID-19 Vaccine Moderna (mRNA-1273) is not affected by this report Most recent FOLLOW-UP information incorporated above includes: On 05-Apr-2022: Significant FU: Autopsy-determined cause of death updated.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 10-Mar-2022 and was forwarded to Moderna on 10-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of CARDIOGENIC SHOCK (Cardiogenic shock), ATRIOVENTRICULAR BLOCK (Atrioventricular block) and ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) in a 93-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 10-Jun-2021 and Comirnaty BNT162b2 on 22-Jul-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2. On 26-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Feb-2022, the patient experienced CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death, hospitalization and life threatening), ATRIOVENTRICULAR BLOCK (Atrioventricular block) (seriousness criteria death, hospitalization and life threatening) and ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria death, hospitalization and life threatening). The patient died on 05-Feb-2022. The reported cause of death was Cardiogenic shock. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. booster vaccination. No concomitant medication were provided. No treatment information were given. Company comment: This regulatory authority case concerns a 93-year-old female patient, with no medical history reported, previously vaccinated with Comirnaty (two doses), who experienced the unexpected fatal AESI of cardiogenic shock, atrioventricular block and myocardial infarction, which all required hospitalization and were additionally considered as life threatening. The events occurred approximately 10 days after the third dose of mRNA-1273. No information regarding clinical course of events or autopsy findings was provided. Reported outcome of all events was fatal. No further information was provided. Patient's advanced age (93) remains as confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per Regulatory Authority reporting.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 11-Mar-2022. The most recent information was received on 16-Jun-2022 and was forwarded to Moderna on 16-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PNEUMONIA (Pneumonia), COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), DEMENTIA ALZHEIMER'S TYPE (Dementia Alzheimer's type), PYREXIA (Pyrexia), VOMITING (Vomiting) and SPUTUM INCREASED (Sputum increased) in a 73-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concomitant products included MEMANTINE HYDROCHLORIDE (MEMANTIN ORION), CLOPIDOGREL HYDROCHLORIDE (CLOPIDOGREL TEVA [CLOPIDOGREL HYDROCHLORIDE]), SIMVASTATIN (LIPCUT) and RIVASTIGMINE (EXELON PATCH 5) for an unknown indication. On 03-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 10-Jan-2022, the patient experienced PNEUMONIA (Pneumonia) (seriousness criterion death), DEMENTIA ALZHEIMER'S TYPE (Dementia Alzheimer's type) (seriousness criterion death) and SPUTUM INCREASED (Sputum increased) (seriousness criterion death). 10-Jan-2022, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion death), PYREXIA (Pyrexia) (seriousness criterion death) and VOMITING (Vomiting) (seriousness criterion death). The patient died on 10-Jan-2022. The reported cause of death was Dementia Alzheimer's type. An autopsy was not performed. No treatment information was provided. Company comment: This Regulatory Authority case concerns a 73-year-old male patient with multiple co-morbidities among (suggested by concomitant medications), who experienced the unexpected serious (fatal) events of Pneumonia, Dementia Alzheimer's type, Pyrexia, Vomiting, and Sputum increased that occurred 7 days after receiving mRNA-1273 vaccine given as third in the COVID-19 vaccination series. Additionally, COVID-19

Case ID	Narrative (Complete)
	immunisation (Revaccination with different COVID-19 vaccine) was also reported. Patient died on the same day as the onset of events. Cause of death was reported as Dementia Alzheimer's type. An autopsy was not performed. No information was provided on the first two doses of COVID-19 vaccination. The multiple co-morbidities (among which is the progressive Alzheimer's disease as suggested by use of Rivastigmine and Memantine hydrochloride) and the advanced age of the patient could be considered as contributory risk factors for the events and fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report. Most recent FOLLOW-UP information incorporated above includes: On 16-Jun-2022: Follow up document received on 16 Jun 2022 contains Cause of death, new events were added and concomitant drug name updated as CLOPIDOGREL TEV.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 11-Mar-2022 and was forwarded to Moderna on 11-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism), DIABETES MELLITUS INADEQUATE CONTROL (Diabetes mellitus inadequate control) and FEELING ABNORMAL (Feeling bad) in a 79-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 017G21A) for Revaccination with different COVID-19 vaccine. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Gastroesophageal reflux, Thyroidectomy, Carcinoma breast (treated with surgery and radiotherapy) in 2015 and Cataract operation. Previously administered products included for Product used for unknown indication: COVID-19 Vaccine Janssen on 25-Aug-2021. Past adverse reactions to the above products included No adverse event with COVID-19 Vaccine Janssen. Concurrent medical conditions included Hypothyroidism, Hypertension arterial, Chronic pain (Back chronic pain) and Type 2 diabetes mellitus. On 26-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 dosage form. On 26-Jan-2022, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), DIABETES MELLITUS INADEQUATE CONTROL (Diabetes mellitus inadequate control) (seriousness criterion medically significant) and FEELING ABNORMAL (Feeling bad) (seriousness criterion medically significant). On 30-Jan-2022, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criteria death and medically significant). On 26-Jan-2022, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) had resolved. The patient died on 30-Jan-2022. The reported cause of death was 10084465, 10007617 and 10037377. An autopsy was performed. The autopsy-determined cause of death was Pulmonary embolism. At the time of death, DIABETES MELLITUS INADEQUATE CONTROL (Diabetes mellitus inadequate control) and FEELING ABNORMAL (Feeling bad) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In October 2021, Laboratory test: normal (normal) blood cell count normal except for moderate lymphopenia, renal function normal, ionogram within normal values, TSH slightly above normal values. HbA1c 9.6%.. On 26-Jan-2022, Diabetes mellitus management: abnormal (abnormal) blood sugar imbalance. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PULMONARY EMBOLISM (Pulmonary embolism) to be possibly related. No further causality assessments were provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine), DIABETES MELLITUS INADEQUATE CONTROL (Diabetes mellitus inadequate control) and FEELING ABNORMAL (Feeling bad). Concomitant medication was not provided. Treatment information was not provided. Company Comment: This regulatory authority case concerns a 79-year-old, female patient with medical history of Carcinoma breast (treated with surgery and radiotherapy) in 2015 and Concurrent medical condition of Type 2 Diabetes mellitus, who experienced the fatal unexpected serious AESI of Pulmonary embolism and unexpected serious events of Diabetes mellitus inadequate control and Feeling abnormal (seriousness criterion Medically significant). The events Diabetes mellitus inadequate control and Feeling abnormal occurred on the same day and the event Pulmonary embolism occurred 4 days after a dose of mRNA-1273 vaccine administration. The patient died 4 days after the vaccination. The reported causes of death were COVID-19 vaccination, Cardio-respiratory arrest and Pulmonary embolism. The autopsy-determined cause of death was Pulmonary embolism. Additionally, event of COVID-19 immunisation (had a dose of Janssen 5 months 1 day before the current vaccination) interchange of vaccine products is also noted. Patients medical history of Carcinoma breast could be confounding for Pulmonary embolism and Concurrent medical condition of Type 2 Diabetes mellitus could be confounding for Diabetes mellitus inadequate control. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events were assessed as serious as per Regulatory Authority´s report
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Mar-2022 and was forwarded to Moderna on 14-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death) in a 75-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000027BA) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Nontoxic multinodular goitre (the patient had been consulting with an endocrinologist), Hypertension and Hypercholesterolaemia. Concomitant products included FENOFIBRATE, ROSUVASTATIN CALCIUM (ROSULIP F) from 29-Jul-2021 to 12-Feb-2022 for Hypercholesterolemia, MOXONIDINE (MOXONIDIN) from 29-Jul-2021 to 12-Feb-2022, BISOPROLOL FUMARATE (CONCOR) from 29-Jul-2021 to 12-Feb-2022 and AMLODIPINE BESILATE, INDAPAMIDE, PERINDOPRIL ARGININE (TRIPLIXAM) from 29-Jul-2021 to 12-Feb-2022 for Hypertension, PREDNISOLONE (PREDNISOLONE V) from 02-Feb-2022 to an unknown date for Nontoxic multinodular goitre. On 20-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 20-Dec-2021, the patient experienced NAUSEA (Nausea) and PYREXIA (Pyrexia). On 13-Feb-2022, NAUSEA (Nausea) and PYREXIA (Pyrexia) had resolved. The patient died on 14-Feb-2022. An autopsy was performed, but no results were provided. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Dec-2021, Body temperature: 00 00 % (% percent).

Case ID	Narrative (Complete)
	For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment information was provided. Company comment: This regulatory authority case concerns 75-years-old, female patient with relevant Concurrent medical conditions of Hypertension and Hypercholesterolemia, who experienced the unexpected Fatal event of death (seriousness criteria death). Patient died after 1 month 26 days after the third dose of mRNA-1273 vaccine. At the time of report, very limited information has been provided about the patient and about the event leading to the fatal outcome. The cause of death was also unknown. The autopsy was performed with reports not provided. Patient's elderly age and concurrent medical conditions of Hypertension and Hypercholesterolemia remains a confounder, The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 11-Mar-2022 and was forwarded to Moderna on 11-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC ARREST (The day after the injection: feeling as if there was a rubber band around the wrist heart rhythm disorder) and ARRHYTHMIA (The day after the injection: feeling as if there was a rubber band around the wrist heart rhythm disorder) in a 76-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 018J21ABS) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Arrhythmia since an unknown date. Previously administered products included for Product used for unknown indication: BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3ML on 29-Mar-2021, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3ML on 10-May-2021. Past adverse reactions to the above products included No adverse event with BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0,3ML, BioNTech/Pfizer vaccin (Comirnaty) COVID-19 VACCIN PFIZER INJVLST 0 and3ML. Concomitant products included DOPAMINE HYDROCHLORIDE (SEMINIET) for an unknown indication. On 29-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Jan-2022, the patient experienced CARDIAC ARREST (The day after the injection: feeling as if there was a rubber band around the wrist heart rhythm disorder) (seriousness criterion death), ARRHYTHMIA (The day after the injection: feeling as if there was a rubber band around the wrist heart rhythm disorder) (seriousness criterion death) and PARAESTHESIA (The day after the injection: feeling as if there was a rubber band around the wrist heart rhythm disorder). The patient died on 18-Jan-2022. The reported cause of death was heart rhythm disorder and followed by cardiac arrest.. It is unknown if an autopsy was performed. At the time of death, PARAESTHESIA (The day after the injection: feeling as if there was a rubber band around the wrist heart rhythm disorder) outcome was unknown. No treatment information was provided. COMPANY COMMENT : This regulatory authority case concerns a 76-year-old male patient with a relevant past medical history of arrythmia, who experienced the unexpected fatal serious (seriousness criteria death) AESI event of arrhythmia, unexpected serious (seriousness criteria death) event of cardiac arrest, which occurred 20 days after receiving third dose of mRNA- 1273 vaccine. The patient was noted to have received two doses of COMIRNATY 9 months prior to current vaccination with mRNA-1273 (Interchange of vaccine products). It is reported date of death is 18-january-2022, cause of death is arrhythmia and cardiac arrest. Past medical history of arrythmia remains as confounding. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 11-Mar-2022. The most recent information was received on 30-Mar-2022 and was forwarded to Moderna on 07-Apr-2022. This case was reported by a pharmacist via the Drug Information Center. On 14-Mar-2022, follow-up information, reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a pharmacist, was received via the PMDA (Ref. 4.1(b)). On 30-Mar-2022, Follow-up information was received from a pharmacist. The vaccine recipient had an Atomic Bomb Survivors Certificates. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 37.0 degrees Celsius. On 08-Mar-2022, just after 14:00, the patient received the 3rd vaccination with this vaccine. After vaccination, the patient was followed up. On 09-Mar-2022, around dawn, the patient died at home. In the morning, the patient was found dead in the home. Based on inspections by the police and the attending physician, it was determined that the patient died with suspected heart disease. No autopsy was performed. The outcome of suspected heart disease was reported as fatal. No follow-up investigation will be made. Follow-up received on 14-MAR-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments Follow-up received on 30-MAR-2022 Updated: Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Cardiac disorder can be also considered as an accidental disease although it developed after the administration of ELASOMERAN.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 10-Mar-2022. The most recent information was received on 28-Mar-2022 and was forwarded to Moderna on 05-Apr-2022. This case was reported by a physician via a medical representative. On 28-Mar-2022, additional information was received from a physician. On an unknown date, the patient received the 1st dose of this vaccine. On an unknown date, the patient received the 2nd dose of this vaccine. On 04-Mar-2022, the patient received the 3rd dose of this vaccine. On 05-Mar-2022, the patient was presumed dead. On 08-Mar-2022, the police heard that the patient was diagnosed with congestive cardiac failure and hypertensive disease. The outcome of congestive cardiac failure and hypertensive disease was reported as fatal. No follow-up investigation will be made. Follow-up received on 28-MAR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 14-Mar-2022. The most recent information was received on 30-Mar-2022 and was forwarded to Moderna on 07-Apr-2022. This case was reported by a pharmacist via a medical representative. On 30-Mar-2022, follow-up information was received from a pharmacist. The vaccine recipient was being treated with dialysis for renal impairment. On 05-Mar-2022, the patient received this vaccine (the number of doses was unknown). Acute interstitial pneumonia and pyrexia between 38 degrees Celsius and 39 degrees Celsius developed. On 07-Mar-2022, the patient visited the reporting hospital. Pyrexia persisted. A coronavirus antigen test was negative. Dialysis was then performed. At 14:00, X-ray revealed interstitial

Case ID	Narrative (Complete)
	pneumonia-like shadows globally on the left and right sides. The repeated antigen test was negative. At 17:00, the patient received intravenous injection of piperacillin sodium 2g plus normal saline 50 mL. The patient went home thereafter. On 08-Mar-2022, at 13:00, the patient visited the hospital for intravenous drip infusion of antibiotics. The patient collapsed in front of the reception desk at when he came to the hospital. The patient lost consciousness. Oxygen 10 L and KN 1 infusion were started, and the patient was intubated. At 13:30, diazepam and dopamine (DOA) were administered. At 14:00, the patient received 500 of methylprednisolone sodium succinate plus 100 mL of normal saline. At 15:33, the patient had cardiac arrest temporally. The patient received 1A of adrenaline. At 15:50, the patient died. No autopsy was performed. The cause of death was interstitial pneumonia. The outcome of acute interstitial pneumonia and cardiac arrest was reported as fatal. The outcome of loss of consciousness was unknown. No follow-up investigation will be made. Reporter comments continuation: The patient's condition has been stable for several years, and although the patient was vaccinated with this vaccine on 05-Mar-2022, the occurrence of adverse events does not seem to be related to pathological factors including underlying disease and complications. There is a causal relationship between the cause of death and adverse events based on time series. The patient had regularly been visiting the reporting hospital for dialysis and was in stable condition. The symptoms developed immediately after the vaccination with this vaccine, and based on this situation, it is highly likely that the patient experienced adverse events due to this vaccine, and a causal relationship between this vaccine and death is strongly suspected. Cardiac failure or pneumocystis carinii pneumonia is unlikely. Follow-up received on 30-MAR-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 11-Mar-2022 and was forwarded to Moderna on 15-Mar-2022. On 11-Mar-2022, this sponraneous case report was provided by a family member of a vaccine recipient via the Drug Information Center. On 14-Mar-2022, follow-up information was receved from a local official. On an unknown date, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 03-Mar-2022, the patient received the 3rd dose of this vaccine as a municipal group vaccination. On 04-Mar-2022, when a family member spoke to the patient while he was taking a bath, he replied in a sleepy voice. However, the family member went to see the patient after a while and found him drowned. According to a local official, a physician concluded that there was no possibility of suspected adverse reactions. No follow-up investigation will be made. Company Comment: Drowning can be also considered as an accidental disease although it developed after the administration of the ELASOMERAN.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 15-Mar-2022. The most recent information was received on 07-Apr-2022 and was forwarded to Moderna on 15-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 07-Apr-2022, follow-up information was received from a physician. On 08-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.7 degrees Celsius. On 24-Feb-2022, at 14:00, the patient received the 3rd vaccination with this vaccine. After the vaccination, the patient did not complain of physical deconditioning. On 25-Feb-2022, at 21:00, the patient was found dead at home. On an unknown date, an autopsy was conducted in the police. A sample of cerebrospinal fluid was taken, and no blood was found; therefore, it was determined that the cause was not in the brain. It is highly likely the sudden death resulting from cardiac causes occurred. The autopsy diagnosis was lethal arrhythmia. The outcome of lethal arrhythmia was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The causality is unknown because the patient died approximately 24 hours after the vaccination, but it was considered as necessary to make a report of the adverse reactions. If thrombosis occurs in approximately 24 hours (platelet count as high as 587,000), the possibility cannot be ruled out and the onset of adverse events is thus related to the time of administration of the vaccine. The incidence of adverse events is not associated with concomitant drugs because no drug that causes lethal arrhythmia is included in the concomitant drugs. On 25-Jun-2020, the symptoms developed. CAG stated #2 50%, #12 99% delay. PCI was not performed. The occurrence of adverse events is related to the pathological factors of old myocardial infarction, since it is stated that some cardiomyopathy was also considered with high NT proBNP levels. The patient was taking aspirin and understood that hyper thrombocythemia was not a contraindication to vaccination. This was a case in which vaccination was performed as usual, as the patient had been vaccinated twice before. Other contributing factors are unknown. Follow-up received on 07-APR-2022 Updated: Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Sudden cardiac death occurred after the administration of ELASOMERAN, but it is possible that it was influenced by the concurrent conditions.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 15-Mar-2022 and was forwarded to Moderna on 15-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of MALLORY-WEISS SYNDROME (Mallory-Weiss syndrome) in a 65-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3006320) for COVID-19 vaccination. Concurrent medical conditions included Dyslipidaemia, Hypertension arterial and Cirrhosis liver. On 26-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, after starting mRNA-1273 (Spikevax), the patient experienced MALLORY-WEISS SYNDROME (Mallory-Weiss syndrome) (seriousness criterion death). The patient died on 07-Feb-2022. The reported cause of death was Multiorgan failure. An autopsy was not performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication information was provided. No treatment medication was provided. Cause of death reported as multi visceral defaillance Company comment include This regulatory case concerns a 65 – year – old, male patient with relevant medical history of cirrhosis liver, who experienced the serious fatal unexpected event of Mallory-Weiss syndrome, 12 days after the administration of a dose of mRNA-1273 vaccine (reported as R1). The patient died the same day the event started, and the cause of death was reported as multiorgan failure. An autopsy was not performed. Patient´s medical history of cirrhosis liver remains as confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 16-Mar-2022 and was forwarded to Moderna on 16-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (cause of death unknown), DEEP VEIN THROMBOSIS (Deep vein thrombosis) and PULMONARY EMBOLISM (Fulminant pulmonary embolism) in an 87-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination.

Case ID	Narrative (Complete)
	Previously administered products included for Prophylactic vaccination: Comirnaty on 14-Feb-2021, Comirnaty on 07-Mar-2021 and Comirnaty on 15-Sep-2021. Past adverse reactions to the above products included No adverse event with Comirnaty, Comirnaty and Comirnaty. On 04-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 4 dosage form. In January 2022, the patient experienced DEEP VEIN THROMBOSIS (Deep vein thrombosis) (seriousness criteria hospitalization and life threatening) and PULMONARY EMBOLISM (Fulminant pulmonary embolism) (seriousness criteria hospitalization and life threatening). The patient died on 23-Jan-2022. The cause of death was not reported. An autopsy was performed, but no results were provided. At the time of death, DEEP VEIN THROMBOSIS (Deep vein thrombosis) and PULMONARY EMBOLISM (Fulminant pulmonary embolism) had not resolved. Post-mortal: SARS-CoV-2 infection without symptoms. No Concomitant medication information was reported. No treatment medications were provided. Company comment: This Fatal Regulatory Authority case concerns a 87-year-old, female patient, with no reported medical history, who experienced the unexpected, serious (life threatening/ hospitaliation) AESI of deep vein thrombosis and pulmonary embolism in the same month after receiving a dose of mRNA-1273 vaccine, exact events dates were not reported. She received 3 doses of Cominarty's COVID-19 vaccine previously. The patient died 19 days after vaccination, cause of death was reported as unknown. Autopsy report is not available. No further clinical information was provided for medical reviewing. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 14-Mar-2022. The most recent information was received on 07-Apr-2022 and was forwarded to Moderna on 15-Apr-2022. This case was reported by a hospital staff via a medical representative. On 18-Mar-2022, follow-up information, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a nurse, was received via PMDA (Ref. 4.1(b)). On 07-Apr-2022, follow-up information was received from a nurse. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (unknown product name). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (unknown product name). On an unknown date, body temperature before the vaccination: 35.5 degrees Celsius. On 11-Mar-2022, at 14:20, the patient received the 3rd vaccination with this vaccine. Immediately after the vaccination, acute cardiac failure developed. The patient did not complain of adverse reactions. At 20:30, the patient talked without problem. BP: 124/84, and SpO2: 100%. At 23:30, the patient was found in cardio-respiratory arrest. Cardiac massage was started. Oxygen 10 L was given via an Ambu mask. Intubation was performed. Ventilator was installed. A peripheral vein was secured in the right inguinal region. Physiological saline injection of 500 mL was started in a fully open state. At 23:45, fosfomycin calcium hydrate 1 A was administered by intravenous injection. At 23:51, the patient was resuscitated for 30 minutes but did not return to consciousness. At 23:57, the patient was confirmed dead. The outcome of acute cardiac failure and cardio-respiratory arrest was reported as fatal. No follow-up investigation will be made. Follow-up received on 18-MAR-2022 Updated: Reporter Information, Patient Information, Lab Data, Product Information, Event Information, Narrative Follow-up received on 07-APR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Narrative, Reporter Comments Company Comment: The events developed after the administration of LASOMERAN and there is temporal relationship.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue) in a 70-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Patient had no specific medical history, but had undergone surgery for intestinal rupture in August at the hospital and was subject to continuous treatment of a pulmonary embolism. On 27-Dec-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 08-Jan-2022, the patient experienced FATIGUE (Fatigue) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. second dose of Moderna at the Medical Clinic on 27-Dec-2021. At 11:45 pm on 07-Jan-2022, the nurse noticed that the patient was pale when was feeding the patient and called for an ambulance to take the patient to hospital and informed the family. died before arriving at the hospital.Patient was discharged from the hospital on 08-Dec after being transferred to the General Hospital in November. The patient received the first dose of Moderna was administered on July 9, 2021 did not report any discomfort to his family after receiving the second dose of Moderna on 27-Dec, and was found to be pale at 23:45 on January 7, 2022, when the nurse tried to assist to take the medication. The patient was taken to Hospital by an ambulance after first aid but OHCA before arriving at the hospital. This case concerns a 70-year-old, male patient with relevant medical history of surgery for intestinal rupture and pulmonary embolism approximately 1 month after the administration of the first dose of the mRNA-1273 vaccine and 4 months prior the administration of the second dose of the vaccine, who experienced the fatal serious unexpected event Fatigue. The event occurred approximately 13 days after the administration of the 2nd dose of the mRNA-1273 vaccine. Cause of death was not provided. Autopsy was also not done. Event seriousness assessed as per Regulatory Authority as Death. Limited information was provided at this time. Patient received the second dose of the vaccine with no discomfort reported after this administration. The same day of the fatal outcome the patient was pale when she was feeding, received first aids and die before arriving at the hospital. Reported medical history remains as a confounder for the event. Inappropriate schedule of product administration was noted in the case (Time between first and second dose 5 months and 19 days). The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event´s seriousness assessed as reported. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up Received: Contains No New Information
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (STEMI) in a 70-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported.

Case ID	Narrative (Complete)
	On 21-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Mar-2022, the patient experienced ACUTE MYOCARDIAL INFARCTION (STEMI) (seriousness criterion death). The patient was treated with CEFAZOLIN on 26-Feb-2022 for Urinary tract infection, at an unspecified dose and frequency; PIPERACILLIN SODIUM, TAZOBACTAM SODIUM (TAZOCIN) on 04-Mar-2022 at an unspecified dose and frequency; TEICOPLANIN on 04-Mar-2022 at an unspecified dose and frequency; NOREPINEPHRINE on 26-Feb-2022 at an unspecified dose and frequency; DOPAMINE on 26-Feb-2022 at an unspecified dose and frequency; ATROPINE (ATROPIN [ATROPINE]) on 08-Mar-2022 at an unspecified dose and frequency and EPINEPHRINE on 08-Mar-2022 at an unspecified dose and frequency. The reported cause of death was stemi. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 25-Feb-2022, Catheterisation cardiac: cardiovascular stenosis (abnormal) LAD-atherosclerotic change, proximal to mid-LAD 50-60 percent stenosis, distal LAD total occlusion/ RCA -Diffuse atherosclerotic plaques, mid-RCA 85 percent stenosis. LCX -Diffuse atherosclerotic change without significant stenosis.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medication information reported. On 25-Feb-2022, the patient visited the Cardiology Clinic with intermittent chest pain, gastrointestinal discomfort for several hours, mild dyspnea and cold sweats. After clinical assessment of suspected myocardial infarction, he was referred to the Emergency Room immediately. He was admitted to the hospital on the same day via emergency admission and was first given an emergency cardiac catheterization, which revealed LAD-Atherosclerotic change, proximal to mid-LAD 50-60% stenosis, distal LAD total occlusion/ RCA -Diffuse atherosclerotic plaques, mid-RCA 85% stenosis /LCX -Diffuse atherosclerotic change without significant stenosis. On 26-Feb-2022, patient was admitted to hospital with a suspected urinary tract infection and was given cefazolin antibiotics as an adjunct to IABP with dopamine/norepinephrine for poor cardiac contractility. On 03-Mar-2022 the antibiotic was changed to Tazocin combined with teicoplanin (since 04-Mar-2022) and he was re-catheterized due to bilateral pulmonary infiltrates suspected of being a pulmonary infection and the cardiac catheterization was repeated. On 04-Mar-2022, patient with worsening symptoms of dyspnea was treated with a ventilator after the placement of endotracheal tube. On 07-Mar-2022, he was treated with CVVHD support for acute renal deterioration while the vasopressors were still being used to maintain MAP greater than 65 mmHg. On 08-Mar-2022, at 9:00, patient's blood pressure dropped and SPO2 could not be monitored, so CVVH was aborted and the emergency procedure was started. Patient’s symptoms worsened with multiple organ failure. Atropin and epinephrine were given starting at 11 pm. On 09-Mar-2022, after continuous administration of epinephrine for 30 minutes, the patient showed no vitals and AADD was conducted at the wish of the family. The Worldwide UID was reported as 4.1(b) [redacted] Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received on 25 Apr 2022-In narrative, boosters was updated to Vasopressor, respiratory distress was updated to symptoms of dyspnea and oxygen was updated to SPO2. Company comment: This regulatory authority case concerns a 70-year-old male patient, with no medical history reported, who experienced the Fatal serious unexpected AESI of Acute myocardial infarction (STEMI) approximately 1 month 16 days after receiving the third dose of mRNA-1273 Vaccine. It was reported that the patient consulted Cardiology clinic due to intermittent chest pain, gastrointestinal discomfort, mild dyspnea and cold sweats. Hospitalized due to suspected myocardial infarction. Cardiac catheterization done revealed LAD-Atherosclerotic change, proximal to mid-LAD 50-60% stenosis, distal LAD total occlusion/ RCA -Diffuse atherosclerotic plaques, mid-RCA 85% stenosis /LCX -Diffuse atherosclerotic change without significant stenosis. Due to poor LV function patient was treated with vasopressors, IABP support and antibiotics(cefazolin) for suspected Urinary tract infection. A few days after, antibiotics were changed suspecting pulmonary infection, due to bilateral pulmonary infiltrates and cardiac catheterization was repeated. Due to respiratory distress (symptoms of dyspnea) was intubated the next day, treated with CVVHD support for acute renal deterioration in the following days, patient's condition worsened with multiple organ failure which led to the demise of the patient. The cause of death was not reported but as per narrative considered as Acute myocardial infarction. It is unknown if an autopsy was performed. Elderly age of the patient remains a confounder to the event. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain, Palpitation), PALPITATIONS (Chest pain, Palpitation), HYPOAESTHESIA (Limb numbness) and MUSCULAR WEAKNESS (Limb weakness) in a 66-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Hypertension and Polypectomy on 02-Jul-2020. On 26-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Mar-2022, the patient experienced CHEST PAIN (Chest pain, Palpitation) (seriousness criterion death), PALPITATIONS (Chest pain, Palpitation) (seriousness criterion death), HYPOAESTHESIA (Limb numbness) (seriousness criterion death) and MUSCULAR WEAKNESS (Limb weakness) (seriousness criterion death). It is unknown if an autopsy was performed. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Worldwide UID number was reported as 4.1(b) [redacted]. 26-Feb-2022 Received Moderna COVID-19 vaccine. 01-Mar-2022 He went to the Emergency Department of our hospital due to chest pain, palpitation, right lower limb paralysis and weakness. When he arrived at the hospital, he was conscious, his body temperature was normal, and his blood pressure was 54/52 mmHg. Lab data showed that D-dimer increased (> 10000) and WBC increased (15720/uL). CT aortography: Type A aortic dissection (involving aortic root to bilateral common iliac artery, external and internal iliac artery), hemopericardium, cardiomegaly. He consulted the Cardiac Surgery Department and was arranged surgery (AsAo replacement with 30# intergard graft). Intraoperative findings: 1. Pericardial effusion is turbid with obvious ecchymosis on aortic wall. 2. The ascending aortic has a primary tear extending to the aortic root, which was replaced by 30# graft during operation. In addition, during the operation, Levophed 50mcg+ pump run 10mcg/mL/hr and Doapmin 400mcg/250mL pump run 20mL/hr were given because of low blood pressure, and RI 10U was given because of high blood sugar. 02-Mar-2022 He was transferred to the intensive care unit at 1: 40. At 1: 43, EKG showed PEA. Norepinephrine pump, Calglon STAT and Epinephrine 1mg Q3min for 30 min were given, but EKG still showed PEA. 2:27 expired. No Concomitant medications were reported.

Case ID	Narrative (Complete)
	Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up contains non significant information.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 15-Mar-2022. The most recent information was received on 05-Apr-2022 and was forwarded to Moderna on 13-Apr-2022. This case was reported by a physician via a medical representative. On 05-Apr-2022, follow-up information was received from a physician. The vaccine recipient was being treated for hypertension, dyslipidaemia, osteoporosis, and Alzheimer's type dementia. On 16-Jun-2021, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 07-Jul-2021, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 07-Mar-2022, in the morning, the patient received the 3rd vaccination with this vaccine. On 08-Mar-2022, in the early evening, the patient experienced inability to eat due to sleepiness. Thereafter, faecal incontinence developed. The patient was transported to a hospital by ambulance. During transport, the patient suffered from cardio-respiratory arrest. The patient died. A postmortem CT in the hospital where the patient was transported diagnosed the symptoms as pneumonia and sepsis. No autopsy was performed. The outcome of cardio-respiratory arrest, pneumonia, and sepsis was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The occurrence of adverse events is not related to pathological factors of underlying diseases and complications because they had developed for quite some time and no problem was guessed. Adverse reactions are not related to the case of death. The patient was diagnosed with pneumonia and sepsis in the hospital where the patient was transported, and the relationship is not considered. However, proximity of time is considered as a problem. Follow-up received on 05-APR-2022 Updated: Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Pneumonia and sepsis can be also considered as an accidental disease although it developed after the administration of ELASOMERAN.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue), SOMNOLENCE (Drowsiness) and ASTHMA (Asthma) in an 89-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Osteoporosis. Previously administered products included for Product used for unknown indication: (AZ) covid-19 vaccines (Received Dose 1 and 2 (AZ) covid-19 vaccines) on 16-Jun-2021 and (AZ) covid-19 vaccines (Received Dose 1 and 2 (AZ) covid-19 vaccines) on 16-Sep-2021. Past adverse reactions to the above products included No adverse effect with (AZ) covid-19 vaccines and (AZ) covid-19 vaccines. On 22-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 07-Feb-2022, the patient experienced FATIGUE (Fatigue) (seriousness criterion death), SOMNOLENCE (Drowsiness) (seriousness criterion death) and ASTHMA (Asthma) (seriousness criterion death). The patient died on 07-Feb-2022. The reported cause of death was Fatigue, Drowsiness and Asthma. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Relevant concomitant medications were not reported. On 11-Mar-2022: The family reported a case of suspected COVID-19 vaccine related adverse reaction (death). Patient started to have wheezing during climbing stairs on 01-Feb and then fatigue, somnolence, and inappetence. In the morning of 07-Feb, her son had planned to take the patient to the hospital outpatient, but the patient said no. The patient was found to fall unconsciously in the bathroom by her family at 10 PM on the same day. She was sent to hospital ER after emergency CPR, but the first aid failed. The patient died on 07-Feb-2022. Company comment: This is a regulatory authority case concerning a 89-year-old, female patient initially vaccinated with two doses of Covid 19 vaccine Astra Zeneca with no reported adverse events . who experienced the Serious (death) unexpected , events of Fatigue, Somnolence, Wheezing. The events occurred 16 days after vaccination with the third dose of mRNA-1273 COVID 19 Vaccine. This patient started to have wheezing during climbing stairs on Feb 1 and then fatigue, somnolence, and inappetence (9 days post vaccination with the third dose of the mRNA-1273 vaccine) . In the morning of Feb 7 (16 days post vaccination , her son had planned to take the patient to the Lukang Christian Hospital outpatient, but the patient refused. . The same day at 10 pm this patient was found to fall unconsciously in the bathroom by her family . She was sent to Lukang Christian Hospital ER where CPR was done but the first aid failed. The patient died on Feb 7, 2022. No further information was reported surrounding the death of this patient like treatment medication and official report from the hospital as the cause of death and it is unknown if an autopsy was done. The age of this patient and the history of initial vaccination with two doses of Covid 19 vaccine Astra Zeneca is considered as confounder for the fatal outcome of the events . The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Patient demographic, history, death date, cause of death, product indication, event details updated.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of SYNCOPE (Faint) and SEPSIS (Sepsis) in a 78-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 2100685) for an unknown indication. No Medical History information was reported. On 12-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 18-Feb-2022, the patient experienced SYNCOPE (Faint) (seriousness criterion death) and SEPSIS (Sepsis) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. The patient experienced coma and shock on 18-Feb-2022 and was sent to hospital for hospitalization. The patient died on 04-Mar-2022. At 11:22 on 08-Mar-2022, the patient's daughter was contacted, stating that the patient had past medical history of Parkinson's disease, hypertension and diabetes (received follow-up treatment in hospital) as well as biliary tract removal and prostate surgery history. The patient received the first and second doses of Moderna vaccine on 13-Jul-2021 and 25-Sep-2021, showing no discomfort. The patient was admitted on 09-Feb-2022. Under the arrangement by the family members, the patient received the third dose of Moderna vaccine on 12-Feb-2022, and showed no physical discomfort after vaccination. On 18-Feb-2022, the patient was found to have coma, and was sent to the Emergency Department. The family members were also notified. The physician stated that the patient was in poor conditions and inquired about the catheterization and other measures. The

Case ID	Narrative (Complete)
	patient had ever made an announcement about abandoning first aid and other measures, and choosing hospice care. The patient died on 04-Mar-2022. The cause-of-death diagnosis: 1. sepsis and acute renal failure, chronic kidney disease; 2. chronic kidney disease. The Worldwide UID was reported as 4.1(b) . Company comment: This regulatory authority case concerns a 78 year old male patient with relevant medical history of Parkinson's disease, hypertension and diabetes, who experienced the unexpected serious (seriousness criterion-death) events of Syncope and Sepsis, about 7 days after receiving the third dose of mRNA-1273 vaccine. The events had a fatal outcome with death occurring about 20 days after the third dose. The cause of death was sepsis, acute renal failure and chronic kidney disease. The patient showed no signs of discomfort after the first two doses with the same vaccine. About a week after the third dose, he had shock and coma for which he was hospitalized. The physician opined that the patient's condition was poor and subsequently the patient died. No further information regarding clinical course and management of the events was available from the report. The medical history of Parkinson's disease, hypertension and diabetes could be risk factors for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness retained as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received includes no significant information.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue) in a 68-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Surgery in January 2022. Concurrent medical conditions included Hypertension. On 16-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Feb-2022, the patient experienced FATIGUE (Fatigue) (seriousness criterion death). An autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided by the reporter. 09-Mar-2022: The patient felt tired and wanted to sleep after receiving the third dose of Moderna vaccine on February 16. February 20: He had sudden collapse and eye whites turned and was sent to hospital for emergency treatment at 10:58. However, the patient died on arrival and was pronounced dead. The family thought that the death was related to the vaccination and applied for autopsy for further investigation. The follow-up outcome was as follows. 10-Mar-2022: The forensic preliminary dissection report was uploaded. Awaiting the hospital to upload case record. The worldwide UID was reported as 4.1(b) Company comment include This case concerns a 68-year-old, male patient with relevant medical history of Pancreatic Tumor, recent resection of visceral tumor and hypertension, who experienced the fatal serious unexpected event of Fatigue. The event occurred approximately one day after the administration of the 3rd dose of the mRNA-1273 vaccine. Cause of death was not provided. Autopsy was also not done. Event seriousness assessed as per Regulatory Authority as Death. Limited information was provided at this time. The patient felt tired and wanted to sleep after receiving the third dose of Moderna vaccine, suddenly became paralyzed, was sent to the hospital, and die before arriving. Reported medical history remains as a confounder for the event. There is reported forensic anatomy: ASCVD, RCA 85% occlusion, pancreatic tumor (after operation). Inappropriate schedule of product administration was noted in the case (Time between first and second dose 93 days). The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event´s seriousness assessed as reported. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received contains non-significant information. Verbatim updated.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (Fever) in an 89-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 26-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 28-Feb-2022, the patient experienced PYREXIA (Fever) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication information was provided. The patient's son mentioned that the patient suffered from diabetes and dementia. Before Chinese New Year, the patient had urinary tract infection and sought medical attention at the hospital. The patient took antibiotics, and the treatment course was completed. On 26 Feb 2022, the patient received the Moderna vaccine. On the night of vaccination itself, the patient's temperature was 37 degree C and decreased to 36 degree C after febrifuge was given. On 28 Feb 2022 7:00 am, the patient's temperature was 38 degree C and another febrifuge was given. However, the fever was still there at 8:00 am and the patient was out of his sense. Hence, the patient was sent to the ER of Chi Mei Medical Center with very high WBC. Suspected of urinary tract infection and admitted, died on 01 Mar 2022 at 3 am. The Worldwide UID was reported as 4.1(b) Company Comment: This regulatory authority case concerns a 89 year old male patient with relevant medical history of Dementia , Diabetes and UTI with recent treatment of antibiotics , who experienced Serious (fatal) , unexpected event of pyrexia which occurred 2 days post vaccination with the 3rd dose of mRNA-1273 vaccine. The details regarding the first two doses of the Covid 19 vaccine were not included in this report. This patient was brought the ER due to persistent febrile episode of the patient inspite of antipyretics administration and also he became delirous. The patient was admitted for leukocytosis and suspected urinary tract infection, However one day after admission/ 3 days post vaccination with the mRNA-1273 vaccine this patient

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	died. The cause of death was not reported and it is unknown if an autopsy was done. The age of this patient and the medical conditions mentioned above are considered confounders for this case. The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up received that contains Non significant information.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (No vital signs) in an 80-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 18-Feb-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on 28-Feb-2022 It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. On 28-Feb-2022, Blood type: AB type (patient description). Past medical history: H/T, Parkinson, Alzheimer's, BPH s/p, inner ear imbalance. History of allergy: none. TOCC(-). O: family members witnessed the patient fell to the ground, with no vital signs, unconscious, CPR conducted at the scene. sent to the emergency room, and in the emergency room at the time of reporting. GCS: E1V1M1, no breathing, unconscious, no vital signs, sent to the emergency room from Beipu 91, given LMA+LUCAS for EMT, electric shock not recommended with AED I: Examined by Lai Juncheng, moved to the emergency room by the transfer bed, heart rhythm being monitored by the defibrillator, and heart rhythm is Asystole. The follow-up care was as followed: On 29-Sep-2021, the patient received first dose of BNT vaccine and on 11-Oct-2021 second dose was received. On 18-Feb-2022, the patient received Moderna booster. On 26th and 27th patient had General weakness. And on 28th Feb Sudden fall at home, sent to hospital by ambulance, died on the way, and first aid was ineffective. The detailed cause of death was to be clarified by judicial/administrative autopsy Treatment medications were not reported. WWID: 4.1(b) The is a regulatory case concerning an 80-year-old male patient with a past medical history of H/T, Parkinson, Alzheimer's, BPH, and inner ear imbalance, who presented with the unexpected event of death. The event occurred approximately 10 days after the third dose of mRNA 1273 vaccine. One or two days before the event patient had general weakness and on the day of the event family members witnessed the patient to fall to the ground with no vital signs and unconscious. Patient was sent to the hospital by ambulance and died on the way and first aid was ineffective. The cause of death was not reported and it is unknown if an autopsy was performed. The benefit risk relationship of vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non-Significant follow up received updated event verbatim.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache), MYALGIA (Muscle pain), ALTERED STATE OF CONSCIOUSNESS (Change in consciousness) and MUSCULAR WEAKNESS (Limb weakness) in a 92-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 072F21A-1101207-CDC) for an unknown indication. No Medical History information was reported. On 13-Nov-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Nov-2021, the patient experienced HEADACHE (Headache) (seriousness criterion death), MYALGIA (Muscle pain) (seriousness criterion death), ALTERED STATE OF CONSCIOUSNESS (Change in consciousness) (seriousness criterion death) and MUSCULAR WEAKNESS (Limb weakness) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Worldwide UID was reported as 4.1(b) . On 15-Feb-2021, the patient developed general weakness, had difficulty eating, and did not respond to call. On the evening of 19-Feb-2021, the patient sought treatment at the emergency department. The patient was diagnosed with brain thrombosis and recommended for operation by the physician. Considering that the patient was old, the family did not consider operation and the patient was transferred to the ICU. On 06-Dec-2021, the patient was transferred to the acute care unit and discharged on 27-Dec-2021. As the family members could not care for the patient, the patient was transferred to Nursing Home. After admission, the patient often went to Hospital for medical treatment due to the slower heartbeat. On 22-Feb-2022, the patient died of pneumonia. Company Comment: This regulatory authority case concerns a 92-year-old, female patient with no medical history reported, who experienced the fatal unexpected serious events of Headache, Myalgia, Altered state of consciousness and Muscular weakness which occurred 1 day after the first dose of mRNA-1273 vaccine. Patient died 3 months 9 days after the vaccination. The reported cause of death was Pneumonia. It is unknown if an autopsy was performed. The patient developed general weakness, had difficulty eating, and did not respond to call On 15-Feb-2021 (3 months and 2 days after vaccination), 4 days later she was treated at emergency department and was diagnosed with brain thrombosis and recommended for operation by the physician. Considering the patients age, the family did not consider operation and the patient was transferred to the ICU, then to the acute care unit, was discharged, and eventually transferred to a nursing home. After admission, patient was often brought to the hospital due to a slower heartbeat. 3 months 9 days after vaccination (22-02-2022), the patient died of pneumonia. The patient’s age remains a confounder. The benefit-risk relationship o Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non significant follow up received on 25-APR-2022, contains No new information.

Case ID	Narrative (Complete)
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of EMBOLISM (Coagulation disorders:thromboembolism) and HAEMORRHAGE (Coagulation disorders:hemorrhage) in a 67-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 022d21a) for an unknown indication. No Medical History information was reported. On 12-Aug-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 16-Aug-2021, the patient experienced EMBOLISM (Coagulation disorders:thromboembolism) (seriousness criterion death) and HAEMORRHAGE (Coagulation disorders:hemorrhage) (seriousness criterion death). The patient died on 17-Aug-2021. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not provided. Patient did not receive previous and other dose of vaccine. Treatment medication information was not provided by the reporter. It was reported that the patient experienced other symptoms. Diagnosis: Coagulation disorders: thromboembolism, hemorrhage Company comment: This regulatory authority case concerns a 67-year-old female patient, with no medical history reported, who experienced the unexpected fatal events of embolism and hemorrhage which were considered as serious per death. The events occurred approximately 4 day after the first dose of mRNA-1273. As reported the patient experienced coagulation disorders: thromboembolism and hemorrhage, and died 5 days after first dose. No information regarding diagnostic or laboratory findings was provided. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per Regulatory Authority reporting.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of COVID-19 (COVID 19 positive) and VACCINATION COMPLICATION (Other symptoms/Non-specific report of reaction to vaccine) in a 66-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 080C21A) for an unknown indication. No Medical History information was reported. On 16-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Other) 1 dosage form. On 16-Aug-2021, the patient experienced COVID-19 (COVID 19 positive) (seriousness criteria death and hospitalization) and VACCINATION COMPLICATION (Other symptoms/Non-specific report of reaction to vaccine) (seriousness criteria death and hospitalization). The patient died on 21-Aug-2021. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: positive (Positive) Positive. For mRNA-1273 (Spikevax) (Other), the reporter did not provide any causality assessments. No concomitant medications were reported. The patient received vaccine doses previously. Causality: classification as COINCIDENTAL.C. No treatment medications were reported. Company comment: This regulatory authority case concerns a 66-year-old male patient with no reported medical history who experienced serious due to hospitalization and death, unexpected events of COVID-19 (AESI) and vaccination complication that occurred after the 2nd dose of the mRNA-1273. The vaccination complication was retained as reported due to lack of information on whether these other symptoms were associated with diagnosis of COVID-19 and SARS-CoV-2 test: positive. Based on the current available information, the mRNA-1273 does not contain a virus capable of causing COVID-19 infection after vaccination. The benefit-risk relationship of mRNA-1273 is not affected by this report. The events reported and seriousness assessment retained as per regulatory authority reporting.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of SYNCOPE (Syncope vasovagal), PYREXIA (Fever) and VACCINATION COMPLICATION (Other symptoms) in an 80-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 022D21A) for an unknown indication. No Medical History information was reported. On 12-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Aug-2021, the patient experienced SYNCOPE (Syncope vasovagal) (seriousness criterion death), PYREXIA (Fever) (seriousness criterion death) and VACCINATION COMPLICATION (Other symptoms) (seriousness criterion death). The patient died on 15-Aug-2021. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. The patient date of birth reported was on 03-JUL-1941 12:00 am. Concomitant product use was not provided by the reporter.

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	Patient did not receive any dose previously and also did not receive any other vaccine. The site of application where suspect vaccine was administered was reported as Other. It was reported that patient did not have swelling, pain, erythema, induration, ulceration, abscess, crying incoercible, irritability, confusion, seizures, headache, hypotonia, rash,diarrhea, invagineumoniaion intestinal. The patient died on 15-AUG-2021 at 12:00 am. Treatment information was not provided. It was reported that patient was not hospitalized. No risk of life. No sequelae. Company comment: This is a regulatory case concerning an 80 year-old, female patient with no reported medical history, who experienced the serious Fatal unexpected, events of Syncope, pyrexia and vaccination complication, approximately 3 days after the second dose of mRNA-1273 vaccine. The patient died the same day the events started, cause of death was not further specified. It is unknown whether an autopsy was performed. Patient´s advanced age remains as a confounder for the fatal outcome and the event syncope. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of VACCINATION COMPLICATION (Other symptoms) in an 88-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 022D21A) for an unknown indication. No Medical History information was reported. On 11-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Aug-2021, the patient experienced VACCINATION COMPLICATION (Other symptoms) (seriousness criterion death). The patient died on 11-Aug-2021. It is unknown if an autopsy was performed. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: no (Negative) No. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Previouslypatient did not received the dose. Patient did not received other vaccine. No concomitant medication was reported. No treatment information was provided. COMPANY COMMENT : This regulatory authority case concerns a 88-year-old female patient, with no medical history reported, who experienced unexpected serious (seriousness criterion death) fatal event of vaccination complication, which occurred on same day after the second dose of mRNA-1273 vaccine. It reported that patient died on 11-Aug-2021. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. The event were assessed as serious as per Regulatory Authority´s report .
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of VACCINATION COMPLICATION (Other Symptoms/event supposedly attributable to vaccination or immunization) and SARS-COV-2 TEST POSITIVE ([EST]_PCR_COVID_POSITIVE) in a 75-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 022D21A) for an unknown indication. No Medical History information was reported. On 12-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 22-Aug-2021, the patient experienced VACCINATION COMPLICATION (Other Symptoms/event supposedly attributable to vaccination or immunization) (seriousness criteria death and hospitalization) and SARS-COV-2 TEST POSITIVE ([EST]_PCR_COVID_POSITIVE) (seriousness criteria death and hospitalization). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: yes (Positive) Yes. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. It was reported that the patient previously did not receive any dose of Moderna mRNA Vaccine and did not receive any other vaccines. The site of administration of the suspect vaccine was reported as other. The patient had no pain, no swelling, no erythema, no induration, no ulceration, no abscess, no seizures, no syncope vasovagal, no crying incoercible, no irritability, no confusion, no headache, no hypotonia, no rash, no fever, no [invagineumo niaion] intestinal, no diarrhea and no risk of life and sequelae. The patient died on an unknown date. No treatment details were reported. COMPANY COMMENT:

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	This fatal regulatory case concerns a 75-year-old male patient, with no reported medical history, who experienced the unexpected serious (hospitalization) fatal events of SARS-CoV-2 test positive and Vaccination complication. The events occurred approximately 10 days after 2nd dose of mRNA-1273 vaccine. It is unknown if an autopsy was performed. The benefit-risk relationship of drug is not affected by this report. Events seriousness captured as per Regulatory Authority assessment in Source Document.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIOVASCULAR DISORDER (Acute cardiovascular injury) in a 77-year-old female patient who received mRNA-1273 (Spikevax) (batch no. NK0084) for an unknown indication. No Medical History information was reported. On 13-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 16-Sep-2021, after starting mRNA-1273 (Spikevax), the patient experienced CARDIOVASCULAR DISORDER (Acute cardiovascular injury) (seriousness criteria death and hospitalization). The patient died on 16-Sep-2021. The reported cause of death was acute cardiovascular injury. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: no (Negative) No. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medications were reported. Classification reported as analysis Patient had not received previous dose. Patient had not received other vaccine. Company comment: This regulatory authority case concerns an elderly 77-year-old female patient, with no reported medical history, who experienced the serious (fatal and hospitalisation) unexpected AESI of Cardiovascular disorder (reported as Acute cardiovascular injury). The event occurred approximately 1 month after the second dose of mRNA-1273 vaccine and had a fatal outcome, with death occurring on the same day. It is not known whether autopsy was performed. Elderly age of the patient is a risk factor for the event and the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness retained as per Regulatory Authority reporting.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 16-Mar-2022. The most recent information was received on 18-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism) and CARDIAC ARREST (Cardiac arrest) in a 78-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004498) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect products included non-company products TOZINAMERAN (COMIRNATY) for Vaccination and TOZINAMERAN (COMIRNATY) for Vaccination. No Medical History information was reported. On 31-Mar-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 12-May-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (Intramuscular) 1 dosage form. On 18-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 09-Feb-2022, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criterion death) and CARDIAC ARREST (Cardiac arrest) (seriousness criterion death). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). The patient died on 20-Feb-2022. It is unknown if an autopsy was performed. At the time of death, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 09-Feb-2022, Computerised tomogram: ct detected large pulmonary embolies (abnormal) CT detected large pulmonary embolies. For mRNA-1273 (Spikevax) (Intramuscular), the reporter considered PULMONARY EMBOLISM (Pulmonary embolism) and CARDIAC ARREST (Cardiac arrest) to be possibly related. No further causality assessment was provided for COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). No concomitant medication was reported. No treatment medication was reported. Report number- 4.1(b) [redacted] was found to be a duplicate for Report number- 4.1(b) [redacted] upon receipt of follow up. All information kept in 4.1(b) [redacted] (this report) and report 4.1(b) [redacted] had been nullified. Company comment: This regulatory case concerns a 78-year-old, male patient with no reported medical history, who experienced the unexpected, fatal AESI Pulmonary embolism and unexpected, fatal event of Cardiac arrest. COVID-19 immunisation was reported as an additional event wherein 2 doses of Tozinameran COVID-19 vaccine were administered 6 months prior to mRNA-1273. The events occurred approximately 3 months after receiving mRNA-1273 as booster dose, where CT scan was done which revealed large pulmonary emboli. The patient was then admitted to the medical intensive care where unspecified treatment was administered. Presenting symptoms and initial vital signs were not specified in the case. No direct cause for the pulmonary embolism was found. Prior cardiac arrest has resulted to significant brain damage. The patient died 11 days after events onset. It is unknown if

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	autopsy was performed. The elderly age of the patient remains a confounder for the events and for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 18-Mar-2022: Follow up received contains updated date of death, lab data and reporter's comment.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 15-Mar-2022. The most recent information was received on 21-Apr-2022 and was forwarded to Moderna on 27-Apr-2022. This case was reported by a pharmacist via the Drug Information Center. On 16-Mar-2022, follow-up information, reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a pharmacist, was received via the PMDA (Ref, 4.1(b)). On 16-Mar-2022, follow-up information was reported by a physician via a medical representative. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). Around 27-Feb-2022, the patient had physical deconditioning and poor food intake and tended to lie down. Around 06-Mar-2022, the patient fell and bruised caudal portion at home. Thereafter, the patient often lay down in bed. On 13-Mar-2022, in the afternoon, the patient received the 3rd vaccination with this vaccine. On 14-Mar-2022, at 08:40, the patient experienced physical deconditioning but was confirmed safe. At 09:45, the patient was found in cardio-respiratory arrest. Cardiac massage was performed by the patient's family member. The patient was in cardiac arrest when ambulance teams made contact. The ambulance team transported the patient while performing cardiac massage. At the time of transport, the patient was noted to have acute renal failure. At 09:52, the ambulance arrived at the reporting hospital. The patient's mouth was rigid, and intubation could not be performed. Thereafter, the patient was unable to be resuscitated and was confirmed dead. K was 9.0 at the time of death. There were also findings of hyponatraemia. Rhabdomyolysis, acute renal failure from dehydration, hyperkalaemia, and arrhythmia were considered causes of death. The outcome of physical deconditioning and hyponatraemia was unknown. The outcome of cardio-respiratory arrest, rhabdomyolysis, acute renal failure from dehydration, hyperkalaemia, and arrhythmia was reported as fatal. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 16-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). Fracture of the left caput humeri and suspected hemodyscrasia was assessed as serious by the MAH. On an unknown date, the patient received the 1st dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before vaccination: 35.2 degrees Celsius. On 28-Feb-2022, at 13:15, the patient received the 3rd vaccination with this vaccine. On an unknown date, fracture of the left caput humeri developed. Around 04-Mar-2022, swelling, pain, and internal hemorrhage of the left upper arm were noted. On 07-Mar-2022, the patient went to see a nearby physician. No specific tests were performed, but hemodyscrasia was suspected. After returning home, the patient lost consciousness and was transported to the reporting hospital in a cardio-respiratory arrest state. There was no response to treatment. Test results after cardiac arrest included AST 754, LDH 1,665, CK 1,112 (CKMB 25), and K 12.6. At 16:55, the patient's death was confirmed. The outcome of fracture of the left caput humeri and suspected hemodyscrasia was unknown. The outcome of swelling of the left upper arm, pain, internal hemorrhage, consciousness loss, and cardio-respiratory arrest was reported as fatal. Follow-up investigation will be made. Reporter comments continuation: Since the memory of the family members is vague, the relationship between before and after is unclear, but since there is also a fracture of the left caput humeri, it is likely that this was the main cause of the swelling in the left upper arm, and the degree of involvement of this vaccine is unknown. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 18-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of HENOCH-SCHONLEIN PURPURA (Henoch-Schonlein purpura) in a 71-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 2104025) for COVID-19 vaccination. The patient's past medical history included Adenocarcinoma of colon, Lung cancer in situ and Thyroidectomy. Concurrent medical conditions included Chronic renal failure, Obesity, Hypertension arterial and Hypercholesteremia. Concomitant products included COLECALCIFEROL (UVEDOSE), CALCIUM POLYSTYRENE SULFONATE (RESIKALI), AMLODIPINE, SEVELAMER CARBONATE (RENVELA), CALCIUM CARBONATE (CALCIDIA), SODIUM BICARBONATE (BICARBONATE NA), ALFACALCIDOL (UN-ALFA), LEVOTHYROXINE SODIUM (LEVOTHYROX), FUROSEMIDE and ATORVASTATIN CALCIUM (ATORVASTATINE EG) for an unknown indication. On 21-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced HENOCH-SCHONLEIN PURPURA (Henoch-Schonlein purpura) (seriousness criteria death and hospitalization). The patient died on 08-Nov-2021. An autopsy was not performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Treatment information was not provided. Company Comment: This is a Regulatory Authority case concerning a 71-year-old female patient, with relevant medical history of adenocarcinoma of colon and lung cancer in situ, and in treatment with polypharmacy, who experienced the fatal event of Henoch-Schonlein purpura. The event occurred 20 days after a dose of mRNA-1273 vaccine, and patient died 1 month and 16 days after. An autopsy was not performed. Medical history of adenocarcinoma of colon and lung cancer in situ, as well as polypharmacy, remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 21-Mar-2022 and was forwarded to Moderna on 21-Mar-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of MYOCARDIAL INFARCTION (Heart attack) in a 69-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214030) for COVID-19 vaccination. The patient's past medical history included Gastroduodenal ulcer, Pelvic kidney (Pelvic right kidney), Spasmophilia and Transplant (Right calf graft). Concurrent medical conditions included Hypercholesterolaemia, Hypertrophic cardiomyopathy, Peripheral arterial occlusive disease (AOMI known since 2016), COPD and Arterial hypertension.

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	Concomitant products included ACETYLSALICYLATE LYSINE (KARDEGIC), AMLODIPINE BESILATE, PERINDOPRIL ERBUMINE (COVERSYL AM), FLUTICASONE FUROATE (AVAMYS), PANTOPRAZOLE and ROSUVASTATIN CALCIUM (CRESTOR) for an unknown indication. On 11-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 17-Jan-2022, the patient experienced MYOCARDIAL INFARCTION (Heart attack) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment drug was reported. Company Comment: This is a Regulatory Authority case concerning a 69-year-old male patient, with relevant medical conditions of hypercholesterolemia, hypertrophic cardiomyopathy, peripheral arterial occlusive disease, arterial hypertension, and COPD under treatment, who experienced the fatal event of Myocardial infarction (AESI). The event occurred 6 days after a dose of mRNA-1273 vaccine (reported as R1). No death date was reported. It is unknown if an autopsy was performed. Patient´s mentioned medical history could be consider risk factors for the event. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Mar-2022: Upon query received from business partner, Non-Significant correction was performed on 29-MAR-2022. Updated patient's gender from female to male in company comment.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 23-Mar-2022 and was forwarded to Moderna on 23-Mar-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CARDIAC ARREST (Cardiac arrest) in a 72-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3001653) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Allergy multiple, Dyslipidaemia and Supraventricular tachycardia. On 20-Apr-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 27-Apr-2021, after starting mRNA-1273 (Spikevax), the patient experienced RASH (Rash). On 14-May-2021, the patient experienced VOMITING (Vomiting). On an unknown date, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and medically significant). The patient died on 17-May-2021. The reported cause of death was Cardiac arrest. An autopsy was not performed. At the time of death, VOMITING (Vomiting) had not resolved and RASH (Rash) was resolving. No Concomitant medications were reported No treatment medications were reported Company Comment: This is a regulatory case concerning a 72-year-old, female patient with reported medical history of Supraventricular tachycardia, who had a fatal outcome with unexpected serious event of Cardiac arrest, after receiving the first dose of mRNA-1273 vaccine. The patient died 37 days after the said mRNA-1273 vaccine with cause of death was Cardiac arrest. The clinical course leading to demise was not reported. At the time of reporting, autopsy has not been performed. Medical history of Supraventricular tachycardia remains a confounder for the event Cardiac arrest. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness of the event was assessed as per Regulatory Authority's report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 22-Mar-2022. The most recent information was received on 04-Apr-2022 and was forwarded to Moderna on 12-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 04-Apr-2022, follow-up information was received from a physician via a medical representative. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On 04-Mar-2022, at 14:30, the patient received the 3rd vaccination with this vaccine. After the vaccination, the patient experienced diarrhea as a digestive symptom. On 05-Mar-2022, before dawn, the patient was found dead in his bedroom. A diagnosis of myocardial infarction (presumed) was made. The outcome of diarrhea was unknown. The outcome of myocardial infarction was reported as fatal. No follow-up investigation will be made. Follow-up received on 04-APR-2022 Updated: Patient Information, Other Relevant History, Product Information, Narrative, Reporter Comments Company Comment: Myocardial infarction developed after the administration of ELASOMERAN, but past medical history and other factors may have contributed to the occurrence.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 18-Mar-2022. The most recent information was received on 07-Apr-2022 and was forwarded to Moderna on 15-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 07-Apr-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On 06-Mar-2022, the patient received the 3rd vaccination with this vaccine. On 13-Mar-2022, around 09:00, after breakfast, the patient was confirmed alive for the final time. Around 10:30, the patient was found collapsed in her room. The patient was lying face down with marks of vomiting of food residue. The patient was unconscious, so an ambulance was requested. The patient was transported to the reporting hospital by a doctor helicopter. At 11:50, the patient was transported to the reporting hospital. JCS 300 and severe consciousness disturbance were observed. Right pupil dilation was seen with no light reflex. As there were findings of airway obstruction, the patient was endotracheally intubated and placed on a ventilator. Thereafter, JCS was 200, but decerebrate-rigidity-like leg position was observed. The patient was diagnosed with subarachnoid haemorrhage with hematoma in the right frontal lobe and temporal lobe by head CT. Aneurysm was found at the bifurcation of the right middle cerebral artery. It was judged that the patient was not a candidate for surgery with the diagnosis of severe subarachnoid haemorrhage. The patient was initially treated conservatively. If the condition improved, the patient was planned to be treated for aneurysm. Just after 21:00, the patient had blood pressure decreased with absence of apnea. The brain stem reflex disappeared. Ventilator management was continued. The use of vasopressor was started. On 17-Mar-2022, at 12:30, the patient died. The cause of death was subarachnoid haemorrhage. Necropsy was not performed. The outcome of collapsed, vomiting of food residue, disturbed consciousness, airways obstruction, aneurysm at the bifurcation of the right middle cerebral artery was unknown. The outcome of subarachnoid

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	hemorrhage with hematoma , respiratory arrest, and decreased blood pressure was reported as fatal. No follow-up investigation will be made. Follow-up received on 07-APR-2022 Updated: Patient Information, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 23-Mar-2022 and was forwarded to Moderna on 23-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (fever, runny nose) in an 83-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. pre-existing conditions include Cardiac patient, diabetic. Concurrent medical conditions included Heart disorder. On 08-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Dec-2021, the patient experienced CEREBRAL HAEMORRHAGE (fever, runny nose) (seriousness criterion death). The patient died on 03-Jan-2022. The reported cause of death was Cerebral haemorrhage. It is unknown if an autopsy was performed. Concomitant medication was not reported. Treatment information was not reported. Company Comment: This regulatory case concerns an 83-year-old, female patient with relevant medical history of Diabetes Mellitus, who experienced the unexpected, serious (fatal) AESI of cerebral haemorrhage after administration of the third dose of the Moderna mRNA-1273 vaccine. The reporter stated that 9 days after vaccination, the patient had 'brain bleeding'. No further details were provided. The patient expired on 03Jan2022 (26 days after vaccination). It is unknown if an autopsy was performed. However, the reported cause of death was 'Cerebral haemorrhage'. The medical history of Diabetes Mellitus as well the patient's advanced age, which are known risk factors for cerebral hemorrhage, remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 22-Mar-2022. The most recent information was received on 12-Apr-2022 and was forwarded to Moderna on 19-Apr-2022. This case was reported by a physician via a medical representative. On 12-Apr-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 17-Mar-2022, from 15:00 to 16:30, the patient received the 3rd vaccination with this vaccine. On 18-Mar-2022, around 20:00, the patient was spending time with his family. At 21:00, there were no symptoms. On 19-Mar-2022, around dawn, the patient died. Around 06:30, the family member found the patient falling down on his face. The patient was in a state of cardio-respiratory arrest. At 12:20, post-mortem examination was performed. The autopsy report showed that an unidentified intrinsic death occurred. No necropsy was performed. The outcome of cardio-respiratory arrest was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: There is no evidence for the association and there were many vaccine recipients who took the concomitant drugs of this case; therefore, the occurrence of the adverse events is not associated with concomitant drugs. There is no evidence for the association with the underlying conditions, which were very common diseases; therefore, the occurrence of the adverse event is not related to pathological factors of underlying diseases and complications. The patient was doing well for at least 27 hours after the vaccination and it is unlikely that vaccination with this vaccine was the direct cause of cardio-respiratory arrest; therefore, there is no association between the cause of death and the adverse event. This case was not reported by the primary physician of the vaccine recipient but reported by the physician who conducted the pre-examination at the time of mass vaccination and the physician who conducted the post-mortem examination as a police surgeon. The autopsy was proposed to the bereaved family, but their consent was unable to be obtained. It was concluded that there was no causal relationship with this vaccine and an unspecified intrinsic death occurred. Follow-up received on 12-APR-2022 Updated: Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Cardio-respiratory arrest can be also considered as an accidental disease although it developed after the administration of ELASOMERAN.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 18-Mar-2022 and was forwarded to Moderna on 23-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). Cerebral infarction and decreased level of consciousness was assessed as serious by the MAH. On 25-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 16-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 37.0 degrees Celsius. On 15-Mar-2022, at 14:00, the patient received the 3rd vaccination with this vaccine. Around 16:00, pyrexia of 38.0-38.9 degrees Celsius developed. On an unknown date, pyrexia of 39 degrees Celsius to 40 degrees Celsius persisted. The patient was recommended to take acetaminophen but refused. On 17-Mar-2022, drip infusion was started because insufficient fluid intake was noted. The patient was able to answer calls and talk. On 18-Mar-2022, in the morning, decreased level of consciousness and decreased blood pressure were noted. Computed tomography (CT) of the head, chest, and abdomen was performed to determine the cause. There was no cause of decreased level of consciousness from the chest to the abdomen. However, head CT showed cerebral infarction in the left frontal region, which appeared to be in the acute phase. Intratracheal intubation and drip infusion were performed. At 11:10, the patient died. The outcome of pyrexia, decreased level of consciousness, decreased blood pressure, and cerebral infarction was unknown. Follow-up investigation will be made. Company Comment: Cerebral infarction occurred after the administration of ELASOMERAN, but it is possible that it was influenced by complications, the patient's background and others. Also, death occurred after the administration of ELASOMERAN, but it is possible that it was influenced by concomitant events and others.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 18-Mar-2022 and was forwarded to Moderna on 18-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death) and CHEST PAIN (Chest pain) in an 89-year-old male patient who received mRNA-1273 (Spikevax) (batch no. G26761A) for COVID-19 immunisation. Concurrent medical conditions included Generalised arteriosclerosis, Hypertension and Aortic stenosis. Concomitant products included INDAPAMIDE, PERINDOPRIL ARGININE (COVEREX AS KOMB) from 2008 to an unknown date and DOXAZOSIN MESILATE (CARDURA XL) from 2008 to an unknown date for Hypertension.

Case ID	Narrative (Complete)
	On 04-Feb-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 16-Feb-2021, after starting mRNA-1273 (Spikevax), the patient experienced DEATH (Death) (seriousness criterion death) and CHEST PAIN (Chest pain) (seriousness criterion death). The patient died on 16-Feb-2021. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Reported that death might be resulted by the patient's un-treated cardiac disease. Time to onset after vaccination was 12 days. Based on the above, causality between the adverse events and COVID-19 VACCINE MODERNA was not assessable. No treatment medications were provided. Company Comment: This is a fatal case concerning an 89-year-old male patient with reported medical history of Generalized arteriosclerosis, Hypertension and Aortic stenosis, who experienced the unexpected serious events of Chest Pain and Death. The events led to the eventual demise of the patient as reported by the regulatory authority and occurred 12 days after receiving a dose of mRNA-1273 Vaccine. The patient died on the same day of onset of events, and it is unknown if an autopsy was performed. As reported, the patient's death might be resulted by the patient's un-treated cardiac disease. The mentioned medical history remains a confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 18-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This case was reported by a physician via a medical representative. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 21-Feb-2022, the patient received the 3rd vaccination with this vaccine. On 24-Feb-2022, pneumonia developed. On an unknown date, several days after the vaccination, the patient died. The outcome of pneumonia was reported as fatal. Follow-up investigation will be made. LP Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship. Company comment: This spontaneous case report concerns a 93-year-old female patient with medical history of Dementia, who experienced serious unexpected event of Pneumonia which resulted in fatal outcome. Reportedly, the event occurred three days after the patient had received the mRNA-1273 vaccine (as third dose). It was stated that several days after the vaccination, the patient died and the reported cause of death was pneumonia. It remained unknown whether the autopsy was performed. No additional details were disclosed at the time of this report. The patient's elderly age and medical history remains a confounder for the event and could contribute to the fatal outcome. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 21-Mar-2022. The most recent information was received on 23-Mar-2022 and was forwarded to Moderna on 23-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC FAILURE ACUTE (according to postmortem on heart failure) in a 67-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004670) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Pulmonary embolism (Pulmonary embolism) in 2014. Previously administered products included for COVID-19 immunisation: COMIRNATY (Booster after 2x Comirnaty) and COMIRNATY (Booster after 2x Comirnaty). Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY. Concurrent medical conditions included Hypertension (hypertension), Cardiac hypertrophy (Global cardiac hypertrophy and dilatation), Hepatic steatosis (Fatty liver disease), Anxiety disorder (anxiety disorder that was well controlled), Cardiac dilatation (Global cardiac hypertrophy and dilatation) and Blood pressure high (was well controlled). On 27-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 27-Nov-2021, after starting mRNA-1273 (Spikevax), the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). In December 2021, the patient experienced CARDIAC FAILURE ACUTE (according to postmortem on heart failure) (seriousness criterion death). The patient died on 09-Dec-2021. The reported cause of death was acute heart failure primarily rhythmogenic. An autopsy was performed. The autopsy-determined cause of death was acute heart failure primarily rhythmogenic. At the time of death, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. The time of death was reported as 04:42 and dosage text was reported as third partial vaccination / third dose heterologous. No treatment details were reported. Company comment: This regulatory authority fatal case concerns a 67-year-old male patient, with medical history of Cardiac hypertrophy, Cardiac dilatation, Hypertension, Pulmonary embolism and Hepatic steatosis, who experienced the unexpected serious fatal AESI of CARDIAC FAILURE ACUTE, which occurred approximately 12 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose for COVID19 vaccination (received Comirnaty as doses 1 and 2). The patient died on 09-Dec-2021. The reported cause of death was acute heart failure primarily rhythmogenic. The autopsy-determined cause of death was acute heart failure primarily rhythmogenic. The mentioned medical history remains as a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event´s seriousness assessed as reported. Most recent FOLLOW-UP information incorporated above includes: On 23-Mar-2022: Follow-up received was updated with relevant medical history, cause of death and event cardiac failure was updated to acute cardiac insufficiency. On 23-Mar-2022: Translation received on 31-Mar-2022 that contains non significant information includes event verbatim updated.

Case ID	Narrative (Complete)
4.1(b)	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 24-Mar-2022 and was forwarded to Moderna on 24-Mar-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in a 74-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3004960) for an unknown indication. Co-suspect products included non-company products COVID-19 VACCINE INACT (VERO) CZ02 (CORONAVAC) for an unknown indication and COVID-19 VACCINE INACT (VERO) CZ02 (CORONAVAC) for an unknown indication. No Medical History information was reported. On 14-Apr-2021, the patient received dose of COVID-19 VACCINE INACT (VERO) CZ02 (CORONAVAC) (Intramuscular) 1 dosage form. On 12-May-2021, the patient received dose of COVID-19 VACCINE INACT (VERO) CZ02 (CORONAVAC) (Intramuscular) 1 dosage form. On 25-Nov-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. Death occurred on 05-Mar-2022 at 10:30 AM It is unknown if an autopsy was performed. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment information was reported. The case concerns a 74-year-old male patient with no details on past medical history, presented with unexpected event of death. A co-suspect product in this case is the Coronavac Vero COVID-19 vaccine. The event occurred approximately 3 months and 12 days after the received dose of mRNA 1273 vaccine. Very limited information was provided and it is unknown if an autopsy was performed. The reporter's assessment was not provided in this case. The benefit risk relationship of vaccine is not affected by this report
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 25-Mar-2022 and was forwarded to Moderna on 25-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Found dead) and ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) in a 73-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000153A) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 21-Apr-2021 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 14-Jul-2021. Past adverse reactions to the above products included No adverse reaction with Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca. Concurrent medical conditions included Type II diabetes mellitus and Arterial hypertension. On 18-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Jan-2022, the patient experienced DEATH (Found dead) (seriousness criterion death) and ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criterion death). The patient died on 19-Jan-2022. An autopsy was performed. The autopsy-determined cause of death was Acute myocardial infarction. For mRNA-1273 (Spikevax) (Unknown), the reporter considered DEATH (Found dead) and ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) to be related. No concomitant product was provided. No treatment information was provided. Dosage text was reported as booster dose. Company comment: This regulatory authority case concerns a 73-year-old male patient, with concurrent illness of arterial hypertension and diabetes mellitus and prior ASTRAZENECA COVID-19 vaccination, who experienced the serious, unexpected events of acute myocardial infarction (AESI) and death 1 day after the booster dose of mRNA 1273 COVID-19 vaccine. Autopsy done revealed cause of death as Acute Myocardial infarction. The patient's age, hypertension and diabetes mellitus remain as confounders to events acute myocardial infarction and death. The reporter deemed events as having inconsistent causal association to immunization. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 24-Mar-2022. The most recent information was received on 13-Apr-2022 and was forwarded to Moderna on 20-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 13-Apr-2022, follow-up information was received from a physician. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 09-Mar-2022, at 19:00, the patient received the 3rd vaccination with this vaccine. On 10-Mar-2022, although headache and malaise were noted, the patient had a daily life as usual. Around 22:00, the patient took a bath. At 22:40, the patient was found in a state of cardio-respiratory arrest in the bathtub. On 11-Mar-2022, resuscitation was attempted, but the patient had no response and died. A CT scan indicated that water was taken into the patients lung. The cause of death was near drowning. The direct cause of death was near drowning, but the cause of near drowning is unknown. Myocardial infarction or fatal arrhythmia may have occurred. The outcome of headache and malaise was unknown. The outcome of cardio-respiratory arrest, near drowning, possibility of myocardial infarction, and possibility of lethal arrythmia was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: The patient had underlying diseases of diabetes mellitus and dyslipidemia, and a disease such as myocardial infarction cannot be ruled out; therefore, it is unknown whether the occurrence of adverse events is related to pathological factors of underlying diseases and complications. Thrombotic tendency developed after vaccination with this vaccine, and thus occurrence of myocardial infarction or others cannot be ruled out. The cause

Case ID	Narrative (Complete)
	of death and adverse events are related because the cause of near drowning is unknown, and the causal relationship cannot be ruled out. Follow-up received on 13-APR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Mar-2022 and was forwarded to Moderna on 28-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (intracerebral hemorrhage) in an 84-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005690) for COVID-19 vaccination. Historical Condition: Healthy except for the onset of dementia, living alone, normotonia, without medication. Patient had no k own allergies. On 14-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-Jan-2022, the patient experienced CEREBRAL HAEMORRHAGE (intracerebral hemorrhage) (seriousness criterion death). The patient died on 22-Jan-2022. The reported cause of death was Intra-cerebral haemorrhage. It is unknown if an autopsy was performed. No Concomitant Drug details were reported. No Treatment information was provided. Sender's comment included that on 20.01. - 6 days after the 3rd vaccination - the patient ran out of the house calling for help onto the street because she felt something was wrong with her, according to the Neighbors. She came immediately to the KH, where she was already beginning to be comatose, in the skull CT 8.5 x 3.9 x 6.5 cm intracerebral/intraparenchymal hemorrhage with narrow veins subdural hematoma (possibly result of an additional fall), the 2 days later led to death. Company comment: This regulatory authority case concerns an elderly 84-year-old female patient, with no reported medical history, who experienced the fatal unexpected AESI of Cerebral haemorrhage. The event occurred approximately 6 days after the third dose of mRNA-1273 vaccine and had a fatal outcome. Patient died 2 days after the onset of event. It is not known whether autopsy was performed. In the skull CT 8.5 x 3.9 x 6.5 cm intracerebral/intraparenchymal hemorrhage with narrow veins subdural hematoma (possibly result of an additional fall). Elderly age of the patient is a risk factor for the event and the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event seriousness retained as per Regulatory Authority reporting.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 25-Mar-2022. The most recent information was received on 21-Apr-2022 and was forwarded to Moderna on 26-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 21-Apr-2022, follow-up information was received from a physician. The patient was in a hospital for a long time due to late effects of cerebral infarction. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.5 degrees Celsius. On 17-Mar-2022, at 14:17, the patient received the 3rd vaccination with this vaccine. No apparent adverse reactions were observed after vaccination. BT: 36.3 to 36.6 degrees Celsius, and Sp02: 96 to 99%. On 19-Mar-2022, at 16:20, no abnormality was found. At 16:50, the patient was found in a state of respiratory arrest. Cardio-respiratory arrest was noted. At 17:11, the patient was confirmed dead. The cause of death was acute respiratory failure. No autopsy was not performed. The outcome of cardio-respiratory arrest, and acute respiratory failure was reported as fatal. No follow-up investigation will be made. Follow-up received on 21-APR-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Cardio-respiratory arrest and acute respiratory failure can be also considered as an accidental event although it developed after the administration of ELASOMERAN
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Mar-2022 and was forwarded to Moderna on 28-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (HEART ATTACK), NERVOUS SYSTEM DISORDER (CNS DAMAGE), LETHARGY (TOTAL KNOCKED OUT) and HEMIPLEGIA (PARALYZED LEFT SIDE) in a 77-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005835) for COVID-19 vaccination. The patient's past medical history included Stroke in 2012 and Muscle pain (MUSCLE PAIN OF STATINS). Concurrent medical conditions included Diabetes since 2012 and Expressive aphasia since 2017. On 05-Jan-2022, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced MYOCARDIAL INFARCTION (HEART ATTACK) (seriousness criterion death), NERVOUS SYSTEM DISORDER (CNS DAMAGE) (seriousness criterion death), LETHARGY (TOTAL KNOCKED OUT) (seriousness criterion death) and HEMIPLEGIA (PARALYZED LEFT SIDE) (seriousness criterion death). The reported cause of death was Myocardial infarct. It is unknown if an autopsy was performed. Concomitant medications was not provided by the reporter. Treatment information was not provided. Company comment: This is a fatal regulatory case concerning a 77-year-old male patient with diabetes, expressive aphasia, past medical history of stroke and concomitant use of statins, who experienced the serious unexpected event myocardial infarction, nervous system disorder, hemiplegia and lethargy with a fatal outcome. The events occurred on the same day after receiving the first dose of mRNA-1273. Date of death was not provided. The reported cause of death was Myocardial infarct. It is unknown if an autopsy was performed. Patient´s medical history, advanced age and underlying conditions related to the use of statins remains as confounder for the events and the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 28-Mar-2022 and was forwarded to Moderna on 29-Mar-2022.

Case ID	Narrative (Complete)
	This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a (physician), was received via the PMDA (Ref, 4.1(b)). On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 02-Mar-2022, the patient received the 3rd vaccination with this vaccine. On 04-Mar-2022, dyspnoea was observed. At 10:00, the patient was transported by ambulance to the reporting hospital. The patient was considered to experience worsening of cardiac failure which was caused by adverse reaction to this vaccine and was hospitalized. The patient was treated with drip infusion of furosemide. On 05-Mar-2022, bloody stool was observed. Progression of anaemia was noted, and blood transfusion was performed. On 08-Mar-2022, large intestine endoscopy showed polyp. On 10-Mar-2022, resection of the polyp was performed. After surgery, the patient's level of consciousness gradually decreased, and the patient suffered cardio-respiratory arrest. Temporary pacing was inserted, but the patient died. The outcome of dyspnoea, decreased level of consciousness, and cardio-respiratory arrest was reported as fatal. The outcome of worsening of cardiac failure, bloody stool, progression of anaemia, and polyp was unknown. Follow-up investigation will be made. Company Comment: Although cardiac failure developed after the administration of ELASOMERAN, possibility of complication can also be considered. Although dyspnoea developed after the administration of ELASOMERAN, influence of intercurrent event can also be considered.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 28-Mar-2022. The most recent information was received on 17-Jun-2022 and was forwarded to Moderna on 17-Jun-2022. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDITIS (death attributed to myocarditis after 28 days from AntiCovid vaccine with Moderna Vaccine) in an 81-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214003) for COVID-19 vaccination. The patient's past medical history included Atypical depressive disorder, Gonarthrosis and Cognitive disorders (Initial cognitive turbes). Previously administered products included for SARS-CoV-2 vaccination: SPIKEVAX (SPIKEVAX (EX COVID-19 VACCINE MODERNA) (MODERNA BIOTECH SPAIN and S.L.) (J07BX03)) on 28-May-2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX. Concurrent medical conditions included Hypertensive heart disease (sclerohypertensive heart disease), Polyarthropathy, Obesity and Diabetes (fasting hyperglycemia). Concomitant products included METFORMIN, OMEPRAZOLE, PAROXETINE, CHOLINE ALFOSCERATE (DELECIT), HYDROCHLOROTHIAZIDE, VALSARTAN (VALSARTAN D) and ACETYLSALICYLIC ACID (CARDIOASPIRIN) for an unknown indication. On 02-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 30-Jul-2021, after starting mRNA-1273 (Spikevax), the patient experienced MYOCARDITIS (death attributed to myocarditis after 28 days from AntiCovid vaccine with Moderna Vaccine) (seriousness criterion death). The patient died on 31-Jul-2021. The reported cause of death was Acute myocarditis. An autopsy was performed. The autopsy-determined cause of death was Acute myocarditis. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Autopsy: inconclusive (Inconclusive) INCONCLUSIVE. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment information were provided. Company comment: This is a regulatory case, reported by a physician, concerning an 81-year-old female patient, with medical history of Diabetes and Hypertensive heart disease, who experienced the serious Fatal unexpected, AESI of Myocarditis, 28 days after the mRNA-1273 vaccine, probably the second dose. The patient died one day after the onset of the event, an autopsy was performed and the result was reported as acute myocarditis. Patient's advanced age and mentioned medical history remain as confounders for the fatal outcome. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 04-Apr-2022: Follow-up contains no new information. On 17-Jun-2022: Follow-up document received on 17-Jun-2022 included: lab test results and concomitant medications updated.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 30-Mar-2022 and was forwarded to Moderna on 30-Mar-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and COVID-19 (covid-19) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 214011) for COVID-19 vaccination. The patient's past medical history included Alcohol use (2-3 glasses/week) and Arteriopathic disease. On 11-Aug-2021, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 22-Jan-2022, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criterion death) and COVID-19 (covid-19) (seriousness criterion death). The patient died on 25-Jan-2022. The reported cause of death was pneumopathie covid-19. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No Concomitant Drug details were reported. No Treatment information was provided.

Case ID	Narrative (Complete)
	Dosage text was reported as D2. Company comment. This fatal regulatory authority case concerns an 80 – year – old male patient with relevant medical history of arteriopathy disease, who experienced the unexpected AESI of COVID-19 approximately 5 months and 11 days after receiving a dose of mRNA-1273, reported as second dose of his COVID – 19 immunization schedules. Vaccination failure was also reported; however, no information regarding the first dose was provided. Death occurred three days after the onset of COVID – 19, and the cause of death was reported as pneumopathy COVID-19. It is unknown if an autopsy was performed. Patient´s age and medical history of arteriopathy disease could be a confounding factor for severe COVID-19 illness. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 29-Mar-2022. The most recent information was received on 14-Apr-2022 and was forwarded to Moderna on 21-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a (physician), was received via the PMDA (Ref, 4.1(b)). On 14-Apr-2022, follow-up information was received from a physician. On 04-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 25-Jun-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 09-Feb-2022, at 14:30, the patient received the 3rd vaccination with this vaccine. On 10-Feb-2022, in the afternoon, depressed level of consciousness was noted, and the patient visited a medical institution. Blood collection was performed, and drip infusion was attempted but did not go in. The patient was advised to be hospitalized but refused and returned home. Depressed level of consciousness was resolving. On 11-Feb-2022, around 11:00, the family member found the patient dead. No autopsy was performed, and postmortem examination was performed. The cause of death was unknown. The outcome of depressed level of consciousness was reported as resolving. No follow-up investigation will be made. Reporter comments continuation: The relationship between the occurrence of adverse events and pathological factors such as underlying diseases and complications is unknown. The relationship between the cause of death and adverse events is unknown. The causality is unknown. The drugs the patient took are unspecified except aspirin. Follow-up received on 14-APR-2022 Updated: Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: Depressed level of consciousness and death could also be due to a past medical history or an accidental disease although it developed after the administration of ELASOMERAN.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 30-Mar-2022 and was forwarded to Moderna on 30-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of LOSS OF CONSCIOUSNESS (He had a very strong headache, could not speak clearly, and after 15 minutes, during which the ambulance arrived, he lost consciousness due to heavy brain bleeding.), HEADACHE (He had a very strong headache, could not speak clearly, and after 15 minutes, during which the ambulance arrived, he lost consciousness due to heavy brain bleeding.) and CEREBRAL HAEMORRHAGE (He had a very strong headache, could not speak clearly, and after 15 minutes, during which the ambulance arrived, he lost consciousness due to heavy brain bleeding.) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 030g21a) for COVID-19 vaccination. No Medical History information was reported. On 20-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 22-Feb-2022, the patient experienced LOSS OF CONSCIOUSNESS (He had a very strong headache, could not speak clearly, and after 15 minutes, during which the ambulance arrived, he lost consciousness due to heavy brain bleeding.) (seriousness criterion death), HEADACHE (He had a very strong headache, could not speak clearly, and after 15 minutes, during which the ambulance arrived, he lost consciousness due to heavy brain bleeding.) (seriousness criterion death) and CEREBRAL HAEMORRHAGE (He had a very strong headache, could not speak clearly, and after 15 minutes, during which the ambulance arrived, he lost consciousness due to heavy brain bleeding.) (seriousness criterion death). It is unknown if an autopsy was performed. No concomitant and treatment medications were reported. Company comment: This regulatory case concerns an 80-year-old male patient with no medical history reported, who experienced the unexpected serious (fatal) events Cerebral haemorrhage, Headache and loss of consciousness, two days after a dose of mRNA-1273. The patient experienced strong headache, could not speak clearly and within fifteen minutes, lost consciousness due to heavy brain bleeding. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 06-May-2022: No new information received. On 20-May-2022: Follow up document received on 20 May 2022 contains sender's comment was updated.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 30-Mar-2022. The most recent information was received on 14-Apr-2022 and was forwarded to Moderna on 21-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 14-Apr-2022, follow-up information was received by a physician. On 18-Apr-2022, follow-up information was reported by a healthcare professional via the Drug Information Center. The vaccine recipient had regular visits to a hospital. On 24-Jul-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 13-Aug-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.6 degrees Celsius. On 28-Mar-2022, at 11:30, the patient received the 3rd vaccination with this vaccine. At 20:00, after dinner, the patient went to bed. On 29-Mar-2022, around 01:00, the patient went to the bathroom with assistance. Around 03:00, the family member woke the patient up to encourage her to go to the bathroom. However, the patient was in a state of unconsciousness. An emergency call was made immediately, and the patient was raced to an emergency hospital. At 05:34, death was confirmed. The cause of death was unknown. No autopsy was performed. The outcome of the patient had no consciousness was unknown. No follow-up investigation will be made. Reporter comments continuation: Since adverse events developed within 24 hours after the vaccination, there was a relationship between the cause of death and adverse events. Adverse events developed within 24 hours after vaccination, and other factors cannot be ruled out, but details are unknown. Follow-up received on 14-APR-2022 Updated: Reporter Information, Patient Information, Other Relevant History, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 30-Mar-2022 and was forwarded to Moderna on 30-Mar-2022.

Case ID	Narrative (Complete)
	This regulatory authority case was reported by a consumer and describes the occurrence of GRANULOMATOSIS WITH POLYANGIITIS (After the 3rd vaccination on 18.12.2021, a strong outbreak of granulatosis again, none more drugs struck, death on 21.02.2022. Time correlation to vaccination and none pre-existing conditions!) in a 77-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000087A) for COVID-19 vaccination. Previously administered products included for Prophylactic vaccination: COMIRNATY on 14-Apr-2021 and COMIRNATY on 26-May-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY; and Wegener's granulomatosis with COMIRNATY. Concurrent medical conditions included Wegener's granulomatosis. On 18-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 04-Jan-2022, the patient experienced GRANULOMATOSIS WITH POLYANGIITIS (After the 3rd vaccination on 18.12.2021, a strong outbreak of granulatosis again, none more drugs struck, death on 21.02.2022. Time correlation to vaccination and none pre-existing conditions!) (seriousness criterion death). The patient died on 21-Feb-2022. The reported cause of death was Wegener's granulomatosis. It is unknown if an autopsy was performed. Company comment: This regulatory case concerns a 77-year-old, female patient with no preexisting illness and past drug history of administration of two doses of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine) with medical history of Wegener´s granulomatosis after the second dose, who experienced the unexpected, serious (fatal) event of granulomatosis with polyangiitis (Wegener's granulomatosis). The event occurred 17 days after administration of the third dose of the Moderna mRNA-1273 vaccine. Two to three weeks after receiving the second dose of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine), the patient complained of cough and shortness of breath. She was admitted and was diagnosed with Granulomatosis with Polyangiitis, an immune disease of the lungs. She was discharged and therapy with cyclophosphamide was started. The patient recovered well by Dec2021. There were no more complaints and the patient's condition stabilized after a few months. The Chest X-ray and Computed Tomogram (CT) scan showed decreased changes in the lungs which showed good healing of the lung damage. However, 2 weeks after receiving the third dose of the Moderna mRNA-1273 vaccine, the patient again experienced 'discomfort cough' and shortness of breath. At the beginning of Feb2022, there was dramatic deterioration. There was further severe lung damage which was detected in the CT scan. Therapy was attempted with rituximab but this no longer occurred. The patient expired on 21Feb2022 (2 months, 3 days after vaccination with the third dose of the Moderna mRNA-1273 vaccine). The reported cause of death was 'Wegener's granulomatosis'. It is unknown if an autopsy was performed. The history of Wegener's granulomatosis after the second dose of Comirnaty, and past drug history of administration of two doses of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine) remain as confounders. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 30-Mar-2022: Upon internal review on 21-Apr-2022, non-significant correction was performed. The company comment was updated.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST DISCOMFORT (Chest tightness and respiratory asthma) and ASTHMA (Chest tightness and respiratory asthma) in an 87-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Diabetes and Hard of hearing. On 21-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Jan-2022, the patient experienced CHEST DISCOMFORT (Chest tightness and respiratory asthma) (seriousness criterion death) and ASTHMA (Chest tightness and respiratory asthma) (seriousness criterion death). The patient was treated with PARACETAMOL (PANADOL) at an unspecified dose and frequency. The patient died on 02-Mar-2022. The reported cause of death was Chest tightness and respiratory asthma. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. WWID and patient ID in site was reported as 4.1(b) [redacted]. No concomitant drug was reported. On 21-Jan-2022, patient had Moderna booster and went to seek medical advice due to discomfort. On 22-Jan-2022, patient started to have dyspnea and chest distress lasted for 3 days. Panadol was taken. On 25-Jan, 27-Jan and 07-Feb-2022, patient visited Pulmonary Medicine outpatient. The doctor found no abnormalities. Medications for oral administration were prescribed. On 14-Feb-2022, dyspnea worsened. Patient's face was pale and went to the cardiology department of hospital. Admitted to ICU and diagnosed as myocardial infarction, heart failure, and suspected pneumonia. Cardiac catheterization, coronary balloon dilation, and stent placement were performed. On 21-Feb-2022, patient was discharged. On 01-Mar-2022, patient had chest distress. On 02-Mar-2022 at 3:00pm, patient was found dead in room. Company Comment: This is a fatal case from regulatory authority that concerns an 87-year-old female patient, with medical history of diabetes, who experienced the unexpected, serious fatal events of CHEST DISCOMFORT and ASTHMA, one day after receiving a third dose of mRNA-1273 vaccine. Details of primary doses were not provided. According to the narrative of the source document, she consulted several times for dyspnea, and she was admitted to the intensive care unit with a myocardial infarction, heart failure and suspected pneumonia. A cardiac catheterization was performed with coronary vascular balloon dilation and vascular stent placement. She was subsequently discharged but 10 days later had chest distress again. The next day, she was found dead at home. Death occurred around 40 days post-vaccination. It is unknown if an autopsy was performed. The medical history of diabetes remains a confounder. The patient's advanced age could also be a contributory factor for the fatal outcome. The benefit risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received: Events were updated from "Chest distress, wheezing" to "Chest tightness and respiratory asthma" and I-narrative was updated.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (ST-segment elevation myocardial infarction (STEMI)) in an 85-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006K21A 1110210-CDC) for COVID-19 vaccination. The patient had a history of HTN, PU, and ERSD.

Case ID	Narrative (Complete)
	On 22-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 06-Feb-2022, the patient experienced ACUTE MYOCARDIAL INFARCTION (ST-segment elevation myocardial infarction (STEMI)) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported. The patient received two doses AstraZeneca vaccines on16-Jun-2021 and 29-Sep-2021 respectively. On 22-Jan-2022 patient received COVID-19 booster vaccine (Moderna) at 14.00. It was reported that on 6-Feb-2022, the patient visited the emergency department of hospital due to abdominal pain and the patient had the change in consciousness. The brain CT showed no abnormality, chest X-ray showed cardiac hypertrophy and ECG showed elevation of ST segment. After examination by the doctor, the patient received aspirin 300 mg PO, ticagrelor 180 mg PO and NTG 30 ml IVD (run 1.2 ml/hr) by ST and was recommended to be transferred to another hospital. The patient was transferred to the emergency department of another hospital and was advised to receive heparin 4000 IU IVA and atorvastatin 80 mg PO by ST. After emergency consultation in the Department of Cardiology, the patient underwent direct catheterization. After PTCA, 5 metal stents were placed in the left coronary artery and 1 in the left circumflex artery. The patient was admitted to the ICU for further treatment. After admission, the patient was given vasopressor (dopamin+norepinephrine+epinephrine) to treat hypotension, and CVVH was used to treat ESRD after reporting to the Department of Nephrology. On 06-Feb-2022 laboratory tests were performed and below are the results. Troponin-I: 3.74, BNP: 4530, CK-MB: 28. On 07-Feb-2022: Troponin-I: >100, BNP: 4530, CK-MB: 575-774, PCT: 0.15. On 7-Feb-2022 in the afternoon, the patient developed bradycardia and the family refused emergency treatment. The patient died at 18:42. As the relevance of the vaccine to the patient's health condition could not be completely excluded, the event was still reported as an adverse event. The WWID number was reported as 4.1(b) . Company comment: This is a regulatory, fatal case concerning an 85-year-old female patient with reported medical history of Hypertension and End-Stage Renal Disease, who experienced the fatal unexpected serious adverse event of special interest, Acute Myocardial Infarction which occurred 15 days after receiving the third dose of mRNA-1273 Vaccine. As reported, the patient initially presented with abdominal pain and changes in consciousness. She was then rushed to the hospital where chest x-ray revealed cardiac hypertrophy, ECG abnormality and elevated cardiac markers. The patient was then transferred to another hospital where she was admitted at the ICU, treated with medications, and underwent cardiac catheterization. However, despite treatment, the patient's condition deteriorated and eventually died. The medical history of Hypertension, End-Stage Renal Disease and advance age remains a confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received include : No new information.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue), HEADACHE (Headache), MYALGIA (Muscle pain) and PAIN IN EXTREMITY (Limb pain) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. patient past medical history include diabetes. On 20-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 24-Feb-2022, the patient experienced FATIGUE (Fatigue) (seriousness criterion death), HEADACHE (Headache) (seriousness criterion death), MYALGIA (Muscle pain) (seriousness criterion death) and PAIN IN EXTREMITY (Limb pain) (seriousness criterion death). The patient died on 13-Mar-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The worldwide UID was reported as 4.1(b) Concomitant medication was not reported. On 06/24/2021 and 09/25/2021 patient received the AZ vaccine for the other 2 doses , On 17/03/2022 patient after receiving third dose on 02/10/2022 experienced adverse reactions, on 18/03/2022 patient started experiencing discomfort such as headache. on 12/02 he took 1 aspirin tablet but he did not seek medical attention and his symptoms was relived for 1 week and experienced swelling at the back of the head and neck tightness . on 24/02 he was sent to general hospital after fainting and becoming unconsciousness in the community 1 Week after vaccination, he was then transferred to intensive care unit for the treatment, patient was incubated and under went cardiac catherization. on 13/03 at 8:00pm patient passed away and family did not agree for autopsy and the patient has been encoffined patient family agree to apply for drug injury relief which was interviewed by center health education. This fatal regulatory case concerns a 75-year-old male patient with medical history of diabetes and 2 Astra-Zeneca Covid-19 vaccines on 06/24/2021 and 09/25/2021 who experienced the serious unexpected events of FATIGUE, HEADACHE, MYALGIA and PAIN IN EXTREMITY The events occurred 35 days after a dose of mRNA-1273 vaccine (3rd Covid-19 vaccine dosis). The patient death on March, 13, 2022, 52 days after vaccination. Autopsy was not performed. The medical history and age remains as confounders. The benefit-risk relationship of drug is not affected by this report Terms and onset dates were captured as provided The case was assessed as serious by the Regulatory Authority´s report due to Death Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received and had no new information.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of PULMONARY MASS (Pulmonary lesions) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 082F21B) for COVID-19 vaccination. Patient did not had past history of chronic disease or drug allergy. Previously administered products included for Product used for unknown indication: MODERNA COVID-19 VACCINE (The patient received Dose 1 (Moderna) vaccine in Far Eastern Memorial Hospital) on 14-Jul-2021.

Case ID	Narrative (Complete)
	Past adverse reactions to the above products included No adverse event with MODERNA COVID-19 VACCINE. On 22-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 30-Dec-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PULMONARY MASS (Pulmonary lesions) (seriousness criterion death). The patient died on 12-Mar-2022. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, X-ray: pneumonia was found with (abnormal) Pneumonia was found and immune storm was suspected. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No Concomitant medication was reported. The age of the patient was reported as 65.7 years. July 14, 2021, 1st dose of Moderna vaccine. At the end of December 2021, she went to hospital for medical exams for respiratory diseases and then was transferred to Fu University for medical treatment on 30 Dec. On 03 Jan 2022, she was transferred to the Hospital for further treatment. One week later, Immune storm causing pulmonary lesions and she was transferred to the intensive care unit. She died in the early morning of 12 March 2022. On March 14, 2022, called the patient son in law of the patient called 1922 and said they want to apply for vaccine injury relief and want to confirm whether the case has been reported as adverse reactions after vaccination No Treatment medication was provided. WWID number for the case was 4.1(b) . Company Comment: This regulatory authority case concerns a 65-year-old female patient with no relevant medical history reported, who experienced the fatal unexpected serious event of Pulmonary mass which occurred 2 months 10 days after the second dose of mRNA-1273 vaccine. The patient died 4 months 20 days after vaccination. It is unknown if an autopsy was performed. Its reported at the end of December 2021, patient went to hospital for medical exams for respiratory diseases and then was transferred for medical treatment on 30 Dec. 4 days later, she was transferred to the Hospital for further treatment. One week later, Immune storm causing pulmonary lesions and she was transferred to the intensive care unit. She died in the early morning of 12 March 2022. The patient received the second dose 98 days after the first dose, which is not in accordance with the recommended vaccine interval. The benefit-risk relationship of mRNA-1273 is not affected by this report. The event was assessed as serious as per Regulatory Authority´s report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received included: Event updated to pulmonary lesions
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (Fever) and ACUTE MYELOID LEUKAEMIA (Acute myeloid leukemia) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for an unknown indication. No Medical History information was reported. On 05-Oct-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 07-Oct-2021, the patient experienced PYREXIA (Fever) (seriousness criterion death) and ACUTE MYELOID LEUKAEMIA (Acute myeloid leukemia) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient age was reported as 68.2. On 13-Jul-2021, the patient received dose 1 Moderna and had muscle soreness the next day and fever for three days. On 05-Oct-2021, the patient received dose 2 (Moderna) vaccine and on 07-Oct-2021 patient started developing fever and chills and patient went to clinic for medical advice and was prescribed cold medication. No improvement. On 23-Oct-2021, the patient was referred to ER of the hospital and was diagnosed as acute spinal leukemia and was admitted immediately. The patient received 2 times of self-paid target therapy. Blood was drawn and transfusion of platelet, red blood cell, potassium ion, and magnesium ion were done every day during hospitalization. On 14-Jan-2022,the patient died suddenly in the early hours of the morning and the first aid was failed. The follow-up care was as follows on18-Mar-2022, follow-up was given to the family on the reporting day and assistance was given for injury relief matters. The Worldwide UID was reported as 4.1(b) . Company Comment: This regulatory authority case concerns a 68-year-old female patient, with no reported medical history, who experienced the serious (fatal), unexpected events fever and acute myeloid leukemia. The patient received first dose of mRNA 1273 COVID-19 vaccine and experienced muscle soreness and fever the next day which lasted for three days. Twelve weeks after the first dose, patient received the second dose of mRNA 1273 COVID-19 vaccine. Two days after the second dose, patient experienced fever and chills, she sought consult and was given cold medication which did not afford relief of symptoms. Eighteen days after the second dose, patient was diagnosed to have acute myeloid leukemia and was hospitalized. Patient received 2 courses of targeted therapy and had transfusions of platelets, red blood cells, potassium ions and magnesium ions daily. The patient passed away 3 months after the second dose of mRNA 1273 vaccine. Cause of death was not provided. It is unknown if autopsy was performed. The patient's acute myeloid leukemia is a confounder to patient's fever and subsequent death. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up received contains non-significant information.

Case ID	Narrative (Complete)
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 31-Mar-2022 and was forwarded to Moderna on 31-Mar-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (central pulmonary artery emboli on both sides) in an 84-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Patient had allergies to MCP (MCP intolerance) and Lactose (Lactose intolerance). Information on risk factors or previous illnesses were reported as Coronary 1-vessel disease (HKU dated April 17, 2019): Good long-term result after 2-DE implantations in the proximal and medial RIVA 2017, unchanged high-grade stenosis of a strong R.septalis (no intervention target) Z.n. PCI with implantation of a DE in the medial RIVA on 2-Jun-2017 ?Z.n. PCI with implantation of a DE in the proximal RIVA on 01-Dec-2017. Patient had Hypertensive heart disease, Sleep Apnea Syndrome with CPAP Therapy. Reflux esophagitis grade I with erosive gastritis, .V. a. Grade II hepatic steatosis, Poor echo area dorsal in the liver of 6 x 2.5 cm segment. Cardiovascular Risk Factors included Arterial hypertension, Hypercholesterolemia and Positive family history for Obesity. On 24-Feb-2022, the patient received fourth dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 10-Mar-2022, the patient experienced PULMONARY EMBOLISM (central pulmonary artery emboli on both sides) (seriousness criterion death). The patient died on 10-Mar-2022. The reported cause of death was Lung embolism. It is unknown if an autopsy was performed. No concomitant medications were mentioned. It was reported that patient developed central pulmonary artery embolism on both sides and after 3 days the patient was dead. No treatment details were reported. Company comment: This regulatory authority case concerns an 84-year-old female patient, with medical history of arterial hypertension, hypercholesterolemia, PCI (percutaneous coronary intervention) implantation, who experienced the serious (fatal), unexpected AESI of Pulmonary embolism 14 days after the fourth dose of mRNA 1273 COVID-19 vaccine. The patient had a central pulmonary artery embolism on both sides and after 3 days, patient died. The cause of death was pulmonary embolism. It was unknown if an autopsy was performed. The patient's age, medical history of hypertension, hypercholesterolemia, and prior PCI implantation are possible confounders to the patient's pulmonary embolism and death. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 31-Mar-2022 and was forwarded to Moderna on 31-Mar-2022. This regulatory authority case was reported by a physician and describes the occurrence of CARDIAC FAILURE (Decompensation cardiac) in a 91-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 007G21A) for COVID-19 vaccination. The patient's past medical history included Aortic incompetence, Lymphoma, Atrial fibrillation, Aortic valve stenosis, Goiter nodular, Cardiac insufficiency and Cataract. On 03-Feb-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Feb-2022, the patient experienced CARDIAC FAILURE (Decompensation cardiac) (seriousness criteria death, hospitalization and life threatening). The patient died on 10-Mar-2022. The reported cause of death was Decompensation cardiac. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication were given. No treatment given. Company comment: This regulatory authority case reported by a physician concerns a 91-year-old, male patient with relevant medical history of Aortic stenosis, Aortic Incompetence, Atrial fibrillation, goiter nodular and cardiac insufficiency, who experienced the unexpected serious (Hospitalization, Life threatening and death) AESI event of Cardiac Failure which occurred 02 days after the third booster dose of mRNA-1273 Vaccine. Details of primary doses of covid 19 vaccines were not provided. Advanced age of the patient and medical history of Aortic valvular heart disease, nodular goiter, Atrial Fibrillation and cardiac failure could be considered as a confounders for the event. The patient was hospitalized and the treatment details are not provided. The event was fatal and the patient died 37 days later. Details of autopsy were not known. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 31-Mar-2022. The most recent information was received on 22-Apr-2022 and was forwarded to Moderna on 22-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of MYOCLONUS (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), PRION DISEASE (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), CONFUSIONAL STATE (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), SOPOR (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), DYSTONIA (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), HALLUCINATION (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), NERVOUS SYSTEM DISORDER (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), DYSPHAGIA (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), ATAXIA (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease), PSYCHOMOTOR HYPERACTIVITY (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) and RESPIRATORY FAILURE (Confusion state, psychomotor agitation

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	crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000030A) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: COMIRNATY(BIONTECH MANUFACTURING GMBH) (J07BX03) on 23-Feb-2021 and COMIRNATY(BIONTECH MANUFACTURING GMBH) (J07BX03) on 13-Sep-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY(BIONTECH MANUFACTURING GMBH) (J07BX03) and COMIRNATY(BIONTECH MANUFACTURING GMBH) (J07BX03). On 18-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 20-Jan-2022, the patient experienced MYOCLONUS (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), PRION DISEASE (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), CONFUSIONAL STATE (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), SOPOR (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), DYSTONIA (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), HALLUCINATION (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), NERVOUS SYSTEM DISORDER (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), DYSPHAGIA (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), ATAXIA (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death), PSYCHOMOTOR HYPERACTIVITY (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death) and RESPIRATORY FAILURE (Confusion state, psychomotor agitation crisis, hallucinations, neurological disorders: ataxia, myoclonus, dystonia, dysphagia, progressive soporous state; respiratory insuf Prion disease) (seriousness criterion death). The patient died on 09-Mar-2022. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment medication was reported. 22/03/2022: Clinical report is attached by the signaller. The outcome of the autopsy will be attached, as soon as the report is available Company Comment: This regulatory authority case concerns a 80-year-old male patient with no relevant medical history reported, who experienced the fatal unexpected serious events of Myoclonus, Prion disease, Confusional state, Sopor, Dystonia, Hallucination, Nervous system disorder, Dysphagia, Ataxia, Psychomotor hyperactivity and Respiratory failure which occurred 2 days after receiving a dose of mRNA-1273 vaccine. The patient died 50 days after vaccination. The reported cause of death was unknown. It is unknown if an autopsy was performed. Patient had received initial schedule of vaccination with COMIRNATY (interchange of vaccine products).The benefit-risk relationship of mRNA-1273 is not affected by this report. Events seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 22-Apr-2022: Significant followup received on 22-APR-2022: Sender's comments updated. On 22-Apr-2022: Significant live followup received on 22-APR-2022: Event Prion disease added and all Events verbatim updated. On 06-May-2022: Follow-up received is NNI.
4.1(b) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] on 31-Mar-2022. The most recent information was received on 06-May-2022 and was forwarded to Moderna on 11-May-2022. This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] on 31-Mar-2022. The most recent information was received on 06-May-2022 and was forwarded to Moderna on 11-May-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b) [redacted]). On 06-Mar-2022, follow-up information was received from a physician. The vaccine recipient was receiving hyaluronic acid injections for gonarthrosis once every two weeks at the reporting hospital and was undergoing follow-up treatment by a nearby physician for internal diseases. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.2 degrees Celsius. On 25-Feb-2022, at 15:00, the patient received the 3rd vaccination with this vaccine. On 26-Feb-2022, at 12:45, interstitial pneumonia developed. The patient was found falling at home and was raced to the reporting hospital. The patient was hospitalized. CT showed ground-glass appearances in both lower lung fields. The patient was considered to have aspiration pneumonia and treated with ceftriaxone sodium hydrate 2 g for five days. BP: 128/84, P: 82, and Sp02: 96% (room air). Since there were no symptoms, the patient was considered to be making satisfactory progress. On an unknown date, pneumonia was aggravated, and respiratory failure developed. On 09-Mar-2022, Sp02 was 90%, so another CT scan was performed. Pneumonia images spread. The PCR test for COVID-19 was negative. On 10-Mar-2022, the patient was considered to have infectious pneumonia, and lascufloxacin hydrochloride (150) 2V was infused. The patient took nine tablets of sulfamethoxazole/trimethoprim in three divided doses and two tablets of azithromycin hydrate (250) in one devised dose for three days. Drip infusion of hydrocortisone sodium succinate (100) 3 V was performed. Oxygen was administered due to a tendency of decreased SpO2. Mycoplasma nucleic acid test was negative. The reporting hospital consulted with an acute-care hospital but was refused because beds were full. On 11-Mar-2022, drip infusion of methylprednisolone sodium succinate 500 mg once daily for four days was started. Drip infusion of lascufloxacin hydrochloride (150) 1V for three days was performed. On 12-Mar-2022, there was no treatment effect. Administration of oxygen 10 L was continued with a reservoir mask. β-D glucan was normal. On 15-Mar-2022, the patient died. Treatments for all types of infections were performed but ineffective. No necropsy was performed. The outcome of collapsed was unknown. The outcome of interstitial pneumonia was reported as fatal. No follow-up investigation will be made. Reporter comments continuation: Therefore, the occurrence of adverse events is temporally related to the timing of administration of this vaccine. Since there were no new medications and the patient was living alone and healthy until the day before the vaccination, the occurrence of adverse events is not related to concomitant drugs. Since the patient was living alone and healthy until the day before the vaccination, the occurrence of adverse events is not related to pathological factors of underlying diseases and complications. The

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	case of death is related to adverse events because the patient had physical deconditioning rapidly after the vaccination, which led to death. The patient experienced interstitial pneumonia rapidly after receiving this vaccine, which resulted in death. All possible infection tests were negative. As for the cause of the pneumonia, infection was negative. Despite all possible treatments, the patient died helplessly. Follow-up received on 06-MAY-2022 Updated: Patient Information, Other Relevant History, Lab Data, Product Information, Event Information, Narrative, Reporter Comments Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via Health Canada (Reference number: 4.1(b)) on 04-Apr-2022 and was forwarded to Moderna on 04-Apr-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of FEEDING DISORDER (Feeding disorder), GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration), HERPES ZOSTER (Herpes zoster), HYPOKINESIA (Hypokinesia), LETHARGY (Lethargy), NEURALGIC AMYOTROPHY (Neuralgic amyotrophy), OEDEMA PERIPHERAL (Oedema peripheral) and PSYCHOMOTOR RETARDATION (Psychomotor retardation) in a 71-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 immunisation. Concomitant products included TACROLIMUS (ADVAGRAF), HYDRALAZINE HYDROCHLORIDE (APRESOLINE), CARVEDILOL (COREG), TINZAPARIN SODIUM (INNOHEP), ATORVASTATIN CALCIUM (LIPITOR), PREGABALIN (LYRICA), MAGNESIUM, AMLODIPINE BESILATE, TELMISARTAN (NORVASC T), ALFACALCIDOL (ONE ALPHA), CALCIUM CARBONATE (OSCALVIT), PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTOLOC), PREDNISONE, BENSERAZIDE HYDROCHLORIDE, LEVODOPA (PROLOPA), PARACETAMOL (TYLENOL [PARACETAMOL]) and VALACICLOVIR HYDROCHLORIDE (VALTREX) for an unknown indication. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced FEEDING DISORDER (Feeding disorder) (seriousness criterion death), GENERAL PHYSICAL HEALTH DETERIORATION (General physical health deterioration) (seriousness criterion death), HERPES ZOSTER (Herpes zoster) (seriousness criterion death), HYPOKINESIA (Hypokinesia) (seriousness criterion death), LETHARGY (Lethargy) (seriousness criterion death), NEURALGIC AMYOTROPHY (Neuralgic amyotrophy) (seriousness criterion death), OEDEMA PERIPHERAL (Oedema peripheral) (seriousness criterion death) and PSYCHOMOTOR RETARDATION (Psychomotor retardation) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No medical history were reported. No treatment information was provided. Company comment: This is a regulatory case concerning a 71-year-old male patient with no medical history reported, who experienced Fatal unexpected, events of Feeding disorder, General physical health deterioration, Herpes zoster, Hypokinesia, Lethargy, Neuralgic amyotrophy, Oedema peripheral, Psychomotor retardation, which occurred on an unknown date. On an unknown date, the patient received a dose of mRNA-1273 vaccine. No further information regarding the clinical course and treatment of the events were provided. The cause of death was not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 29-Mar-2022 and was forwarded to Moderna on 04-Apr-2022. This case was reported by a physician via a medical representative. On an unspecified date in Jun-2021, the patient received the 1st dose of this vaccine. On an unspecified date in Jun-2021, focal swelling at the vaccination site developed. On an unspecified date in Jun-2021, the patient received the 2nd dose of this vaccine. Immediately after the vaccination, transient fever developed. On an unknown date, four days after the vaccination, basilar artery occlusion developed. The patient experienced dysarthria and right hemiparesis upon awakening. On examination, blood pressure was 218/106 mmHg, and heart rate was regular (85 beats/min). There was no petechia or purpura. Neurological examination revealed disturbed consciousness (GCS: E4V1M5), right-sided oculomotor paralysis, right-sided central facial palsy, dysarthria, and right-sided hemiparesis. There were high elevation of LDL cholesterol (184 mg/dL) and mild elevation of HbA1c (6.1 %). D-dimer elevated to 23.98 mcg/mL. Platelet count, PT-INR, and APTT were normal. Anti-phospholipid antibody, protein C, and protein S were negative. No decreased platelet count was noted, anti-PF4 antibody was negative, and VITT was ruled out. Atrial fibrillation and arteriovenous shunt were not observed. Diffusion-weighted brain magnetic resonance (MR) imaging showed high-intensities involving the left cerebellar hemisphere, bilateral pons, right midbrain, and right frontal lobe. MR angiography showed basilar artery occlusion; however, cerebral venous thrombosis was not observed On an unknown date, five days after the vaccination, therapy with anti-platelet agents was performed. The patient was given aspirin 100 mg and clopidogrel 75 mg, but cerebral infarction progressed. Multiple thrombosis developed. The patient suddenly presented with deep coma, loss of light reflex, loss of oculocephalic reflex, and cyanosis of distal right lower extremity. Brain MR imaging showed hemorrhagic pontine infarction and new bilateral thalamic infarctions. CT did not demonstrated malignancy but left renal infarction and right anterior tibial artery thrombosis. On an unknown date, anti-platelet agents were discontinued and heparinization was administered. D-dimer elevated up to 47.34 mcg/mL; however, further thrombosis was not detected. No thrombocytopenia was observed throughout the course. On 21-Jul-2021, aspiration pneumonia developed. Administration of ampicillin/sulbactam 6 g/day was performed. On 10-Aug-2021, aspiration pneumonia improved with antibiotics. On an unknown date, 64 days after the vaccination, the patient was transferred to another hospital. The patient died. The outcome of focal swelling at the injection site, fever, basilar artery occlusion, coma, cyanosis, hemorrhagic pontine infarction, bilateral thalamic infarctions, and left renal infarction was unknown. The outcome of multiple thrombosis was reported as fatal. The outcome of aspiration pneumonia was reported as resolving. Follow-up investigation will be made. Reporter comments continuation: Although serious adverse events of mRNA vaccine were rare, thrombosis with thrombocytopenia after administration of these novel vaccines, which is known as vaccine-induced thrombosis with thrombocytopenia (VITT) or thrombocytopenia with thrombosis syndrome (TTS), have been reported. VITT or TTS usually develops 4 to 28 days after vaccination characterized with thrombocytopenia and progressive thrombosis including cerebral vein thrombosis and venous thrombosis. On the one hand, this patient was characterized by the absence of thrombocytopenia and anti PF-4 antibody. On the other hand, the patient had a tendency to thrombus formation after the 2nd vaccination, and multiple thrombosis developed even after administration of antiplatelet agents. The usefulness of existing SARS-CoV-2 vaccines is widely recognized of the disease; however, need further investigations are needed to clarify the pathomechanism of thrombosis after administration of mRNA 1273-SARS-CoV-2 vaccine. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 05-Apr-2022 and was forwarded to Moderna on 05-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of CEREBRAL HAEMORRHAGE (Cerebral haemorrhage) in a 91-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000125A) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 26-Mar-2021 and Comirnaty BNT162b2 on 07-Sep-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2.

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	On 27-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-Mar-2022, the patient experienced CEREBRAL HAEMORRHAGE (Cerebral haemorrhage) (seriousness criteria death, hospitalization and life threatening). The patient died on 06-Mar-2022. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication reported. No treatment medication details reported. Company comment: This regulatory authority case concerns a 91-year-old female patient, with no medical history reported, previously vaccinated with two doses of Comirnaty COVID-19 vaccine, who experienced the fatal AESI of Cerebral Haemorrhage (seriousness criteria death, hospitalization and life threatening), which occurred 1 month and 8 days after the third dose (reported as booster dose) of mRNA-1273. Cause of death was not provided, neither if an autopsy was performed. The patient died 1 month and 8 days after vaccination. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 04-Apr-2022 and was forwarded to Moderna on 06-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a hospital employee, was received via the PMDA (Ref, 4.1(b)). On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 15-Feb-2022, the patient received the 3rd dose of this vaccine. On 22-Feb-2022, at 19:45, the patient was transported to hospital due to cardiopulmonary arrest. The patient was in cardiac arrest at arrival of the emergency medical assistance. After arriving at the reporting hospital, there was no request for life-prolonging treatment from family members, and only fluid replacement and administration of oxygen were performed. At 20:15, the patient confirmed dead. Postmortem CT was performed. The patient was diagnosed with acute dissection of the ascending aorta. The outcome of cardio-respiratory arrest and acute dissection of the ascending aorta was reported as fatal. Follow-up investigation will be made. Reporter comments continuation: In addition, the patient visited the reporting hospital for the first time, and the details of his past medical history of aortic dissection are also unknown. As another contributing factor, there is a possibility that the patient had the surgical history of aortic dissection at another hospital approximately 10 years ago, and it recurred. Company Comment: Aortic dissection developed after the administration of ELASOMERAN, but past medical history may have contributed to the occurrence.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 05-Apr-2022 and was forwarded to Moderna on 05-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Painful, weak shaky legs, puncture site pain) in an 85-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000112A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Prophylactic vaccination: SPIKEVAX on 18-Dec-2021. Past adverse reactions to the above products included No adverse event with SPIKEVAX. On 19-Jan-2022, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Jan-2022, the patient experienced PAIN IN EXTREMITY (Painful, weak shaky legs, puncture site pain), DEATH (Painful, weak shaky legs, puncture site pain) (seriousness criterion death), VACCINATION SITE PAIN (Painful, weak shaky legs, puncture site pain) and FATIGUE (Painful, weak shaky legs, puncture site pain). On an unknown date, the patient experienced DIZZINESS (Dizziness). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, PAIN IN EXTREMITY (Painful, weak shaky legs, puncture site pain), DIZZINESS (Dizziness), VACCINATION SITE PAIN (Painful, weak shaky legs, puncture site pain) and FATIGUE (Painful, weak shaky legs, puncture site pain) had not resolved. No concomitant medication reported. No treatment information was provided. On 18-Dec-2021, the patient experienced DIZZINESS (Dizziness). Sender's comment: Information on risk factors or pre-existing conditions High blood pressure/18.12.2021 pain in the arm and dizziness 19.11.2022 still dizziness until then, accompanied by aching weak legs. Company comment: This regulatory authority case concerns an 85 year old female patient with relevant medical history of hypertension, who had a fatal outcome (PT: Death) on the same day of receiving the second dose of mRNA-1273 vaccine. The patient also had dizziness, fatigue, pain in extremity and vaccination site pain. The cause of death was reported as unknown. Autopsy details were not available in the report. Elderly age and medical history of hypertension could be risk factors for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness retained as per Regulatory Authority reporting.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 06-Apr-2022. The most recent information was received on 24-Jun-2022 and was forwarded to Moderna on 24-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Death NOS) in an 81-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Concurrent medical conditions included Glaucoma. On 30-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on 31-Dec-2021 The patient died on 31-Dec-2021. The cause of death was not reported. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	No concomitant and treatment medications were provided by the reporter. Company Comment: This is a Regulatory Authority fatal case concerning an 81-year-old, female patient with no relevant medical history reported, who experienced the serious unexpected event of Death, one day after receiving a dose of mRNA-1273 of an unknown dose and sequence of administration. The cause of death was not provided, and it is unknown if autopsy was performed. Event seriousness assessed as per Regulatory Authority as Death. Limited information was provided at this time. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 24-Jun-2022: Significant follow-up received: Medical history updated.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIOGENIC SHOCK (CARDIOGENIC SHOCK SECONDARY TO ACUTE MYOCARDIAL INFARCTION , COVID PROBABLE) in a 66-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 010G21B) for COVID-19 vaccination. No Medical History information was reported. On 07-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 21-Mar-2022, the patient experienced CARDIOGENIC SHOCK (CARDIOGENIC SHOCK SECONDARY TO ACUTE MYOCARDIAL INFARCTION , COVID PROBABLE) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment information was provided. The patient had difficulty of breathing. This regulatory case concerns a 66-year old male patient, with no reported medical history, who experienced an unexpected, fatal AESI event of Cardiogenic shock, approximately 2 months after receiving a dose of mRNA-1273 vaccine. In addition, the patient reported difficulty of breathing. Clinical course and treatment details are not available in this report. Cause of death is not available in this report. It is unknown if an autopsy was performed. The elderly age of the patient remains to be a confounder for the event. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness was assessed as per Regulatory Authority's report.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (CHEST PAIN) in a 67-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 04-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 21-Mar-2022, the patient experienced CHEST PAIN (CHEST PAIN) (seriousness criterion death). It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. No treatment medication was reported. Company comment: This regulatory authority case concerns a 67-year-old, male patient with no medical history reported, who experienced Fatal unexpected event of Chest pain, 2 months 17 days after receiving a dose of mRNA-1273. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Events seriousness assessed as per Regulatory Authority reporting.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of ELECTROLYTE IMBALANCE (Multiple electrolyte imbalance sec. To poor oral intake; ulcer grade 1) in a 77-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 055E21A) for COVID-19 vaccination. No Medical History information was reported. On 22-Dec-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced ELECTROLYTE IMBALANCE (Multiple electrolyte imbalance sec. To poor oral intake; ulcer grade 1) (seriousness criterion death). It is unknown if an autopsy was performed. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Patient had loss of appetite. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. Company Comment: This regulatory case concerns a 77-year-old female patient with no medical history reported, who had a fatal outcome with unexpected serious event of Electrolyte imbalance, which occurred on unknown date after a dose of mRNA-1273 vaccine. Patient reported loss of appetite, multiple electrolyte imbalance secondary to poor oral intake and grade 1 ulcer. The clinical course leading to demise, diagnostic procedures and treatment were not reported.

Case ID	Narrative (Complete)
	It is unknown whether an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness assessed as per Regulatory Authority reporting.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Apr-2022 and was forwarded to Moderna on 07-Apr-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of VACCINATION FAILURE (Vaccine failure), DYSPNOEA (Dyspnoea) and COVID-19 PNEUMONIA (COVID-19 pneumonia) in a 68-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3005790, 300042722 and 3000494) for COVID-19 vaccination. The patient's past medical history included Effort angina, Ischaemic heart disease, COVID-19 (COVID-19 has passed) and Solid organ transplant (RENAL) in 2017. Concurrent medical conditions included Type I diabetes mellitus and Chronic renal failure (DIALYSIS DUE TO DIABETIC NEPHROPATHY). On 08-Mar-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Apr-2021, received second dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 17-Sep-2021, received third dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 14-Dec-2021, the patient experienced VACCINATION FAILURE (Vaccine failure) (seriousness criteria death and hospitalization) and DYSPNOEA (Dyspnoea) (seriousness criteria death and hospitalization). On 24-Dec-2021, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death and hospitalization). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 23-Dec-2021, SARS-CoV-2 test positive: positive (Positive) Positive. On 24-Dec-2021, Chest X-ray: bilateral infiltrate (abnormal) bilateral infiltrate. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication details was reported. No treatment medication details was reported. Company Comment: This regulatory authority case concerns a 68-year-old male patient, with relevant medical history of Effort angina, Ischemic heart disease, COVID-19, Solid organ transplant (RENAL), Type I diabetes mellitus and Chronic renal failure, who experienced the unexpected serious events of Vaccination failure, Dyspnea and the AESI COVID-19 pneumonia. The events occurred approximately 3 months after receiving the third dose of mRNA-1273 Vaccine requiring hospitalization. Diagnostic test showed SARS-CoV-2 test positive and Chest X-ray with bilateral infiltrates. No treatment information was provided. The events led to a fatal outcome. It is unknown if an autopsy was performed. The patient's medical history of Effort angina, Ischemic heart disease, COVID-19, Solid organ transplant (RENAL), Type I diabetes mellitus and Chronic renal failure, remain as confounders for the occurrence of the events. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Apr-2022: Translation document received on 10-Apr-2022 contains translated event verbatim with no new information.
4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of ASTHENIA (GENERALIZED BODY WEAKNESS) in a 66-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. In December 2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 05-Jan-2022, the patient experienced ASTHENIA (GENERALIZED BODY WEAKNESS) (seriousness criterion death). It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. No treatment information was provided. Company comment-This regulatory case concerns a 66-year-old female patient with no medical history reported, who experienced the serious fatal unexpected event of Asthenia at an unknown interval after a dose of mRNA-1273 vaccine. No further information regarding the event and "cause" of death have been provided. No treatment details provided. It is unknown if an autopsy was performed. Patient´s elderly age remains as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.
4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of SEIZURE (Seizure) in an 85-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 22-Dec-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 25-Jan-2022, the patient experienced SEIZURE (Seizure) (seriousness criteria death and medically significant). It is unknown if an autopsy was performed. No concomitant medication was reported. Treatment medication was not provided by the reporter. Company comment: This regulatory case concerns an 85-year-old, female patient, with no reported medical history, who experienced the unexpected, fatal outcome of Seizure. The event occurred 34 days after administration of an unknown dose of mRNA-1273. There was no information provided on

Case ID	Narrative (Complete)
	the dosing regimen, circumstances leading to death, clinical course, concurrent diseases, medical history and autopsy details. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness retained as per Regulatory Authority's report.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of LOSS OF CONSCIOUSNESS (Unresponsiveness) in a 72-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 057D21A) for COVID-19 vaccination. No Medical History information was reported. On 23-Aug-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 28-Mar-2022, the patient experienced LOSS OF CONSCIOUSNESS (Unresponsiveness) (seriousness criterion death). It is unknown if an autopsy was performed. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. Company comment-This regulatory case concerns a 72-year-old female patient with no medical history reported, who experienced the serious fatal unexpected event of Loss of consciousness approximately 7 months 5 days after a dose of mRNA-1273 vaccine. No further information regarding the event and “cause” of death have been provided. It is unknown if an autopsy was performed. Patient´s elderly age remains as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DYSPNOEA (Difficulty breathing) in an 86-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 055E21A) for COVID-19 vaccination. No Medical History information was reported. On 12-Dec-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 29-Mar-2022 at 11:37 PM, the patient experienced DYSPNOEA (Difficulty breathing) (seriousness criterion death). It is unknown if an autopsy was performed. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication information was provided. No treatment medication information was provided. Company comment: This regulatory case concerns an 86-year-old female patient with no reported medical history who experienced the unexpected fatal event of Dyspnoea which occurred approximately 3 months and 17 days after administration of an unspecified dose of mRNA-1273 vaccine. Details regarding investigations, treatment, time and cause of death and autopsy details are not available. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 06-Apr-2022 and was forwarded to Moderna on 06-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (death: found dead in bed very pushed head) and THROMBOSIS (death: blood clot in the nose) in an 86-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 018J21A) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: COVID-19 VACCINE on 01-Nov-2020 and COVID-19 VACCINE on 01-Mar-2021. Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE and COVID-19 VACCINE. On 17-Mar-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEATH (death: found dead in bed very pushed head) (seriousness criterion death) and THROMBOSIS (death: blood clot in the nose) (seriousness criterion death). The patient died on 17-Mar-2022. The reported cause of death was Cerebral thrombosis. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant and treatment information was provided. Patient was found dead in bed very pushed head and had blood clot in the nose on 16-Mar-2022. Company Comment: This regulatory case concerns an 86-year-old, female patient with past drug history of administration of two doses of 'COVID-19 vaccine' (brands not specified), who experienced the unexpected, serious (fatal) AESI of thrombosis and the unexpected, serious (fatal) event of death. The events occurred 1 day after administration of an unspecified dose of the Moderna mRNA-1273 vaccine. The patient experienced a blood clot in the nose and was reported to have been found dead in bed with head 'very pushed/very stuffed'. No further details were provided. The patient expired on 17Mar2022. It is unknown if an autopsy was performed. However, the reported cause of death was 'Cerebral thrombosis'. The benefit-risk relationship of the Moderna mRNA-1273 vaccine is not affected by this report.
4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Died) in a 71-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 05621A) for COVID-19 vaccination. No Medical History information was reported.

Case ID	Narrative (Complete)
	On 18-Aug-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. Death occurred on 25-Feb-2022 at 1:43 PM It is unknown if an autopsy was performed. No concomitant medication information was provided. No treatment medication was provided. Company Comment: This regulatory case concerns a 71-year-old, male patient, with no reported medical history, who experienced an unexpected, serious event of Death approximately 6 months after receiving a dose of mRNA-1273 COVID-19 vaccine. Cause of the patient's fatal outcome was not reported. No further information was provided on the clinical course, diagnostics, treatment details and autopsy report for medical review. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness assessed per Regulatory Authority reporting. Age at the onset of reaction was reported as 71 years old; however, manual calculation of the patient's age based on the provided birthdate equated to 68 years old.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 08-Apr-2022. The most recent information was received on 19-Apr-2022 and was forwarded to Moderna on 19-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of HYPOXIA (death; hypoxia) in a 78-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000060ABS) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included CVA and COVID-19 on 08-Jan-2021. Previously administered products included for Product used for unknown indication: PFIZER BIONTECH COVID-19 VACCINE on 17-Apr-2021 and SPIKEVAX on 21-Dec-2021. Past adverse reactions to the above products included No adverse event with PFIZER BIONTECH COVID-19 VACCINE and SPIKEVAX. Concurrent medical conditions included Endometrial carcinoma. Concomitant products included CLOPIDOGREL, CANDESARTAN and ROSUVASTATIN CALCIUM (ROSUVASTATINE CF) for an unknown indication. On 21-Mar-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 22-Mar-2022, the patient experienced PYREXIA (Fever: 38 to 40.5 degrees Celcius), HEADACHE (headache) and HYPOXIA (death; hypoxia) (seriousness criterion death). The patient died on 22-Mar-2022. The reported cause of death was hypoxia, there was a lot of foaming in the mouth. An autopsy was not performed. At the time of death, PYREXIA (Fever: 38 to 40.5 degrees Celcius) and HEADACHE (headache) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Jan-2021, SARS-CoV-2 test positive: positive (Positive) Positive. On 22-Mar-2022, Pyrexia: 38 to 40.5 (High) Fever: 38 to 40.5 degrees Celsius. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment medications were reported. Company comment: This regulatory case concerns a 78-year-old female patient with relevant medical history of endometrial carcinoma, CVA and interchange of vaccine products, experienced the unexpected serious (fatal) event Hypoxia, one day after a dose of mRNA-1273 vaccine. It was reported that the patient had hypoxia, foaming in the mouth. Non-serious events of pyrexia and headache were experienced 14 hours post-vaccination. Clinical course leading to demise and treatment details were not provided in the case. An autopsy was not performed. The patient also received one dose of Tozinameran as first COVID-19 vaccine approximately 8 months prior to the dose of mRNA-1273 vaccine. The elderly age of the patient could be a risk factor. Medical history of endometrial carcinoma, CVA could be confounders for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 19-Apr-2022: Significant follow up received - Updated Batch number
4.1(b)	This literature-non-study case was reported in a literature article and describes the occurrence of SHOCK HAEMORRHAGIC (He died on hospital day 26 due to hemorrhagic shock of probable gastrointestinal origin) and ACUTE DISSEMINATED ENCEPHALOMYELITIS (Acute disseminated encephalomyelitis) in an 81-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: Ballout AA, Babaie A, Kolesnik M, Li JY, Hameed N, Waldman G, et al.. A single-health system case series of new-onset CNS inflammatory disorders temporally associated with mRNA-based SARS-CoV-2 vaccines. Front Neurol. 2022;13:796882 No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced SHOCK HAEMORRHAGIC (He died on hospital day 26 due to hemorrhagic shock of probable gastrointestinal origin) (seriousness criteria death, hospitalization and medically significant) and ACUTE DISSEMINATED ENCEPHALOMYELITIS (Acute disseminated encephalomyelitis) (seriousness criteria hospitalization prolonged and medically significant). The patient was hospitalized for 26 days due to ACUTE DISSEMINATED ENCEPHALOMYELITIS. The patient was treated with METHYLPREDNISOLONE (METHYLPREDNISOLONE NATIV) (intravenous) for Acute disseminated encephalomyelitis, at an unspecified dose and frequency; IMMUNOGLOBULINS NOS (IMMUNOGLOBULIN I.V) (intravenous) for Acute disseminated encephalomyelitis, at an unspecified dose and frequency and VANCOMYCIN (oral) for Clostridium difficile infection, at an unspecified dose and frequency. The patient died on an unknown date. The reported cause of death was he died on hospital day 26 due to hemorrhagic shock of probable gastrointestinal origin. It is unknown if an autopsy was performed. At the time of death, ACUTE DISSEMINATED ENCEPHALOMYELITIS (Acute disseminated encephalomyelitis) outcome was unknown.

Case ID	Narrative (Complete)
	DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Adenovirus test: negative (Negative) Negative. On an unknown date, Anti-aquaporin-4 antibody: negative (Negative) Negative and negative (Negative) Negative. On an unknown date, Biopsy brain: inflammatory demyelinating (abnormal) leptomeninges and cortex, and showed an acute inflammatory demyelinating process. On an unknown date, Body temperature: 102 degree fahrenheit (High) Patient had a fever of 102 degree Fahrenheit without skin rashes or nuchal rigidity.. On an unknown date, C-reactive protein (Unknown-less than 4.9 mg/l): 10.8 mg/l (High) 10.8 mg/L. On an unknown date, CSF myelin basic protein: more than 167.0 ng/ml >167.0 ng/mL. On an unknown date, CSF protein (5mg/dl-45mg/dl): 45 mg/dl (normal) 45 mg/dL, 52 mg/dl (High) 52mg/dL and 45 mg/dl (normal) 45 mg/dL. On an unknown date, CSF test (40mg/dl-70 mg/dl): 69 mg/dl 69 mg/dL. On an unknown date, CSF white blood cell count (0 cells/µl-5 cells/µl): 3 cells/µl (normal) 3 cells/µL, 11 cells/µl (High) 11 cells/µL mild lymphocytic pleocytosis and 69 cells/µl (High) pleocytosis of 69 cells/µL with 83% lymphocytic predominanc. On an unknown date, Clostridium difficile infection: positive (Positive) positive. On an unknown date, Clostridium test: positive (Positive) Positive. On an unknown date, Computerised tomogram head: unremarkable unremarkable. On an unknown date, Computerised tomogram neck: unremarkable unremarkable. On an unknown date, Culture urine: negative (Negative) Negative. On an unknown date, Enterovirus test: negative (Negative) Negative. On an unknown date, HIV antibody: negative (Negative) Negative. On an unknown date, Influenza virus test: negative (Negative) Negative. On an unknown date, Legionella test: negative (Negative) Negative. On an unknown date, Magnetic resonance imaging: possible inflammatory or infectious process. (abnormal) diffusion restricting lesion involving the right dorsal medulla with corresponding T2 FlAIR hyperintensity very faint left pontine, midbrain, and thalamic T2 FlAIR hyperintensity and minimal T2 sulcal hyperintensity without apparent enhancement and adem (abnormal) multiple, non-enhancing, T2 hyperintense lesions involving bilateral frontoparietal lobes, lentiform nuclei, thalami, cerebral peduncles, pons, and right posterior medulla. The clinical and neuroradiological findings were deemed most consistent with ADEM. On an unknown date, Neurological examination: minimal response to noxious stimuli (abnormal) minimal response to noxious stimuli, right gaze preference, minimal horizontal eye movements upon oculocephalic testing, absent pupillary response to light, absent right corneal reflex, diffuse hypertonicity, and extensor plantar responses bilaterally.. On an unknown date, Red blood cell sedimentation rate (1mm/h-15 mm/h): 86 mm/hr (High) 86 mm/hr. On an unknown date, Respiratory syncytial virus test: negative (Negative) Negative. On an unknown date, SARS-CoV-2 test: negative (Negative) Nasopharyngeal COVID-19 PCR and SARS-CoV-2 antibodies against nucleocapsid protein were negative. On an unknown date, Serology test (3.8 k/µl-10.5k/µl): 12.5 k/µl mild leukocytosis with WBC count of 12.5 K/µL. On an unknown date, Viral test: negative (Negative) Negative. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter considered SHOCK HAEMORRHAGIC (He died on hospital day 26 due to hemorrhagic shock of probable gastrointestinal origin) and ACUTE DISSEMINATED ENCEPHALOMYELITIS (Acute disseminated encephalomyelitis) to be related. Company Comment: This Literature Non study fatal case report, concerns an 81-year-old male patient with no preexisting neurological illness nor pre-existing history of autoimmune disease, who experienced the unexpected serious fatal event of hemorrhagic shock and the AESI of Acute Disseminated Encephalomyelitis (ADEM). Event ADEM occurred 13 days after receiving the first dose of mRNA-1273 vaccine. Patient had prodromal symptoms of viral-like illness marked by several days of low-grade fever, fatigue, and myalgia and new neurological symptoms like severe confusion. Blood cultures drawn on admission (day 1) and twice afterwards (day 5 and 10) were without growth, including bacterial, fungal, and viral sources. Serologies for blastomycoses, cryptococcus, coccidioidies, HIV, and galactomannan were negative. QuantiFERON testing was performed twice and was indeterminate, imaging was negative for tuberculoma, and CSF glucose and total nucleated cell count was normal lowering suspicion of tuberculosis meningitis. His neurological condition deteriorated rapidly to a comatose state within the subsequent 24 h and required emergent intubation. On day 10, patient was found to be positive for clostridium difficile and was started on oral vancomycin for which he completed a course. A right frontal lobe biopsy was performed on hospital day 16, and showed an acute inflammatory demyelinating process. Repeated Brain MRI with gadolinium on hospital on day 17 were consistent with ADEM. The patient was treated with high-dose IV methylprednisolone, IVIG therapy, and later plasmapheresis, after a reasonable exclusion of alternative etiologies, without a clinical response. He died on hospital day 26 due to hemorrhagic shock of probable gastrointestinal origin. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. No concomitant medications were reported. Patient undergone plasmapheresis (PLEX) for 4days. Patient had prodromal symptoms of viral-like illness marked by several days of low-grade fever, fatigue, and myalgia and new neurological symptoms like severe confusion. Blood cultures drawn on admission (day 1) and twice afterwards (day 5 and 10) were without growth.Patient neurological condition deteriorated rapidly to a comatose state within the subsequent 24 h and required emergent intubation. He continued to spike fevers despite broad-spectrum antibiotics and a negative infectious . Stains for infectious agents were negative, including bacterial, fungal,
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 13-Apr-2022 and was forwarded to Moderna on 13-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of LEUKOPENIA (Leucopenia) and HYPERPYREXIA (Hyperpyrexia) in a 79-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 20-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Jan-2022, the patient experienced LEUKOPENIA (Leucopenia) (seriousness criteria death, hospitalization and life threatening) and HYPERPYREXIA (Hyperpyrexia) (seriousness criteria death, hospitalization and life threatening). The cause of death was not reported. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No Concomitant Drug details were reported. No Treatment information was provided. This fatal regulatory case concerns a 79-year-old male patient with no medical history who experienced the serious unexpected events of LEUKOPENIA and HYPERPYREXIA The event occurred 2 days after a dose of mRNA-1273 vaccine The data date of death and if autopsy was performed is unknown The benefit-risk relationship of drug is not affected by this report Terms and onset dates were captured as provided The case was assessed as serious by the Regulatory Authority´s report due to hospitalization, Life-threatening and Death
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of CARDIAC DEATH (Cardiac death) in a 75-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000074A) for COVID-19 vaccination. No Medical History information was reported. On 12-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. The reported cause of death was Cardiac death. An autopsy was not performed. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. Patient has not had symptoms associated with COVID-19. Not had a COVID-19 test. The patient received vaccine at 13.35 walked upon road and collapsed. CRP initiated by member of public prounced deceased by paramedic. It was reported that vaccine was the spring booster. No symptoms were reported to staff about the following vaccine. Reporter did not report any medical conditions or stated any medication details of patient. Patient did not had COVID in the past 28 days. Patient was not enrolled in clinical trial. Dosage text was reported as Dose 4. Treatment information was not provided. Company Comment: This regulatory authority report concerns a 75-year- old male patient, with no reported medical history, who experienced unexpected, serious (fatal, life threatening) event of Cardiac death on the same day of vaccination with a fourth dose of mRNA-1273. After receiving the vaccine, the patient walked upon the road and collapsed. Cardiopulmonary resuscitation was initiated by a member of the public, but the patient was pronounced deceased by the paramedic. An autopsy was not performed. The age of the patient could be a contributory factor. The benefit risk relationship of mRNA-1273 is not affected by this report. Event seriousness is assessed as per regulatory authority's report. Most recent FOLLOW-UP information incorporated above includes: On 24-Apr-2022: Follow-up included event death details added. Addition seriousness criteria of death and medically significant added. Suspect action taken, outcome of event and narrative updated.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 13-Apr-2022. The most recent information was received on 20-Apr-2022 and was forwarded to Moderna on 20-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of PANCREATIC CARCINOMA (Pancreatic cancer) in a 90-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3002616, 214009 and 057G21A) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Moderna Vaccine (Dose 1: Moderna Vaccine, , Left Arm, Intramuscular Injection, Lot #: 3002616) on 29-May-2021, Moderna Vaccine (Dose 2: Moderna Vaccine, on Left Arm, Intramuscular Injection and Lot #: 214009) on 10-Jul-2021. Past adverse reactions to the above products included No adverse event with Moderna Vaccine and Moderna Vaccine. Concurrent medical conditions included Depression, Spasm eyelid, Anemia microcytic and Hypertension arterial. On 29-May-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 2 dosage form. On 10-Jul-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 2 dosage form. On 31-Dec-2021, received dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 09-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced PANCREATIC CARCINOMA (Pancreatic cancer) (seriousness criteria death and life threatening). It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication reported. No treatment information was provided. Company comment-This regulatory authority case concerns a 90 year old female patient with no relevant medical history, who experienced the unexpected serious (seriousness criteria-death, life threatening) event of Pancreatic carcinoma, about 152 days after receiving the second dose of mRNA-1273 vaccine. The event had a fatal outcome. No further information on clinical course and management of the event was available in the report. It was

Case ID	Narrative (Complete)
	not known whether an autopsy was done. Inappropriate schedule of product administration was also noted in the case (2nd dose of mRNA 1273 vaccine was given with 42 days interval).The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness retained as per Regulatory Authority reporting Most recent FOLLOW-UP information incorporated above includes: On 20-Apr-2022: Added medical history - Depression, Spasm eyelid, Anemia microcytic and Hypertension arterial.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 13-Apr-2022. The most recent information was received on 06-May-2022 and was forwarded to Moderna on 11-May-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On 06-May-2022, follow-up information was received from a physician. The vaccine recipient made regular visits to a hospital for low back pain. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 09-Apr-2022, in the morning, the patient noted low back pain that made the patient unable to move enough. At 10:00, the patient received the 3rd vaccination with this vaccine. At 19:30, the patient took a bath. At 20:30, a family member found the patient in a state of loss of consciousness in the bathtub. At 20:51, the ambulance team contacted the patient. Cardio-pulmonary resuscitation was initiated. At 21:10, the patient was transported to the reporting hospital by ambulance. Although resuscitation was performed, the heartbeat did not resume. At 21:20, tracheal intubation was performed. Administration of adrenaline 1 mg was performed three times. At 21:30, the patient was confirmed dead. Postmortem CT showed no findings other than the finding of acute pulmonary congestion that could have caused death. Unidentified intrinsic death was considered. Myocardial infarction and fatal arrhythmia were most likely causes of death based on the circumstances of death. The outcome of state of loss of consciousness was unknown. The outcome of acute pulmonary congestion, possibility of acute myocardial infarction, possibility of lethal arrhythmia, and acute cardiac arrest was fatal. No follow-up investigation will be made. Reporter comments: Since the cause of death was unknown, it could not be said that there was no cause of death; therefore, the cause of death was related to adverse events. This event developed about 12 hours after the vaccination with this vaccine and could not be considered unrelated. However, since the patient had no underlying disease that could have caused acute cardiac arrest and no findings other than pulmonary congestion on postmortem diagnostic imaging CT after the death, the relationship cannot be ruled out or affirmed, and the occurrence of adverse events is temporally related to the timing of administration of this vaccine. The relationship between the occurrence of adverse events and concomitant drugs was unknown. The relationship between the occurrence of adverse events and pathological factors of underlying diseases and complications was unknown. After the death, there were no findings other than the finding of acute pulmonary congestion that could have been the cause of death on postmortem diagnostic imaging CT, and acute myocardial infarction or lethal arrhythmia were most likely causes of death. However, since the patient was transported for cardiac arrest and spontaneous circulation did not return, it was difficult to make any further determination. Follow-up received on 06-MAY-2022 Updated: Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b)) on 15-Apr-2022. The most recent information was received on 19-May-2022 and was forwarded to Moderna on 19-May-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Died in sleep) in an 83-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000076A) for COVID-19 vaccination. The patient's past medical history included Chemotherapy (for Squamous cell carcinoma) in 2010 and Radiotherapy (for Squamous cell carcinoma). Previously administered products included for COVID-19 vaccination: SARS-COV-2 VIRUS, SARS-COV-2 VIRUS and SARS-COV-2 VIRUS. Past adverse reactions to the above products included No adverse drug reaction with SARS-COV-2 VIRUS, SARS-COV-2 VIRUS and SARS-COV-2 VIRUS. Concurrent medical conditions included Neoplasm (Recently had treatment for cancer, leukaemia or lymphoma (radiotherapy or chemotherapy)), Hypertension, Squamous cell carcinoma, Gastrointestinal neoplasm (Gastrointestinal stomach tumours) and Benign pleural neoplasm. Concomitant products included SENNA [SENNA ALEXANDRINA] for Constipation, DONEPEZIL, MEMANTINE and MIRTAZAPINE for Dementia, FLUOXETINE for Depression, ALLOPURINOL, ATENOLOL, LANSOPRAZOLE, SIMVASTATIN and PARACETAMOL for an unknown indication. On 12-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. Death occurred on 12-Apr-2022 The patient died on 12-Apr-2022. The cause of death was not reported. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Mar-2022, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Resident had previously had two COVID-19 vaccines and the first booster with no ill affects. It was reported that the resident was found to have passed away 2 hours following receiving the COVID-19 booster. Patient has not had symptoms associated with COVID-19. Patient has not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. Report was not related to possible blood clots or low platelet counts. Report was not related to possible myocarditis or pericarditis. For investigations referred to coroner.

Case ID	Narrative (Complete)
	No treatment information was provided. Company Comment: This regulatory case concerns an 83-year-old, female patient with relevant medical history of Squamous cell carcinoma status post chemotherapy and radiotherapy; Gastrointestinal stomach tumors; Hypertension; and past drug history of administration of three doses of COVID-19 vaccine (brand/s unspecified), who experienced the unexpected, serious (fatal and medically significant) event of death (died in sleep). The event occurred 2 hours after receiving the fourth (booster) dose of the mRNA-1273 vaccine. It was reported that the patient was found to have passed away 2 hours after receiving the COVID-19 booster dose. It was also reported that the patient had previously received two COVID-19 vaccines and the first booster (brand/s unspecified) with no reported side effects. Details of any relevant investigations or tests included referral to coroner. The cause of death was unexplained. No further details were provided and no autopsy was performed. The patient's age and relevant medical history mentioned above remain as confounders. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 19-May-2022: Follow-up information included medical history updated, cause of death, death date added and event outcome updated.
4.1(b) [redacted]	This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Passed away) and MYOCARDIAL INFARCTION (Heart attack) in an 85-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Stroke in 2018. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form and third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. In November 2021, the patient experienced MYOCARDIAL INFARCTION (Heart attack) (seriousness criterion medically significant). The patient died on 13-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, MYOCARDIAL INFARCTION (Heart attack) outcome was unknown. The patient did not receive a second booster dose. The patient experienced a heart attack around Thanksgiving 2021. It was reported that the father's death was not in relation to the vaccine. No concomitant medication was reported. No treatment medication was reported. Company comment: This case concerns an 85-year-old male patient, who experienced unexpected, serious (medically significant) AESI of Myocardial infarction and who had a fatal outcome with unexpected serious event of Death. Onset latency cannot be determined as the start date of the events as well as the vaccination dates were not reported. The patient reportedly received 3 doses of mRNA-1273 vaccine Clinical course and treatment details are not available in this report. Cause of death was not reported in this case. It is unknown if an autopsy was performed. The event was considered unrelated to the mRNA-1273 vaccine as per the reporter's assessment. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Apr-2022: Follow-up documents contains no new information.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 18-Apr-2022 and was forwarded to Moderna on 18-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CARDIAC FAILURE (collapse, heart failure) in an 86-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000114A) for COVID-19 vaccination. Patient concurrent medical history include long-term oxygen therapy with 2l for chronic heart suffer. as well as pulmonary hypertension with partial heart attack hypoxemia - diastolic heart failure severity I - COPD - permanent atrial fibrillation. Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 30-Jun-2021 and Comirnaty BNT162b2 on 22-Jul-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2. Concurrent medical conditions included COPD, Hypertension, Tricuspid valve incompetence, Cardiac insufficiency, Decompensation cardiac, Bladder incontinence, Dyspnoea exertional, Hypoxaemia and Atrial fibrillation. On 30-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Jan-2022, the patient experienced CARDIAC FAILURE (collapse, heart failure) (seriousness criterion death). The patient died on 13-Jan-2022. The reported cause of death was Heart failure (NOS). It is unknown if an autopsy was performed. No concomitant medications were provided by the reporter. It was reported as sudden unexpected collapse on the evening of 08 Jan 2022, resuscitation measures over 30 min long. Unstable briefing on the ITS. On 09 Jan 2022 independent breathing possible, awakens is responsive and without consequential damage. Phone calls without any abnormalities. Relocation to normal station on 11 Jan 2022. verstorben on the 2nd night on 13 Jan 22. Cancelled resuscitation measures. No treatment information was provided by the reporter. Company Comment:This regulatory authority case concerns an 86-year-old, male patient with relevant medical history of Hypertension, Tricuspid valve incompetence, Cardiac failure, and Atrial fibrillation who experienced the unexpected fatal adverse event of special interest of Cardiac failure. The event occurred 14 days after administration of mRNA-1273 taken as third dose of COVID-19 vaccination. Interchange of vaccine products is also noted in this case as patient received two doses of Comirnaty with the last dose taken approximately five months prior to administration of mRNA-1273 vaccine. Cardiopulmonary resuscitation was done after patient presented with sudden onset of loss of consciousness. Information about the concomitant medications, clinical course, diagnostic evaluation, and treatment details were not provided. The patient died five days after the event started. The cause of death was reported as Cardiac failure and it is unknown if an autopsy was performed. Patient´s advanced age and medical history remain as

Case ID	Narrative (Complete)
	confounders for the event and the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per regulatory authority's report.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 18-Apr-2022 and was forwarded to Moderna on 20-Apr-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b) 、4.1(b)). The vaccine recipient had drinking and smoking habits. On an unknown date, the patient received the 1st dose of a novel coronavirus vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 36.7 degrees Celsius. On 28-Feb-2022, the patient received the 3rd vaccination with this vaccine. On an unknown date, pyrexia developed. On 07-Mar-2022, ARDS developed. The patient visited the outpatient department because of persistent pyrexia. The patient tested negative for the tests of influenza and COVID-19 antigen. The patient did not want any oral medications and returned home. On 10-Mar-2022, the patient returned to the hospital because he was suffering from persistent pyrexia. Pneumonia was confirmed, and the patient was hospitalized. On that evening, the patient died. The outcome of ARDS and pneumonia was reported as fatal. Follow-up investigation will be made. Company Comment: The event of pneumonia developed after the administration of ELASOMERAN, but it is also possible that the event was an accidental event. The event of acute respiratory distress syndrome developed after the administration of ELASOMERAN, but the event is considered to have been caused by a concurrent event.
4.1(b)	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 11-Apr-2022 and was forwarded to Moderna on 13-Apr-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of MYOCARDIAL INFARCTION (Myocardial infarction) in a 68-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 27-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 27-Feb-2022, the patient experienced MYOCARDIAL INFARCTION (Myocardial infarction) (seriousness criterion death). The reported cause of death was Myocardial infarction. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication list was not provided. On February 27 the patient suddenly fell to the ground during dancing, with the consciousness changed and could not be woken up. Tthe case was reported for emergency service. The emergency service came to the site (OHCA), and on the ambulance, VT electric shock was performed once. The patient was sent to ER, EKG: PEA performed and the HR was 103 BPM. no pericardial effusions, no obvious PLE or ascites. Brain CT: No ICH. ROSC 38 mins. Cardiac enzyme: CPK/CK-MB/Trop-T:207/64/72.5, favor ascending aortic dissection, suggest: Chest CTA: type A dissection, and epinephrine and ECMO life maintaining system were used. On February 28, the patient came to the hospital because of cardiac arrest. After cardiac catheterization, it was diagnosed as aortic dissection. Aortic dissection needed emergency surgery to survive. However, after emergency treatment, it was found that the heart had no contraction and only electrical activity under cardiac ultrasound, and the conditions were irreversible. The family member of the patient signed the DNR. The patient died (cause of death: natural death: aortic dissection). On March 25, the case was reported as required by the family member of the patient. A 68-year-old male, having no chronic diseases and allergic drugs, received the first and second dose of Moderna on July 15 and October 27 respectively. After vaccination, patient developed chest tightness (without medical treatment). On January 27, patient was vaccinated with Moderna-Enhancer at Clinic of General Cardiology. After vaccination, patient developed chest tightness (without medical treatment). On February 27, patient fainted and changed the consciousness while dancing. on February 28, patient died, and the doctor diagnosed the cause of death as aortic dissection. The family member of the patient did not have the body dissected and asked Health Center to assist in the application. Treatment information was not provided. This fat
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 20-Apr-2022. The most recent information was received on 25-Apr-2022 and was forwarded to Moderna on 25-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of PUPILS UNEQUAL (Anisocoria of pupils), RUPTURED CEREBRAL ANEURYSM (Extensive aneurysmal subarachnoid hemorrhage), SUBARACHNOID HAEMORRHAGE (Extensive subarachnoid hemorrhage with active bleeding on the left adjacent to the basilar artery), HEADACHE (Headaches), COMA (Comatose state image with a GCS of 3), ALTERED STATE OF CONSCIOUSNESS (Progressive impairment of consciousness), RESPIRATION ABNORMAL (Pathological breathing pattern) and RESPIRATORY ARREST (Respiratory arrest/extubated) in a 79-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005241) for COVID-19 vaccination. The patient's past medical history included Minor ischemic stroke (Minor stroke in 2018. Minor Stroke in 2018 RecordsBase: Weakness of the Li. OE for a duration of approximately a quarter of an hour. Diagnoses at discharge: I63.9Subacute mediaischemia in media stream area right arterioarterial embolic genesis state after subacute ischemia in the mediastrom area right (minor stroke) alleged arterio- arterial embolic genesis (14.10.2018)) on 14-Oct-2018, Chronic interstitial nephritis (St.p. kidney transplantation 84/2885 in chronic interstial nephritis -st.p. hemodialysis 2002- 2004 N05.9Renal underlying disease: chronic interstjtial nephritis (kidney puncture 9/1990)) in September 1990, Coronary arterial stent insertion (KHK - CX-Stent 20 .12 .2021) on 20-Dec-2021, Hypertensive crisis (condition after symptomatic hypertensive derailment 5/2020) in May 2020, Hemiparesthesia (State after passageer episode with expressive aphasia and right half paresthesia 10/2021 (DD: epileptic seizure, TIA)) in October 2021, Folic acid deficiency (folic acid deficiency), TIA (State after passageer episode with expressive aphasia and right half paresthesia 10/2021 (DD: epileptic seizure, TIA)) in October 2021, Haemodialysis (St.p. kidney transplantation 84/2885 in chronic interstial nephritis -st.p. hemodialysis 2002- 2004) from 2002 to 2004, Decompensation cardiac (Cardiac decompensation in diastolic dysfunction II 12/2021 125.1KHK - coronary angiography 20.12.2021: LAD-sclerosis, RCA sclerosis, CX: 90% stenosis middle -> dil and stent onyx 2.75/15 mm and postdilation) in December 2021, Paroxysmal atrial fibrillation (148.9Paroxysmal Atrial atrial fibrillation (5/2020) - OAK with eliquis) in May 2020, Kidney transplant (z.n. nTx 2005) on 28-Apr-2005, Hypercholesterolaemia (hypercholesterolemia), Overweight (overweight), Aphasia (Condition after a temporary episode with expressive aphasia and paresthesia of the right half of the body 10/2021 (DD: epileptic seizure, TIA)) in October 2021, Structural epilepsy (G40.9Structural epilepsy with focal sensitive as well as motor seizures of left upper and lower extremities without impaired consciousness 5/2020) in May 2020, Epileptic fit (Condition after a temporary episode with expressive aphasia and paresthesia of the right half of the body 10/2021 (DD: epileptic seizure, TIA)) in October 2021 and Kidney transplant (z.n. nTx 2005) in 2005. Previously administered products included for COVID-19 vaccination: COVID-19 Vaccine Moderna; for Product used for unknown indication: AMLODIPIN, NORVASC, ATORVASTATIN, FUROSEMID [FUROSEMIDE], ADVAGRAF, MYFORTIC and DOXAZOSIN.

Case ID	Narrative (Complete)
	Past adverse reactions to the above products included Edema legs with AMLODIPIN and NORVASC; and No adverse event with ADVAGRAF, ATORVASTATIN, COVID-19 Vaccine Moderna, DOXAZOSIN, FUROSEMID [FUROSEMIDE] and MYFORTIC. Concurrent medical conditions included Internal carotid artery atherosclerosis (CAVK carotid plaques on both sides without hemodynamically relevant stenosis), Prostate adenoma (0 29.1Large compensated prostate adenoma without residual urinary formation), Coronary sclerosis (Cardiac decompensation in diastolic dysfunction II 12/2021 125.1KHK - coronary angiography 20.12.2021: LAD-sclerosis, RCA sclerosis, CX: 90% stenosis middle -> dil and stent onyx 2.75/15 mm and postdilation), COPD (COPD), Renal anaemia (064.9Anemia, comb. renal and iron deficiency), Actinic keratosis (L57.0 Actinic keratoses), Obstructive sleep apnea hypopnea syndrome (sleep apnea hypoventilation syndrome), Axonal and demyelinating polyneuropathy (G62.8Smoothly pronounced sensorimotor axional demyelinating polyneuropathy (18.10.2018)) since October 2018, Meniere's disease (Mb. Meniere), Hypertension arterial (I10Arterial hypertension CAVK), Renal oncocytoma (D36.9Transplant kidney oncocytomas *ED 4/2018 (Bosniak III) *MR finding 4/2020: low size progressive *condition after puncture 8/2020, histology: oncocytic tumor, histologically and immunohistochemically primarily oncocytoma urolog.) since April 2018, Anemia iron deficiency (064.9 Anemia, combined renal and iron deficiency) and Chronic polysinusitis (J32.4Chronic polysinusitis). Concomitant products included APIXABAN (ELIQUIS) for Atrial fibrillation paroxysmal, CLOPIDOGREL, CANDESARTAN, MYCOPHENOLATE SODIUM (MYFORTIC), TACROLIMUS (ADVAGRAF), LEVETIRACETAM, CALCIUM CARBONATE, COLECALCIFEROL (CALCIDURAN VIT. D3), MAGNESIUM HYDROXIDE (MAGNESIUM HYDROXID), PREDNISOLONE (APREDNISLON), FUROSEMIDE (FUROSEMIDA SALA), ATORVASTATIN, DOXAZOSIN, OLODATEROL HYDROCHLORIDE, TIOTROPIUM BROMIDE MONOHYDRATE (SPIOLTO RESPIMAT), NEBIVOLOL HYDROCHLORIDE (NOMEXOR), LERCANIDIPINE HYDROCHLORIDE (ZANIDIP) and SODIUM BICARBONATE (NEPHROTRANS) for an unknown indication. On 01-Mar-2022, the patient received fifth dose of mRNA-1273 (Spikevax) (Subcutaneous) 1 dosage form. On 03-Mar-2022, the patient experienced PUPILS UNEQUAL (Anisocoria of pupils) (seriousness criterion hospitalization), RUPTURED CEREBRAL ANEURYSM (Extensive aneurysmal subarachnoid hemorrhage) (seriousness criteria death and hospitalization), SUBARACHNOID HAEMORRHAGE (Extensive subarachnoid hemorrhage with active bleeding on the left adjacent to the basilar artery) (seriousness criteria death and hospitalization), HEADACHE (Headaches) (seriousness criterion hospitalization), COMA (Comatose state image with a GCS of 3) (seriousness criterion hospitalization), ALTERED STATE OF CONSCIOUSNESS (Progressive impairment of consciousness) (seriousness criterion hospitalization) and RESPIRATION ABNORMAL (Pathological breathing pattern) (seriousness criterion hospitalization). On 06-Mar-2022 at 10:00 AM, the patient experienced RESPIRATORY ARREST (Respiratory arrest/extubated) (seriousness criteria death and hospitalization). The patient died on 06-Mar-2022. The reported cause of death was Respiratory arrest and 160.4extensive subarachnoid hemorrhage with active bleeding on/the the left bordering the basilar artery on 03 .03 .2022 -hunt&hess 5 -genesis: aneurysmatic in basilar aneurysm 148 .0. It is unknown if an autopsy was performed. At the time of death, PUPILS UNEQUAL (Anisocoria of pupils), COMA (Comatose state image with a GCS of 3) and RESPIRATION ABNORMAL (Pathological breathing pattern) had not resolved and HEADACHE (Headaches) and ALTERED STATE OF CONSCIOUSNESS (Progressive impairment of consciousness) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2018, Imaging procedure: basilaris aneurysm not described in cerebral imagi Basilaris aneurysm not described in cerebral imaging!. In October 2018, Computerised tomogram head: disorder in the mediastrom area on the right point precentral not quite recent diffusion disorder in the mediastrom area on the right.. In October 2018, Ejection fraction: 60 60%. In October 2018, Glycosylated haemoglobin: in standard ~ lipids also within normal range in standard ~ lipids also within normal range. On 18-Oct-2018, Electroneurography: low-degree sensorimotor axional demyelinating poly Low-degree sensorimotor axional demyelinating polyneuropathy. On 24-Oct-2018, Computerised tomogram head:. On 24-Oct-2018, Ultrasound Doppler: cavk carotiplaques on both sides without hemodynam CAVK car
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 20-Apr-2022. The most recent information was received on 20-Apr-2022 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (Sudden death), NAUSEA (Nauseous) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) in a 90-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3006270) for COVID-19 vaccination. The patient's past medical history included Ileus, Stroke, COVID-19 immunisation (Comirnaty dos 3) on 20-Oct-2021, COVID-19 immunisation (Comirnaty dos 2) on 09-Feb-2021 and COVID-19 immunisation (Comirnaty dos 1) on 19-Jan-2021. Concurrent medical conditions included Hypertension, Memory impairment and Chronic obstructive pulmonary disease. On 24-Mar-2022, the patient received fourth dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 25-Mar-2022, the patient experienced NAUSEA (Nauseous) (seriousness criterion death). On an unknown date, the patient experienced COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) (seriousness criterion death). The patient died on 27-Mar-2022. The reported cause of death was Sudden death. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. The concomitant medication was not reported. The treatment medication was not reported. COMPANY COMMENT : This regulatory authority case concerns 90 years old female patient with concurrent conditions of hypertension and chronic obstructive pulmonary disease, and history of having a prior stroke, who experienced the unexpected fatal event of sudden death. Additional event of nausea was also reported with fatal criteria. Patient died three days after receiving a dose of mRNA-1273 vaccine, which was the fourth dose of the patient's COVID-19 vaccination schedule (previous three doses were cominarty). Reported cause of death was sudden death and it is unknown if an autopsy was performed. Patient's advanced age as well as history of hypertension, COPD and stroke remain as confounders for the event of sudden death. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event terms and seriousness criteria were assessed as reported. Most recent FOLLOW-UP information incorporated above includes: On 20-Apr-2022: Upon internal review on 26-Apr-2022, significant correction was performed. The MAH causality for events COVID-19 and sudden death was updated.

Case ID	Narrative (Complete)
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 20-Apr-2022. The most recent information was received on 20-Apr-2022 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by an other health care professional and describes the occurrence of COVID-19 (COVID-19) and DRUG INEFFECTIVE (Drug ineffective) in a 90-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 018G21A) for COVID-19 vaccination. 3rd doses Moderna 21.12.2021 PCR positive 30.03.2022. The patient's past medical history included COVID-19. On 21-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced COVID-19 (COVID-19) (seriousness criterion death) and DRUG INEFFECTIVE (Drug ineffective) (seriousness criterion death). The patient died on 31-Mar-2022. The reported cause of death was covid. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Mar-2022, SARS-CoV-2 test: positive (Positive) SARS-CoV-2 test positive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant mediations were not reported Treatment information was not reported Dosage text reported was R1. Company Comment: This regulatory authority case concerns a 90-year-old, male patient with medical history of COVID-19, who experienced the unexpected, serious (Fatal) AESI of COVID-19, which occurred approximately 99 days after receiving a dose of mRNA 1273 (reported as R1). Drug ineffective was also reported in the case. On 30-Mar-2022 patient undergone SARS-CoV-2 test which was positive. The patient died 3 months and 10 days after vaccination and the reported cause of death was COVID-19. An autopsy was not available. The clinical course and treatment details were not mentioned in the case. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 20-Apr-2022: Upon query received from business partner, significant correction was performed on 25-Apr-2022 to update the cause of the death from drug ineffective to COVID-19
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DYSPNOEA (Dyspnea) in an 86-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 055E21A) for COVID-19 vaccination. No Medical History information was reported. On 12-Dec-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 29-Mar-2022 at 11:37 PM, the patient experienced DYSPNOEA (Dyspnea) (seriousness criterion death). It is unknown if an autopsy was performed. The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Concomitant and Treatment medication was not reported. It was reported that the patient had difficulty of breathing. Company comment: This regulatory authority case concerns an 86 year old female patient with no reported medical history, who had the fatal event of Dyspnoea, about 3 months and 17 days after receiving a dose of COVID -19 vaccination with mRNA-1273 vaccine. No further details on clinical course, management of the event and the autopsy were available in the report. Elderly age of the patient could be a risk factor for the event. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness retained as per Regulatory Authority reporting.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 22-Apr-2022. The most recent information was received on 19-May-2022 and was forwarded to Moderna on 19-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson), AUTOIMMUNE PANCREATITIS (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson), TRANSAMINASES INCREASED (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson), DEATH (In ps for confusion. In APR post-vaccine vasculitis for SARSCOV19 (second dose performed on 07/01), under three-weekly dialysis (last session yesterday), M. Parkinson), ACUTE KIDNEY INJURY (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson), THROMBOCYTOPENIA (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson), RASH (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson), VASCULITIS (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson) and EOSINOPHIL COUNT INCREASED (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson) in a 73-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Osteoporosis and Hypothyroidism. Concurrent medical conditions included Disease Parkinson's and Chronic renal failure. Concomitant products included RASAGILINE TARTRATE (ROLDAP), LITHIUM CARBONATE (CARBOLITHIUM) and PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTOPRAZOLO) for an unknown indication.

Case ID	Narrative (Complete)
	On 07-Jan-2022, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 12-Jan-2022, the patient experienced DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson) (seriousness criterion death), AUTOIMMUNE PANCREATITIS (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson) (seriousness criterion death), TRANSAMINASES INCREASED (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson) (seriousness criterion death), DEATH (In ps for confusion. In APR post-vaccine vasculitis for SARSCOV19 (second dose performed on 07/01), under three-weekly dialysis (last session yesterday), M. Parkinson) (seriousness criterion death), ACUTE KIDNEY INJURY (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson) (seriousness criterion death), THROMBOCYTOPENIA (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson) (seriousness criterion death), RASH (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson) (seriousness criterion death), VASCULITIS (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson) (seriousness criterion death) and EOSINOPHIL COUNT INCREASED (In ps for a confusing state. In APR postvaccine vasculitis for SARSCOV19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), M. Parkinson) (seriousness criterion death). The patient died on 10-Apr-2022. The reported cause of death was in ps for a confusing state. in apr postvaccine vasculitis for sarscov19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), m. parkinson, in ps for a confusing state. in apr postvaccine vasculitis for sarscov19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), m. parkinson, in ps for a confusing state. in apr postvaccine vasculitis for sarscov19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), m. parkinson, in ps for a confusing state. in apr postvaccine vasculitis for sarscov19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), m. parkinson, in ps for a confusing state. in apr postvaccine vasculitis for sarscov19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), m. parkinson, in ps for a confusing state. in apr postvaccine vasculitis for sarscov19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), m. parkinson and in ps for a confusing state. in apr postvaccine vasculitis for sarscov19 (second dose performed on 07/01), in three-weekly dialysis (last session yesterday), m. parkinson. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 08-Mar-2022, Eosinophil count: 2374 k[iu] 2374 k[iU]. On 08-Mar-2022, White blood cell count: 16260 k[iu] 16260 k[iU]. On 09-Mar-2022, Alanine aminotransferase: 93 international unit(s) 93 INTERNATIONAL UNIT(S)-(UNDER 100). On 09-Mar-2022, Aspartate aminotransferase: 49 iu 49 INTERNATIONAL UNIT(S)-(UNDER 100). On 09-Mar-2022, Blood creatinine: 6.27 mg (milligram) 6.27 mg (milligram). For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment medication reported. Company comment: This regulatory case concerns a 73-year-old female patient with relevant medical history of Chronic renal failure, who experienced the unexpected fatal AESI of Drug reaction with eosinophilia and systemic symptoms, autoimmune pancreatitis, Acute kidney injury, thrombocytopenia and the unexpected fatal events of Transaminases increased, Death, Rash, Vasculitis and Eosinophil count increased. The events occurred approximately 5 days after receiving a dose of mRNA1273 as second dose of COVID-19 vaccine. The events may be in association with each other. Eosinophil count was 2374, white blood cell count was 16260, alanine aminotransferase was 93 IU, aspartate aminotransferase was 49 IU and blood creatinine was 6.27. It was mentioned that patient was in three-weekly dialysis. No further details regarding clinical course, diagnostic tests or treatment performed were disclosed. The patient's advanced age and underlying medical history of Chronic renal failure and concomitant use of lithium carbonate may be considered as confounders for the event acute kidney injury. Concomitant use of pantoprazole remain as a confounder for the event drug reaction with eosinophilia and systemic symptoms. Autopsy was not performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorp
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 22-Apr-2022. The most recent information was received on 27-May-2022 and was forwarded to Moderna on 27-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of FATIGUE (Strong dysentery concomitant with loss of strength on the lower limbs no longer stood on the legs, severe back pain), DYSENTERY (Strong dysentery concomitant with loss of strength on the lower limbs no longer stood on the legs, severe back pain), BACK PAIN (Strong dysentery concomitant with loss of strength on the lower limbs no longer stood on the legs, severe back pain) and ASTHENIA (Strong dysentery concomitant with loss of strength on the lower limbs no longer stood on the legs, severe back pain) in a 94-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005887) for COVID-19 vaccination. Concomitant products included ACETYLSALICYLIC ACID (CARDIOASPIRIN), FUROSEMIDE (LASIX M), ALLOPURINOL (ZYLORIC), PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTORC), BISOPROLOL FUMARATE (SEQUACOR), CAFFEINE CITRATE, CODEINE PHOSPHATE, PARACETAMOL (TRIATEC [CAFFEINE CITRATE;CODEINE PHOSPHATE;PARACETAMOL]) and POTASSIUM CANRENOATE (ALDACTONE [POTASSIUM CANRENOATE]) for an unknown indication. On 11-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 15-Dec-2021, the patient experienced FATIGUE (Strong dysentery concomitant with loss of strength on the lower limbs no longer stood on the legs, severe back pain) (seriousness criterion death), DYSENTERY (Strong dysentery concomitant with loss of strength on the lower limbs no longer stood on the legs, severe back pain) (seriousness criterion death), BACK PAIN (Strong dysentery concomitant with loss of strength on the lower limbs no longer stood on the legs, severe back pain) (seriousness criterion death) and ASTHENIA (Strong dysentery concomitant with loss of strength on the lower limbs no longer stood on the legs, severe back pain) (seriousness criterion death). The patient died on 06-Mar-2022. The reported cause of death was strong dysentery concomitant with loss of strength on the lower limbs no longer stood on the legs, severe back pain, strong dysentery concomitant with loss of strength on the lower limbs no longer stood on the legs, severe back pain, strong dysentery concomitant with loss of strength on the lower limbs no longer stood on the legs, severe back pain and strong dysentery concomitant with loss of strength on the lower limbs no longer stood on the legs, severe back pain. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	There was causal link with the improbable death (occurred 3 months after vaccination), attached blood chemistry tests suggestive of neoplastic disease. No treatment drug was reported. Company Comment: This regulatory case concerns a 94-year-old male patient, with no reported medical history, who experienced the unexpected serious fatal events of Asthenia, Fatigue, Dysentery, and Back pain that occurred 4 days after receiving a dose (dose number not specified) of mRNA-1273 vaccine. Patient had severe dysentery with loss of strength on the lower limbs and could no longer stand with severe back pain. Patient died 2 months and 19 days from events onset. It was reported that blood chemistry tests were suggestive of neoplastic disease. The reported cause of death was Fatigue, Dysentery, Back pain and Asthenia leading to the fatal outcome. It is unknown whether an autopsy was performed. Elderly age could be risk factor for the events and the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 27-May-2022: Significant follow up: Concomitant products updated and senders comment added.
4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of CREUTZFELDT-JAKOB DISEASE (Creutzfeldt-Jakob Disease ,fatal degenerative brain disorder , and her brain degenerated until she passed away on Aug. 2, 2021) in a 70-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 16-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 17-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced CREUTZFELDT-JAKOB DISEASE (Creutzfeldt-Jakob Disease ,fatal degenerative brain disorder , and her brain degenerated until she passed away on Aug. 2, 2021) (seriousness criteria death, disability and medically significant). The patient died on 02-Aug-2021. An autopsy was performed. The autopsy-determined cause of death was creutzfeldt-jakob disease ,fatal degenerative brain disorder , and her brain degenerated until she passed away on aug. 2, 2021. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Scan brain: abnormalities with her cerebellum abnormalities with her cerebellum. No concomitant medications reported. After getting the second dose of Moderna vaccine on 17-Mar-2021, the patient felt different immediately. Patient developed numbness that spread from the arm in which she received her injection to the entire left side of her body. She complained that something was wrong with her brain, could not put thoughts together or make sense of things. Patient also developed hearing loss, double vision, blindness and began to experience hallucinations. Doctors initially thought that patient had suffered a stroke or anxiety. Scans later showed there were abnormalities with her cerebellum. Patient's condition progressed rapidly, and she was eventually diagnosed with sporadic Creutzfeldt-Jakob Disease and given days to live. Patient lost the ability to walk and communicate, and her brain degenerated until she passed away on 02-Aug-2021. Patient died just five months after receiving her second dose of Moderna. No treatment medications reported. Company comment: This is a spontaneous case concerning a 70-year-old female patient with no medical history reported, who had a fatal outcome with unexpected serious (disability, medically significant) event of Creutzfeldt-Jakob Disease, described as sporadic rapidly evolving fatal degenerative brain disorder, in the context of a dose of mRNA-1273 vaccine. Latency cannot be properly assessed since event onset date was not provided. Patient had received 2-dose primary series of mRNA-1273 vaccine given at an interval of 29 days which falls within the recommended vaccine dosing schedule. It was reported that the patient received her first dose of Moderna without any complaints. After getting the second dose, patient developed numbness that spread throughout the left side of the body, associated with double vision, blindness, deafness, inability to walk and communicate, and brain degeneration described as something was wrong with her brain, couldn't put thoughts together or make sense of things, and hallucinations. Doctors initially thought that the patient had suffered a stroke or anxiety. Patient underwent brain scan and showed abnormalities in the cerebellum. Patient's condition progressed rapidly and she was eventually diagnosed with Creutzfeldt-Jakob Disease and given days to live. Patient died approximately 4 months and 2 weeks after the second mRNA-1273 vaccination. Autopsy was done and confirming her death was caused by Creutzfeldt-Jakob Disease. No further details about the treatments were provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 15-Jun-2022: Follow-up received on 15 Jun 2022-events, lab test added. Narrative updated.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 22-Apr-2022. The most recent information was received on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (Brain hemorrhage) in a 76-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Hypertension arterial and Emphysema pulmonary. On 09-Feb-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Mar-2022, the patient experienced CEREBRAL HAEMORRHAGE (Brain hemorrhage) (seriousness criterion death). The patient died on 20-Mar-2022. The reported cause of death was brain hemorrhage. It is unknown if an autopsy was performed. No concomitant medication reported.

Case ID	Narrative (Complete)
	Flu vaccination has not been carried out. Reaction time was reported as 05:00. No treatment medication reported. Company Comment: This is a Regulatory Authority case concerning a 76-year-old male patient, with relevant medical history of hypertension arterial, who experienced the unexpected, fatal and AESI of Cerebral haemorrhage. Fatal event occurred 1 month and 10 days after a dose of mRNA-1273 vaccine, and patient died 1 month and 11 days after vaccination. The reported cause of death was brain hemorrhage. It is unknown if an autopsy was performed. Medical history of hypertension arterial could be a contributory factor for Cerebral haemorrhage. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 28-Apr-2022: Follow up received included updated medical history and narrative updated. On 02-May-2022: Follow up received on 02APR2022, contains No new information.
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 22-Apr-2022 and was forwarded to Moderna on 22-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction), MALAISE (Malaise), VENTRICULAR FIBRILLATION (Ventricular fibrillation) and DYSPNOEA (Dyspnoea) in a 72-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 21046) for COVID-19 vaccination. The patient's past medical history included Decompensated heart failure, Atrioventricular extrasystoles and Paralysis of diaphragm. Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 26-May-2021 and Comirnaty BNT162b2 on 30-Jun-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2. Concurrent medical conditions included Type II diabetes mellitus, Arterial hypertension and Guillain Barre syndrome in 2015. On 07-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 17-Jan-2022, the patient experienced MALAISE (Malaise) (seriousness criteria death, hospitalization and life threatening) and DYSPNOEA (Dyspnoea) (seriousness criteria death, hospitalization and life threatening). On 18-Jan-2022, the patient experienced ACUTE MYOCARDIAL INFARCTION (Acute myocardial infarction) (seriousness criteria death, hospitalization, medically significant and life threatening) and VENTRICULAR FIBRILLATION (Ventricular fibrillation) (seriousness criteria death, hospitalization, medically significant and life threatening). The patient died on 18-Jan-2022. The reported cause of death was Acute myocardial infarction. An autopsy was not performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant products were reported. No treatment drugs were reported Company comment This regulatory case concerns a 72-year-old female patient with medical history of Type II diabetes mellitus, Arterial hypertension, Decompensated heart failure, Atrioventricular extrasístoles, Paralysis of diaphragm, previously received 2 doses of Comirnaty, who experienced the serious (death, hospitalization, medically significant and life threatening) unexpected events of Acute Myocardial Infarction (AESI), Ventricular Fibrillation (AESI), Malaise and Dyspnoea. Malaise and dyspnoea occurred 10 days after the 3rd dose of mRNA-1273 vaccine and the following day the patient experienced Acute Myocardial Infarction and Ventricular Fibrillation. The reported cause of death was Acute myocardial infarction. An autopsy was not performed. The mentioned medical history and patient's age remains a confounder for the events since they could contribute to acute myocardial infarction. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via United Kingdom MHRA (Reference number: 4.1(b) [redacted]) on 24-Apr-2022 and was forwarded to Moderna on 24-Apr-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of CARDIAC ARREST (Cardiac arrest) in an 87-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000076A) for Booster. The patient's past medical history included Stroke and Pacemaker insertion (cardiac) (on Pacemaker). On 22-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) .25 milliliter. On 22-Apr-2022, the patient experienced CARDIAC ARREST (Cardiac arrest) (seriousness criterion death). The reported cause of death was Cardiac arrest. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications reported by reporter. Patient went into cardiac arrest immediately after receiving his 4th booster dose. Patient had no allergies. Patient took Drug 1 from pharmacy. No reaction occurred as a result of a mistake made in the administration of the vaccine. Patient took Covid-19 Vaccine Moderna for booster. Patient was experienced cardiac arrest. No treatment medications provided by the reporter. Company Comment: This is a regulatory case concerning an 87-year-old male patient with reported medical history of Stroke and on Cardiac Pacemaker, who had a fatal outcome with unexpected serious event of Cardiac arrest, immediately after receiving a dose of mRNA-1273 vaccine. The reported cause of death was Cardiac arrest. The clinical course leading to demise was not reported and it is unknown if autopsy was performed. Medical history of Stroke and Pacemaker insertion remain as relevant factors for the event Cardiac arrest. It should be noted that the dose was reported as 4th dose of COVID-19 vaccine however, there were no information regarding the previous 3 doses of COVID-19 vaccine. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event retained as serious as per Regulatory Authority.

Case ID	Narrative (Complete)
4.1(b)	This case was received via United Kingdom MHRA (Reference number: 4.1(b)) on 24-Apr-2022 and was forwarded to Moderna on 24-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY EMBOLISM (Lung embolism) in an 86-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. No previous health problems but elderly (86 yrs old) and gradual reduction in mobility. On 05-Apr-2022, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 21-Apr-2022, the patient experienced PULMONARY EMBOLISM (Lung embolism) (seriousness criterion death). The patient died on 21-Apr-2022. The reported cause of death was Lung embolism. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. It was reported that the patient was admitted to ED due to shortness of breath. She had COVID vaccines prior with no issues and now had booster on 5-Apr-2022. She felt unwell, generally with headache, myalgia and feverish. Later improved but became acute short of breath, was admitted to ED on 21-Apr-2022 and found to have marked Pulmonary emboli and passed away in the department. It was reported that the reaction did not occur as a result of a mistake made in the administration of the vaccine.Treatment information was not provided. Company comment-This regulatory case concerns a 86-year-old female patient with reduced mobility reported, who experienced the unexpected serious fatal event of Pulmonary embolism (AESI) which occurred 16 days after a booster dose of mRNA-1273 vaccine. The cause of death was reported as Pulmonary embolism. Patient had headache, myalgia and fever after booster dose which resolved. Later was admitted to emergency, due to shortness of breath and was found to have marked pulmonary embolism. No further clinical, lab results or treatment details were given. Patient died on 21st April2022. It is unknown if an autopsy was performed. Patient´s elderly age and reduced mobility remains as confounders. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The event was assessed as serious as per Regulatory Authoritys report
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 25-Apr-2022 and was forwarded to Moderna on 25-Apr-2022. This regulatory authority case was reported by a physician and describes the occurrence of HALLUCINATION (Hallucination), HAEMATURIA (Haematuria), AGITATION (Agitation) and GENERAL PHYSICAL HEALTH DETERIORATION (Reduced general condition) in a 93-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000003A) for COVID-19 vaccination. Historical Condition: Transient Stroke (Out of Institution) Anxiety Osteoarthritis (Out of Institution) Undernutrition Depression Difficulty Walking Dementia Depressive or Delusional Form Moderate Unlabeled Cognitive Impairment with Opposition Access and Aggression - Tendency to Apathy (Outside of facility) Atrial fibrillation, flutter Untreated (Out of facility) Hypoacusis or deafness Parkinson's disease (Out of institution) Left pneumonia 2017 (Outside of facility) Urinary retention 08/2018 implementation of a PSA SAD at 112 ECBU negative TR: recovers prostate non-suspicious medium volume: probed with a CH 12 probe with a ttt per alpha blocking an uro notice during a consultation 31/08/2018 Dr BAKHCHI CH Belley: possible prostate resection but the resident prefers a DAS to change every month (Outside the institution). The patient's past medical history included Difficulty in walking, TIA, Pneumopathy, Starvation, Disease Parkinson's, Atrial fibrillation, Arthrosis, Depression, Anxiety, Cardiac flutter, Dementia, Deafness, Malnutrition, Delusion, Cognitive impairment, Aggression, Apathy, Pneumonia in 2017 and Urinary retention in 2018. On 24-Dec-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 25-Dec-2021, the patient experienced HAEMATURIA (Haematuria) (seriousness criteria death and hospitalization). On 07-Jan-2022, the patient experienced GENERAL PHYSICAL HEALTH DETERIORATION (Reduced general condition) (seriousness criterion death). On an unknown date, the patient experienced HALLUCINATION (Hallucination) (seriousness criterion hospitalization) and AGITATION (Agitation) (seriousness criterion hospitalization). The patient died on an unknown date. The reported cause of death was Haematuria and Reduced general condition. It is unknown if an autopsy was performed. At the time of death, HALLUCINATION (Hallucination) and AGITATION (Agitation) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Prostatic specific antigen: result not reported result not reported. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No Concomitant Drug details were reported. No Treatment information was provided. Dosage text: D1 Company Comment: This is a regulatory case concerning a 93-year-old female patient with relevant medical history of TIA, Delusion, Dementia, Parkinson's Disease, Depression, Anxiety, Cognitive impairment, Aggression, Starvation, Malnutrition, and Urinary retention, who had a fatal outcome with unexpected serious events of Haematuria and General physical health deterioration (reported as reduced general condition), and unexpected serious events of Hallucination and Agitation, which led to hospitalization after receiving the first dose of mRNA-1273 vaccine. Haematuria, Hallucination and Agitation occurred 1 day post-vaccination, while General physical health deterioration occurred 14 days post-vaccination. The patient died on an unknown date. The reported cause of death was Haematuria and Reduced general condition. It is unknown if an autopsy was performed. No further details about the clinical course, other diagnostic procedures and treatments were provided. The relevant medical history of TIA, Delusion, Dementia, Parkinson's Disease, Depression, Anxiety, Cognitive impairment and Aggression remain as confounders for the events of Hallucination and Agitation, while Starvation and

Case ID	Narrative (Complete)
	Malnutrition remain as confounders for the event of General physical health deterioration. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority reporting.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 26-Apr-2022. The most recent information was received on 17-May-2022 and was forwarded to Moderna on 17-May-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of INFECTION (Multiple myeloma relapse with infections after the first dose), DEATH (Death), PLASMA CELL MYELOMA (Multiple myeloma relapse with infections after the first dose,aggravation after the second dose,also) and PYREXIA (constant fever for 2 months after the second dose) in a 72-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Smoker. On 15-Jul-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 15-Jul-2021, the patient experienced PLASMA CELL MYELOMA (Multiple myeloma relapse with infections after the first dose,aggravation after the second dose,also) (seriousness criteria death and medically significant). On an unknown date, the patient experienced INFECTION (Multiple myeloma relapse with infections after the first dose) (seriousness criterion death) and PYREXIA (constant fever for 2 months after the second dose) (seriousness criterion death). The patient died on 01-Mar-2022. The reported cause of death was 10007515 and multiple myeloma relapse. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter considered DEATH (Death) to be unlikely related. No further causality assessments were provided for INFECTION (Multiple myeloma relapse with infections after the first dose), PLASMA CELL MYELOMA (Multiple myeloma relapse with infections after the first dose,aggravation after the second dose,also) and PYREXIA (constant fever for 2 months after the second dose). No concomitant medications was reported. No treatment drug details was reported. Company Comment: This is a regulatory case concerning a 72-year-old female patient no relevant medical history reported, who experienced the Fatal unexpected, event of infection, Death, Pyrexia, and Unexpected serious (fatal and Medically significant), Plasma Cell Myeloma which occurred on the same day after the 1st dose of mRNA-1273 vaccine. The events Infection and Pyrexia occurred on an unknown date. The patient died 7 months and 15 days after the 1st dose. The reported cause of death was Cardiac arrest and multiple myeloma relapse. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 17-May-2022: Follow up received is significant. Event Multiple myeloma was updated to Multiple myeloma progression and Events were added.
4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of PNEUMONIA (Bronchopneumonia) and DEATH (Death) in a 74-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 3004219) for COVID-19 vaccination. No Medical History information was reported. On 09-Sep-2021, the patient received first dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 14-Oct-2021, received second dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. On 02-Dec-2021, after starting mRNA-1273 (COVID-19 Vaccine Moderna), the patient experienced PNEUMONIA (Bronchopneumonia) (seriousness criterion death). The patient died on 30-Dec-2021. The reported cause of death was partly hemorrhagic bronchopneumonia. An autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Nov-2021, Computerised tomogram thorax: segmental pulmonary embolism segmental pulmonary embolism in catheter-associated thrombophlebitis on/the the right arm. On 21-Nov-2021, Culture: a c. difficile infection (Positive) A C. difficile infection. On 03-Dec-2021, Culture: staphylococcus aureus (Positive) staphylococcus aureus. On 13-Dec-2021, Bronchoscopy: invasive tracheobronchial aspergillosis invasive tracheobronchial aspergillosis. No concomitant medication was reported. Company comment: This is a regulatory case concerning a 74 year-old, male patient with no reported medical history, who experienced the serious Fatal unexpected, event of Pneumonia, approximately 49 days after the second dose of mRNA-1273 vaccine. The patient was admitted to hospital with Melaena two weeks after the second dose, it was reported that the gastroscopic cause was an ulcer duodenal. Afterwards pneumonia was diagnosed. During hospitalization, there was further gastrointestinal bleeding in esophageal varices and duodenal ulcers as well as newly diagnosed cirrhosis of the liver. Approximately one month after vaccination a thorax CT showed a segmental pulmonary embolism. A catheter-associated thrombophlebitis on the right arm was found. Patient was transferred to intensive care due to active gastrointestinal bleeding, sepsis and hospital-acquired pneumonia. A Clostridium difficile infection was detected, respiratory deterioration with increased oxygen demand and tachypnea developed due to progressive pneumonia. Staphylococcus aureus was demonstrated in the bronchial secretion, which was the most likely trigger of absceding pneumonia. A bronchoscopy also showed invasive tracheobronchial aspergillosis. The patient died 2 months 16 days after vaccination, an autopsy was performed, and cause of death was informed as partly hemorrhagic bronchopneumonia. The event was considered unrelated to the vaccine per the reporter's assessment. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The 1st Covid-19 mRNA vaccination was carried out on 09.09.21 and on 14.10.21 (lot no. 3004219). Foreign anamnestic information (wife, son) was admitted to hospital abroad with Melaena two weeks after the 2nd vaccination on the 30.10.21 (gastroscopic cause: ulcer bulb duodenal). On 06.11.21, pneumonia was repatriated. During the course of the hospital, there came further gastrointestinal bleeding in esophageal varices and duodenal ulcers as well as newly diagnosed cirrhosis of the liver in the Center Hospital. On the 10.11.21, segmental pulmonary embolism was found in the CT thorax in catheter-associated thrombophlebitis on the the right arm. On the 12.11.21, an initial transfer to intensive care was carried out during active gastrointenstinal bleeding; on 21.11.2021, was retransferred to intensive care unit for sepsis and, above all, hospital-acquired pneumonia. A C. difficile infection was also detected on the 21.11.21. On 29.11.21, there came a respiratory deterioration with increased oxygen demand and tachypnea; progressive pneumonia in the left lower lobe of the lower lower lower lobe and progressive melts in the superior lower lobe on the left lower lobe showed

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	on 02.12.21. The growth of a staphylococcus aureus was demonstrated in the bronchial secretion of 03.12.21. Infectiologically, this germ was considered to be the most likely trigger of absceding pneumonia. The bronchoscopy of 13.12.21 also showed invasive tracheobronchial aspergillosis. The patient passed away on the 30.12.21; autopsy was done. This resulted in extensive, partly hemorrhagic bronchopneumonia as the cause of death. No treatment information was reported. The causal relationship for extensive bronchopneumonia with subsequent exitus of letalis was classified according to the criteria of WHO1) as unlikely for Spikevax in case of formal temporal correlation and the presence of non-drug causes.
4.1(b)	This case was received via United Kingdom MHRA (Reference number: 4.1(b)) on 27-Apr-2022 and was forwarded to Moderna on 27-Apr-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of CARDIAC ARREST (asystole) and CARDIAC ARREST (Cardiac arrest) in an 87-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 0000768) for COVID-19 vaccination. The patient's past medical history included Ischemic heart disease, Atrial fibrillation, Stroke, Artificial cardiac pacemaker user, Obstructive sleep apnea syndrome and Knee replacement. Concomitant products included ATORVASTATIN, EDOXABAN, FUROSEMIDE, INDAPAMIDE and OMEPRAZOLE for an unknown indication. On 22-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 22-Apr-2022, the patient experienced CARDIAC ARREST (asystole) (seriousness criterion life threatening) and CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and life threatening). The patient was treated with ADRENALINE [EPINEPHRINE] for Asystole, at a dose of Adrenaline given every 2nd 2 minute cycle of CPR. The patient died on 22-Apr-2022. The reported cause of death was Cardiac arrest. It is unknown if an autopsy was performed. At the time of death, CARDIAC ARREST (asystole) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-Apr-2022, Blood test: mixed acidaemia mixed acidaemia, normal glucose normal glucose and potassium potassium. On 22-Apr-2022, Echocardiogram: vent standstill, no evidence of tamponade vent standstill, no evidence of tamponade. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Company Comment: This regulatory authority case concerns an 87-year-old, male patient with relevant medical history of Ischemic heart disease, Atrial fibrillation, Stroke, and use of Artificial cardiac pacemaker who experienced the unexpected, life threatening and fatal event of Cardiac arrest (reported as Asystole and Cardiac Arrest) which occurred on the same day after administration of mRNA-1273 taken as fourth dose of COVID-19 vaccination. Information regarding the previous doses of COVID-19 vaccine was not provided. Patient was reported to be well and did not complain of any chest pain nor shortness of breath until he developed sudden onset of loss of consciousness after vaccination. He was noted to have ventricular fibrillation thus started on advanced cardiac life support. He remained in asystole throughout resuscitative efforts. Unspecified blood tests showed mixed acidemia, normal glucose and normal potassium. Echocardiogram showed absence of tamponade. Patient died on the same day that the event started. The cause of death was reported as Cardiac arrest and it is unknown if an autopsy was performed. Patient´s advanced age and medical history remain as confounders for the event and the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per regulatory authority's report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DYSPNOEA (Dyspnoea) and DEATH (Death) in a 78-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 26-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 27-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced DYSPNOEA (Dyspnoea) (seriousness criterion death) and DEATH (Death) (seriousness criterion death). The patient died on 27-Dec-2021. The reported cause of death was Cardiac arrest, Respiratory failure and Bronchial asthma. An autopsy was not performed. No concomitant medication were reported. No treatment information was provided by the reporter. Company Comment: This regulatory case concerns a 78-year-old, female patient, with a body mass index of 26.6 and no reported medical history, who experienced the unexpected, fatal events of Dypnoea & Death 31 days after receiving a 3rd dose of mRNA-1273 vaccine. Fatal events were reportedly caused by cardiac arrest, respiratory failure, & bronchial asthma. Details on the medical history, clinical course, diagnostics, treatments, and autopsy report were not provided for medical review. Patient's age and body mass index remain as confounders to the event death. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 28-Apr-2022: Significant FU - Events added, Drug Dosage and Relevant Information and Relatedness of drug to reaction(s)/event added
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (Lung cervical bleeding shortly after vaccination then died) in an 85-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000103A) for COVID-19 vaccination. The patient's past medical history included COVID-19. On 11-Feb-2022, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 28-Feb-2022, the patient experienced PULMONARY EMBOLISM (Lung cervical bleeding shortly after vaccination then died) (seriousness criterion death). The patient died on 03-Mar-2022. The reported cause of death was Lung embolism. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):

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	On an unknown date, Bronchoscopy: negative bronchoscopy without abnormalities. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Concomitant medications were not provided. Treatment information was not provided. Patient had no allergy in past. Risk factors or pre-existing illnesses included Various diseases. 11.02.2022 vaccinated/11 03.2022 Company comment: This regulatory case concerns an 85-year-old elderly female patient with relevant medical history of COVID who experienced the unexpected fatal AESI of pulmonary embolism which occurred approximately 17 days after first dose of mRNA-1273 vaccine. Medical history of COVID 19 and elderly age are risk factors for the event and fatal outcome. It is unknown whether an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness criteria of event retained as per Regulatory Authority reporting.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 28-Apr-2022 and was forwarded to Moderna on 28-Apr-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (Pulmonary embolism shortly after vaccination shortly then died) in an 85-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000103A) for COVID-19 vaccination. previous illnesses Various diseases, and also survived corona infection with Bronchoscopy without abnormalities. On 11-Feb-2022, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 28-Feb-2022, the patient experienced PULMONARY EMBOLISM (Pulmonary embolism shortly after vaccination shortly then died) (seriousness criterion death). The patient died on 03-Mar-2022. The reported cause of death was Lung embolism. It is unknown if an autopsy was performed. No concomitant medications was reported. No treatment drug details was reported. Company comment: This regulatory case concerns an 85-year-old female patient, with no reported relevant medical history, who experienced, unexpected, fatal, AESI of Pulmonary embolism, 17 days after receiving mRNA-1273 vaccine as a first dose, then subsequently died, four days after the event. The reported cause of death was Lung embolism. Treatment details are not available in this report. It is unknown if an autopsy was performed. The elderly age of the patient remains to be a confounder for the event. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness was assessed as per Regulatory Authority's report.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of COVID-19 (Critical Covid Pneumonia) and ACUTE MYOCARDIAL INFARCTION (Critical Covid Pneumonia, Acute Myocardial Infarction) in a 68-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) for an unknown indication and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) for an unknown indication. No Medical History information was reported. On 21-May-2021, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) (Intramuscular) 1 dosage form. On 30-Jul-2021, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) (Intramuscular) 1 dosage form. On 07-Jan-2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 20-Mar-2022, the patient experienced COVID-19 (Critical Covid Pneumonia) (seriousness criterion death) and ACUTE MYOCARDIAL INFARCTION (Critical Covid Pneumonia, Acute Myocardial Infarction) (seriousness criterion death). The reported cause of death was critical covid pneumonia and critical covid pneumonia, acute myocardial infarction. It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided. Company comment: This Fatal Regulatory Authority case concerns a 68-year-old, male patient, with no reported medical history, who experienced the unexpected, serious (death) AESI of COVID-19 (reported as critical COVID Pneumonia) and Acute myocardial infarction approximately 2 months and 13 days after receiving a dose of mRNA-1273 vaccine, considered as the third dose of the his COVID-19 vaccination schedule, as he previously received two doses of AstraZeneca's COVID-19 vaccine, which remain as co-suspects. Date and cause of death were not reported. Autopsy report is not available. No further clinical information was provided for medical reviewing. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 28-Apr-2022 and was forwarded to Moderna on 02-May-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by an autopsy physician, was received via the PMDA (Ref, 4.1(b)). The vaccine recipient was hospitalized in schizophrenia. On an unknown date, the patient received the 1st dose of a novel coronavirus

Case ID	Narrative (Complete)
	vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a novel coronavirus vaccine (product name unknown). On 25-Apr-2022, at 15:50, the patient received the 3rd vaccination with this vaccine. Pyrexia developed up to 39.9 degrees Celsius. The patient was bedridden and noted incontinence and other symptoms. On 26-Apr-2022, at 17:47, the patient was found in cardio-respiratory arrest. At 19:03, the patient died. The cause was unknown. A pathological examination was scheduled. The outcome of pyrexia, decreased activity, incontinence, and cardio-respiratory arrest was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship..
4.1(b)	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b)) on 01-May-2022. The most recent information was received on 10-May-2022 and was forwarded to Moderna on 10-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death) in an 89-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000075A) for COVID-19 vaccination. Patient was not on any medication. Concurrent medical conditions included Dementia Alzheimer's type and Frailty. Concomitant products included TOZINAMERAN (COMIRNATY) from 27-Sep-2021 to 27-Sep-2021 and NITROFURANTOIN from 08-Apr-2022 to an unknown date for an unknown indication. On 26-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. Death occurred on 27-Apr-2022 The patient died on 27-Apr-2022. The reported cause of death was Frailty and Dementia Alzheimer's type. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: not infected (Negative) Not infected. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient had no symptoms associated with COVID-19. Not had a COVID-19 test. Patient had the vaccine on Tuesday morning and was found in her bed on Wednesday morning. No pulse was present. Death was referred to the coroner. Patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. The report was not related to possible blood clots or low platelet counts. The report was not related to possible myocarditis or pericarditis. No treatment information was provided. The reported cause of death was frailty of old age. Reporter do not have copy of the post-mortem report. Company Comment: This regulatory authority case of Interchange of vaccine products concerning an 89-year-old, female patient with concurrent medical conditions of Dementia Alzheimer's type and Frailty and concomitant medication with Nitrofurantoin, previously vaccinated with a dose of COVID-19 vaccine Comirnaty (dose number not specified; no adverse event reported) who experienced the unexpected serious event of unexplained Death which occurred 1 day after a dose of mRNA-1273 vaccine, dose 4 in vaccine series. The next morning after vaccination, patient was found in her bed without pulse. Reported cause of fatality was Death unexplained. An autopsy was performed and the autopsy-determined causes of death were Frailty and Dementia Alzheimer's type. COVID-19 virus test was negative. At the time of the report, very limited information has been provided about the patient and about the event leading to the fatal outcome. The patient's elderly age, concurrent medical conditions, and concomitant medication with Nitrofurantoin remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 10-May-2022: Patient age updated. Cause of death added. Relevant medical history and concurrent conditions added. Other Concomitant Medications added. The adverse event MedDRA terminology was updated to Death unexplained. Event stop date and Lab Data were added. Action taken updated to Not applicable.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 02-May-2022 and was forwarded to Moderna on 02-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain), NIGHT SWEATS (Night sweat), DYSPNOEA (Dyspnea), DISCOLOURED VOMIT (Dark color vomiting) and WEIGHT DECREASED (Loss of weight) in a 65-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On 31-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form once a day. On 31-Jan-2022, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion death), NIGHT SWEATS (Night sweat) (seriousness criterion death), DYSPNOEA (Dyspnea) (seriousness criterion death), DISCOLOURED VOMIT (Dark color vomiting) (seriousness criterion death) and WEIGHT DECREASED (Loss of weight) (seriousness criterion death). The patient died on 25-Feb-2022. The reported cause of death was Chest pain, Night sweat, Dyspnea, Dark color vomiting and Loss of weight. It is unknown if an autopsy was performed. Suspect dosage text was reported as R1. No concomitant medications were reported. No treatment details were reported. Company comment: This regulatory case concerns a 65-year-old female patient with no reported medical history who experienced the unexpected fatal events of Chest pain, Night sweats, Dyspnoea, Discolored vomit and Weight decreased which occurred on same day after an unspecified dose of mRNA-1273 vaccine. Patient died 25 days after the onset of events. Primary cause of death is not specified. It is unknown whether an autopsy was performed.

Case ID	Narrative (Complete)
	The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness criteria for the events retained as per Regulatory Authority reporting.
4.1(b)	This case was initially received via European Medicines Agency (Reference number 4.1(b)) on 02-May-2022. The most recent information was received on 09-May-2022 and was forwarded to Moderna on 09-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (at 30.03 to which pt was sent to the EH with increasing dyspnea complaints.), GRANULOMATOSIS WITH POLYANGIITIS (exac GPA/Wegener), HAEMOPTYSIS (Hemoptysis) and CONDITION AGGRAVATED (exac GPA/Wegener) in an 86-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Anterior myocardial infarction (Family History: false), Granulomatosis with polyangiitis (Family History: false), COPD exacerbation (Family History: false) and Multiple vessel coronary artery disease (Family History: false). Previously administered products included for Product used for unknown indication: COVID-19 VACCINE on 01-Jan-2021, COVID-19 VACCINE on 19-Feb-2021 and COVID-19 VACCINE on 19-Nov-2021. Past adverse reactions to the above products included No adverse event with COVID-19 VACCINE, COVID-19 VACCINE and COVID-19 VACCINE. Concomitant products included BUDESONIDE, FORMOTEROL FUMARATE (BUDESONIDE AND FORMOTEROL) for COPD, OMEPRAZOLE (OMEPRAZOL [OMEPRAZOLE]), CARBASALATE CALCIUM (CARBASALAATCALCIUM), HYDROCHLOORTHIAZIDE, LOSARTAN POTASSIUM (LOSARTAN TEVA), AMLODIPINE, ATORVASTATIN (ATORVASTATINE [ATORVASTATIN]), BISOPROLOL FUMARATE, AZITHROMYCIN (AZITROMYCINE) and METFORMIN HYDROCHLORIDE (METFORMIN [METFORMIN HYDROCHLORIDE]) for an unknown indication. On 11-Mar-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 12-Mar-2022, the patient experienced COUGH (Since booster is increasingly suffering from dyspnea with progressive cough symptoms.) and DYSPNOEA (Since booster is increasingly suffering from dyspnea with progressive cough symptoms.). On 18-Mar-2022, the patient experienced COUGH (/Presented at 18.03 in HA with increased cough and dyspnea. Wishes AB then. No AB received) and DYSPNOEA (Presented at 18.03 in HA with increased cough and dyspnea. Wishes AB then. No AB received). On 30-Mar-2022, the patient experienced DYSPNOEA (at 30.03 to which pt was sent to the EH with increasing dyspnea complaints.) (seriousness criterion hospitalization). On 31-Mar-2022, the patient experienced HAEMOPTYSIS (Hemoptysis) (seriousness criterion death). On an unknown date, the patient experienced GRANULOMATOSIS WITH POLYANGIITIS (exac GPA/Wegener) (seriousness criterion death) and CONDITION AGGRAVATED (exac GPA/Wegener) (seriousness criterion death). The patient died on 31-Mar-2022. The reported cause of death was pulmonary manifestation gpa/wegener, pulmonary manifestation gpa/wegener, acute pulmonary hemorrhage (primary), Hemoptysis and pulmonary manifestation gpa/wegener. It is unknown if an autopsy was performed. At the time of death, DYSPNOEA (at 30.03 to which pt was sent to the EH with increasing dyspnea complaints.), COUGH (/Presented at 18.03 in HA with increased cough and dyspnea. Wishes AB then. No AB received), COUGH (Since booster is increasingly suffering from dyspnea with progressive cough symptoms.), DYSPNOEA (Presented at 18.03 in HA with increased cough and dyspnea. Wishes AB then. No AB received) and DYSPNOEA (Since booster is increasingly suffering from dyspnea with progressive cough symptoms.) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 30-Mar-2021, Blood test: anemia anemia. On 30-Mar-2021, Renal function test: renal impairment renal impairment. On 30-Mar-2021, Urine analysis: erythrocyturie erythrocyturie. On 30-Mar-2022, Antineutrophil cytoplasmic antibody: positive (Positive) ANCA/PR3 strong positive. On 31-Mar-2022, Chest X-ray: known consolidations in both top fields have been Known consolidations in both top fields have been visible again compared to 1 day before. No indication of pneumothorax. Slim vessel drawing, mediastinum and cor show no indication of overfilling.. On 31-Mar-2022, Laboratory test: used: eries 2068, leu 178, bacteria negative, ery USED: eries 2068, Leu 178, bacteria negative, ery cylinders absent. and creatinine 115, egfr 37, na 129, k 4.2, crp 198, h creatinine 115, eGFR 37, Na 129, K 4.2, CRP 198, Hb 4.7, MCV 84, Leu 12.9, Tr 247, PR3 >177.. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No Treatment medications were provided. CC: This regulatory authority case concerns an 86 year old female patient with relevant medical history of Granulomatosis with polyangiitis, Myocardial infarction, Chronic obstructive pulmonary disease and Coronary artery disease, previously vaccinated with three doses of Covid 19 vaccine type /brand not reported with no reported adverse events , who experienced the Serious(fatal), unexpected events of DYSPNOEA (at 30.03 to which pt was sent to the EH with increasing dyspnea complaints.), GRANULOMATOSIS WITH POLYANGIITIS (exac GPA/Wegener), HAEMOPTYSIS (Hemoptysis) and CONDITION AGGRAVATED (exac GPA/Wegener), which occurred 19-20 days post vaccination with an unknown dose number of mRNA-1273 vaccine. This patient was reported to have died 20 days post vaccination and the reported cause of death were as follows : Pulmonary Granulomatosis , hemoptysis , Pulmonary hemorrhage , Disease Aggravation and Pulmonary manifestation of Granulomatosis Polyangitis /Wegener's . It is unknown if an autopsy was done. Laboratories reported : Antineutrophil cytoplasmi ANCA/PR3 strong positive Blood test;anemia Renal function test: renal impairment; Urinalysis ;erythrocyturie; Chest x-ray: Chest X-ray;31-MAR-2022;Known consolidations in both top fields have been;Known consolidations in both top fields have been visible again compared to 1 day before. No indication of pneumothorax. Slim vessel drawing, mediastinum and cor show no indication of overfilling. The details of the hospitalization and treatment information were not reported. The medical history ofGranulomatosis with polyangiitis, Myocardial infarction, Chronic obstructive pulmonary disease and Coronary artery disease, and the age of this patient plus the history of previous vaccination for 3 doses of Covid 19 vaccine are considered as confounders for all of the events. The benefit -risk relationship of mRNA -1273 is not affected by this report. Events' seriousness assessed as per RA On 31-Mar-2021, the patient experienced GRANULOMATOSIS WITH POLYANGIITIS (exac GPA/Wegener) (seriousness criterion death). Most recent FOLLOW-UP information incorporated above includes: On 09-May-2022: Significant follow up: Concurrent conditions, lab data, event onset date and concomitant medication details added. On 09-May-2022: Translated document attached on12-MAY-2022. Lab data free text was translated and event verbatim was translated.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 04-May-2022 and was forwarded to Moderna on 04-May-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of COVID-19 PNEUMONIA (COVID-19 pneumonitis) and VACCINATION FAILURE (Vaccination failure) in a 78-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination.

Case ID	Narrative (Complete)
	The patient's past medical history included Cardiac hypertrophy, Enlarged clitoris, Failure respiratory, Breast lump NOS, Obesity, Dyslipidaemia, Hysterectomy and Vulvectomy. Concurrent medical conditions included Non-insulin-dependent diabetes mellitus, Arthritis rheumatoid, Biliary atresia and Hypertension arterial. Concomitant products included FOLIC ACID (ACIDE FOLIQUE), SALBUTAMOL, BISOPROLOL FUMARATE (BISOPROLOL LPH), ATORVASTATIN CALCIUM (ATORVASTATINE EG), METHOTREXATE, PREDNISOLONE METASULFOBENZOATE SODIUM (SOLUPRED ORO) and PROCAINE HYDROCHLORIDE (CHLORHYDRATE DE PROCAINE) for an unknown indication. On 27-Apr-2021, the patient received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) .3 milliliter every six weeks. On 08-Jun-2021, received dose of TOZINAMERAN (COMIRNATY) (Intramuscular) dosage was changed to .3 milliliter. On 04-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On an unknown date, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonitis) (seriousness criterion death) and VACCINATION FAILURE (Vaccination failure) (seriousness criterion death). The patient died on 24-Mar-2022. The reported cause of death was multiple organ failure. An autopsy was not performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Suspect dosage text was reported as R1. No treatment details were reported. Company comment:This regulatory authority case concerns a 78 year old female patient with underlying medical history of Cardiac hypertrophy, prior surgery of Hysterectomy, Vulvectomy, Type 2 Diabetes Mellitus, Respiratory Failure, Hypertension, Obesity and Dyslipidaemia, who experienced the unexpected, serious(Fatal) adverse event of special interest of COVID-19 Pneumonia. The event occurred at an unspecified date after receiving a dose of mRNA1273. Vaccination failure was also reported in the case. It should be noted that the patient received 2 doses of different COVID-19 vaccine (Comirnaty) approximately 5 months and 26 days prior to the latest dose of mRNA1273 (inappropriate schedule of vaccine administered). The patient expired on 24-Mar-2022 and the cause of death reported was multiple organ failure .The clinical course that lead to the demise of the patient and treatment details were not provided in the case. The patient's advanced age and underlying medical history of cardiac hypertrophy, prior surgeries, Type 2 diabetes mellitus, respiratory failure, hypertension, obesity and dyslipidaemia may be considered as risk factors for the event of COVID-19 pneumonia. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority.
4.1(b) [redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of ACUTE RESPIRATORY DISTRESS SYNDROME (Vaccine-induced acute respiratory distress syndrome) in an 88-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. LITERATURE REFERENCE: Yoshimura Y, Sasaki H, Miyata N, Miyazaki K, Okudela K, Tateishi Y, et al. An autopsy case of COVID-19-like acute respiratory distress syndrome after mRNA-1273 SARS-CoV-2 vaccination. Int J Infect Dis. 2022;121:98-101 The patient's past medical history included Uterine fibroids, Hysterectomy (Patient had a history of a hysterectomy for uterine fibroids.) and High-flow nasal cannula oxygen therapy (percutaneous oxygen saturation 92% with oxygen therapy at 10 L/min) since an unknown date. Concurrent medical conditions included Non-smoker (Patient had never smoked), Hypertension, Dyslipidemia, Asthma, Peripheral neuropathy and Insomnia. Concomitant products included MONTELUKAST for Asthma, PRAVASTATIN for Dyslipidemia, AMLODIPINE for Hypertension, METHYLEPHEDRINE HYDROCHLORIDE-DL (DL-METHYLEPHEDRINE) and ZOLPIDEM for Insomnia, DIHYDROCODEINE for Peripheral neuropathy, CHLORPHENIRAMINE [CHLORPHENAMINE] and MECOBALAMIN for an unknown indication. In 2021, the patient received second dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. In 2021, received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. In 2021, the patient experienced ACUTE RESPIRATORY DISTRESS SYNDROME (Vaccine-induced acute respiratory distress syndrome) (seriousness criteria death, hospitalization and medically significant). The patient was hospitalized for 10 days due to ACUTE RESPIRATORY DISTRESS SYNDROME. The patient was treated with MORPHINE for Adverse event, at a dose of initiated sedation on day 15; METHYLPREDNISOLONE for Adverse event, at a dose of 80 milligram once a day; METHYLPREDNISOLONE for Adverse event, at a dose of 500 milligram once a day; HEPARIN for Adverse event, at a dose of 10000 international unit once a day and CEFTRIAXONE for Adverse event, at a dose of 2 gram once a day. The patient died in 2021. The reported cause of death was acute respiratory distress syndrome/respiratory failure. An autopsy was performed. The autopsy-determined cause of death was Diffuse alveolar damage. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Autopsy: diffuse alveolar damage Both lungs were edematous and heavy. The cut surfaces felt solid and firm and appeared partially glittering, gray-white, brownish-red in color, with partially viscous exudate. Histologically, the gray-white firm areas were in the proliferative stage of diffuse alveolar damage with pneumocytes, macrophages, and myofibroblastic cell proliferation. The brownish-red areas were in the exudative stage with the presence of hyaline membranes. Did not find any significant pathological changes, such as thrombosis and myocarditis, in any of the organs examined. On an unknown date, Blood immunoglobulin G: 114,585 au/ml 114,585 AU/mL. On an unknown date, Blood lactate dehydrogenase: 452 u/l 452 U/L. On an unknown date, Body temperature: 38.1°c. 38.1°C.. On an unknown date, Brain natriuretic peptide: 7.3 pg/ml 7.3 pg/mL. On an unknown date, C-reactive protein: 7.4 mg/dl 7.4 mg/dL. On an unknown date, Chlamydia test: negative (Negative) serologic markers for Chlamydophila pneumoniae was negative.. On an unknown date, Computerised tomogram: ground-glass opacities (abnormal) Multifocal dilated bronchi, bilateral ground-glass opacities and consolidations, mainly in the peripheral lung areas. On an unknown date, Fibrin D dimer: 2.19 µg/ml 2.19 µg/mL. On an unknown date, Immunology test: negative (Negative) Negative. On an unknown date, KL-6: 1,194 u/ml 1,194 U/mL. On an unknown date, Laboratory test: 0.02 s/c Day 9 levels of SARS-CoV-2 nucleocapsid (N) was 0.02 S/C and negative (Negative) On autopsy, the lesions were immunohistochemically negative for SARS-CoV-2 spike and N protein. On an unknown date, Legionella test: negative (Negative) Negative. On an unknown date, Lymphocyte count: 653 /µl 653 /µL. On an unknown date, Mycoplasma test: negative (Negative) Serologic markers for Mycoplasma pneumoniae was negative..

Case ID	Narrative (Complete)
	On an unknown date, Nasopharyngeal swab: negative (Negative) SARS-CoV-2 polymerase chain reaction (PCR) and rapid antigen testing with nasopharyngeal swabs were negative. On an unknown date, Neutrophil count: 8,400 /µl 8,400 /µL. On an unknown date, Oxygen saturation: 92% Percutaneous oxygen saturation 92%. On an unknown date, PO2: 112 mmhg 112 mmHg. On an unknown date, Physical examination: tachypnea (38 breaths/min) Tachypnea (38 breaths/min) and fine crackles Fine crackles on both lungs and no edema in the extremities was reported. On an unknown date, Protein S: negative (Negative) On autopsy, western blot for the S protein of the lung lysate showed negative results and the lesions were entirely immunohistochemically negative for SARS-CoV-2 spike protein.. On an unknown date, SARS-CoV-2 antibody test: elevated (High) Elevated. On an unknown date, SARS-CoV-2 test: negative (Negative) negative and negative (Negative) On autopsy, PCR confirmed that SARS-CoV-2 was not present in the lung and other organs, including the heart, liver, spleen, and kidney. On an unknown date, Sputum culture: normal flora (normal) Normal for flora and negative (Negative) Sputum and pharyngeal swab multiplex PCR was negative with the Seeplex RV15 Onestep ACE Detection assay kit (Seegene, Inc., Seoul, Republic of Korea) for adenovirus, coronavirus 229E/NL63, parainfluenza virus 1/2/3/4, bocavirus 1/2/3/4, enterovirus, influenza A/B virus, metapneumovirus, coronavirus OC43, respiratory syncytial viruses A/B, and human rhinovirus A/B/C.. On an unknown date, White blood cell count: 9,470 /µl 9,470 /µL. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter considered ACUTE RESPIRATORY DISTRESS SYNDROME (Vaccine-induced acute respiratory distress syndrome) to be related. Patient was reported to be of Japanese origin and patient did not have any allergies. Patient met the Berlin definition criteria for ARDS and the Brighton collaboration case definition for AR. Most recent FOLLOW-UP information incorporated above includes: Upon receipt of follow up on 15-Jun-2022, Case 4.1(b) is identified as duplicate of 4.1(b) Therefore all the information of 4.1(b) has been incorporated into 4.1(b) which will be retained for further follow up and case 4.1(b) will be deleted from the safety database. Upon receipt of follow up on 15-Jun-2022, Case 4.1(b) is identified as duplicate of 4.1(b) Therefore all the information of 4.1(b) has been incorporated into 4.1(b) which will be retained for further follow up and case 4.1(b) will be nullified from the safety database.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in a 72-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Hypertension and Diabetes. On 12-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 03-Oct-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 30-Mar-2022, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. Death occurred on 02-Apr-2022 The patient died on 02-Apr-2022. The cause of death was not reported. An autopsy was performed, but no results were provided. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not reported. Reported that on 02 Apr 2022 patient was found dead at home by his family. There was no trauma at the time of examination. The family questioned whether it was related to vaccination, so an autopsy was performed to determine the cause of his death. The patient complained that his heart was uncomfortable but not severe after being vaccinated on 30 Mar 2022. In the morning of 02 Apr 2022, his family members left home after leaving medication for his chronic diseases. When they returned home at noon, they found that the patient did not take medicine and had no respiration or heartbeat. On 07 Apr 2022 the patient was dissected. His family was informed to apply for VICP. The patient had a forensic autopsy on 07 Apr 2022. Treatment information was not provided. Company Comment: This regulatory authority case concerns a 72-year-old old, male patient with relevant medical history of Hypertension, and Diabetes mellitus who experienced the fatal, unexpected event of Death which occurred three days after receiving the third dose of mRNA-1273 vaccine. Patient complained of chest discomfort on the same day after vaccination. There was no information if patient sought medical consult. He was found dead at home three days after vaccination. The cause of death was not reported. Autopsy was performed but the findings were not provided. Patient´s advanced age and medical history remains as confounders for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness was assessed as per regulatory authority's report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Upon query received from business partner, non-significant correction was performed on 10-May-2022. The cause of death was updated to unknown cause of death.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue) and PYREXIA (Fever) in an 83-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Stroke (15 years) and Myocardial infarction (3 years ago). Concurrent medical conditions included Diabetes mellitus (15 years) and Hypertension (15 years). On 08-Apr-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 09-Apr-2022, the patient experienced FATIGUE (Fatigue) (seriousness criterion death) and PYREXIA (Fever) (seriousness criterion death). The patient was treated with

Case ID	Narrative (Complete)
	PARACETAMOL (PANADOL) on 09-Apr-2022 for Fever, at an unspecified dose and frequency. The patient died on 10-Apr-2022. The reported cause of death was Fever and Fatigue. An autopsy was not performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The patient ID in site was reported as 4.1(b) . Concomitant product use was not provided by the reporter. It was reported on 09-Apr-2022 that the patient had a fever on the next day of vaccination and took panadol and felt relieved. In the morning of April 10, patient looked tired and his family found his consciousness changed at noon and CPR was immediately performed and the patient was taken to Feng Yuan Hospital, but died before arrival. The follow-up outcome was done on 12-Apr-2022 that on April 11, his family went to the Health Center and applied for administrative examination. During the examination by the director of the center, his family mentioned that the patient received Dose 3 (Moderna) vaccine on April 8 and had a fever next day and took a tablet of panadol and felt relieved. In the morning of April 10, patient looked tired and his family found him not alright at noon. CPR was immediately performed and the patient was taken to hospital, but patient died anyway. The family wondered if it was caused by COVID-19 vaccination and wanted to report the adverse reaction of the vaccine and apply for drug injury relief. Patient was treated regularly in hospital. Therefore, the medical records of hospital in recent six months are attached. The family said there would be no autopsy and cremation was expected on April 23. On 11-Apr-2022 they brought the VICP application form home to fill out. The center will assist in reporting of vaccination injury relief. This patient was under continuous follow-ups. Company comment:This is a regulatory case concerning a 83-year-old male patient with medical history of Hypertension, Diabetes mellitus and Stroke 15 years ago, Myocardial infarction 3 years ago, who experienced the unexpected events of fatigue and pyrexia, which occurred the day after the 3rd dose of mRNA-1273 and led to death on the next day. It was reported that the day after the 3rd dose, he had fever, took Panadol and felt relieved. On the next day, he looked tired and his family found his consciousness changed at noon. CPR was immediately performed and the patient was taken to the Hospital, but he died before arrival. The reported cause of death was Fever and Fatigue. An autopsy was not performed. All the mentioned medical history and patient's age could be contributory factors to death. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 02-May-2022. The most recent information was received on 01-Jun-2022 and was forwarded to Moderna on 08-Jun-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, body temperature before the vaccination: 36.4 degrees Celsius. On 25-Apr-2022, at 15:50, the patient received the 3rd vaccination with this vaccine. On 26-Apr-2022, at 07:56, pyrexia of 39.3 degrees Celsius developed. The patient took one tablet of acetaminophen 300 mg. At 13:30, body temperature was 39.9 degrees Celsius, and malaise and chills were noted. The patient was unable to sit up for himself and assisted. The patient took one tablet of acetaminophen 300 mg. At 14:18, the patient wanted to urinate but had incontinence. At 14:55, a nurse bought water on behalf of the patient. The patient was unable to fill out the form and said thank you. At 17:47, the patient lay down prone in bed. The patient experienced apnoea, and cardiopulmonary resuscitation was performed. Thereafter, the patient died. The outcome of pyrexia, malaise, chills, inability to sit up for himself, and incontinence was unknown. The outcome of apnoea was reported as fatal. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of DEATH (brother passed away of unknown circumstances on 04Jan2022) in a 70-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. Death occurred on 04-Jan-2022 The patient died on 04-Jan-2022. The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant medications were provided by the reporter. No treatment information was provided by the reporter. It was reported that patient was now deceased who was in a Moderna Covid-19 vaccine clinical study in 2020. The trial was conducted by the Hackensack Medical Center. It was reported that the patient passed away due to unknown circumstances on 04Jan2022. The patient received a placebo injection in the study. After the trial ended, patient got unblinded and then received the Moderna Covid-19 vaccine. The reporter did not report any side effects or adverse reactions to Moderna Covid-19 vaccine. The reporter did not had dates of administration or lot numbers for the patient's Moderna Covid-19 vaccines. Deceased patient was listed as a contact in the case. On 05May2022 the reported answered the phone and said that he would try to call Moderna back with the information about vaccine lot numbers and dates of administration of the vaccine. Company comment: This Spontaneous case concerns a 70-year-old male patient, with no reported medical history, who had a serious, unexpected fatal outcome unspecified day, after receiving a dose of mRNA-1273 vaccine. Patient had passed away due to unknown circumstances and the cause of death was not reported. It is unknown if an autopsy was performed. The patient was reported to have been included in a clinical trial and have received a placebo injection while in the study. After the trial ended, the patient received a dose of mRNA-1273 vaccine on unknown date. Clinical course, circumstances surrounding the event and treatment details were not reported in this case. The benefit-risk relationship of mRNA-1273 is not affected by this report. This case was linked to 4.1(b) (Patient Link).
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 05-May-2022 and was forwarded to Moderna on 05-May-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of VACCINATION FAILURE (Failure of vaccination) in an 85-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3004234 and 3005834) for COVID-19 vaccination. The patient's past medical history included Cardiac failure, Stroke and Anaemia.

Case ID	Narrative (Complete)
	Concurrent medical conditions included Chronic obstructive airways disease, Hypertension arterial, Type 2 diabetes mellitus and Chronic renal failure. On 07-Sep-2021, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 2 dosage form. On 07-Oct-2021, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 2 dosage form. On 08-Feb-2022, the patient experienced VACCINATION FAILURE (Failure of vaccination) (seriousness criterion death). The patient died on 09-Apr-2022. The reported cause of death was epileptic seizure. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication were reported. No treatment information was provided by the reporter. Company Comment: This regulatory case concerns an 85-year-old female patient with medical history and concurrent conditions of Cardiac failure, Stroke, Anaemia, Chronic obstructive airways disease, Hypertension arterial, Type 2 diabetes mellitus and Chronic renal failure, who experienced the unexpected serious event of Vaccination failure approximately 4 months and 1 day after receiving second dose of mRNA-1273 vaccine that led to a fatal outcome. Patient died 6 months and 2 days after vaccination (2 months and 1 day from event onset) with cause of death reported as epileptic seizure. No autopsy was provided nor COVID-19 test reported. The interval between the first and second dose of mRNA-1273 vaccines was noted to be 30 days. The advanced age of the patient and the medical history and concurrent conditions of Cardiac failure, Stroke, Anaemia, Chronic obstructive airways disease, Hypertension arterial, Type 2 diabetes mellitus and Chronic renal failure could be considered as contributory factors to the event and fatal outcome. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report. This case was linked to 4.1(b) (E2B Linked Report).
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 06-May-2022. The most recent information was received on 06-May-2022 and was forwarded to Moderna on an unknown date. This regulatory authority case was reported by a consumer and describes the occurrence of INTERSTITIAL LUNG DISEASE (BREATHING EXCHANGES AT MAXIMUM LEVELS, UNCONSCIOUS STATE, PASSED AWAY ON THE MORNING OF 15/05/21 DUE TO INTERSTITIAL PNEUMONIA, MOLECULAR NEGATIVE COVID) and LOSS OF CONSCIOUSNESS (BREATHING EXCHANGES AT MAXIMUM LEVELS, UNCONSCIOUS STATE, PASSED AWAY ON THE MORNING OF 15/05/21 DUE TO INTERSTITIAL PNEUMONIA, MOLECULAR NEGATIVE COVID) in a 77-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3001655 / 3002186) for COVID-19 vaccination. No Medical History information was reported. On 11-May-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 14-May-2021, the patient experienced INTERSTITIAL LUNG DISEASE (BREATHING EXCHANGES AT MAXIMUM LEVELS, UNCONSCIOUS STATE, PASSED AWAY ON THE MORNING OF 15/05/21 DUE TO INTERSTITIAL PNEUMONIA, MOLECULAR NEGATIVE COVID) (seriousness criterion death) and LOSS OF CONSCIOUSNESS (BREATHING EXCHANGES AT MAXIMUM LEVELS, UNCONSCIOUS STATE, PASSED AWAY ON THE MORNING OF 15/05/21 DUE TO INTERSTITIAL PNEUMONIA, MOLECULAR NEGATIVE COVID) (seriousness criterion death). The patient was treated with RABEPRAZOLE for Adverse event, at a dose of 1 dosage form; CICLOSPORIN (CYCLOSPORIN) for Adverse event, at a dose of 1 dosage form; PREGABALIN for Adverse event, at a dose of 1 dosage form; NALOXONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE (TARGIN) for Adverse event, at a dose of 1 dosage form; FUROSEMIDE (LASIX [FUROSEMIDE]) for Adverse event, at a dose of 1 dosage form; FOLIC ACID (FOLINA [FOLIC ACID]) for Adverse event, at a dose of 1 dosage form; ALLOPURINOL for Adverse event, at a dose of 1 dosage form; FERROUS SULFATE (TARDYFER) for Adverse event, at a dose of 1 dosage form; ZOLPIDEM TARTRATE (STILNOX) for Adverse event, at a dose of 1 dosage form; MIRTAZAPINE for Adverse event, at a dose of 1 dosage form; CANRENONE (LUVION [CANRENONE]) for Adverse event, at a dose of 1 dosage form and BETAMETHASONE SODIUM PHOSPHATE (BENTELAN) for Adverse event, at a dose of 1 dosage form. The reported cause of death was breathing exchanges at maximum levels, unconscious state, passed away on the morning of 15/05/21 due to interstitial pneumonia, molecular negative covid. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Negative. Concomitant medications were not reported. Treatment medication included CLARITROMOCINA. Company comment: This fatal regulatory authority case concerns a 77-year-old male patient, with no medical history reported, who experienced the unexpected, serious (due to death) events of Interstitial lung disease and Loss of consciousness, 3 days after an unspecified dose of mRNA-1273. He died on the following day the symptoms developed. A molecular COVID test was negative on an unknown date. The reported cause of death was interstitial pneumonia. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 06-May-2022: Non Significant Follow Up document received on 06-May-2022 contains NNI (Non new information) On 06-May-2022: Significant correction was performed on 12-May-2022. Cause of death and lab data were added.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of VOMITING (Vomit) and DECREASED APPETITE (Inappetence) in a 75-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 25-Sep-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 01-Oct-2021, the patient experienced VOMITING (Vomit) (seriousness criterion death) and DECREASED APPETITE (Inappetence) (seriousness criterion death). The patient died on 16-Feb-2022. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. The worldwide UID was reported as 4.1(b) [redacted]. No concomitant medication information was provided. The patient daughter said that the patient had inappetence and vomiting within 5 days after vaccination of MOD-2 on October 1, 2021. The patient came to China Medical University Hospital (Hsinchu Branch) and doctors there did not find any problem. Therefore, she went to Linkou Chang-Geng Memorial Hospital on October 24, 2021, and had surgery twice. On 16 Feb 2022, the patient died. No treatment medication was provided. Company comment: This regulatory case concerns a 75-year-old female patient with no medical history reported who experienced the unexpected fatal events of Vomiting and Decreased appetite which occurred approximately 6 days after second dose of mRNA-1273 Vaccine. Patient underwent surgery (details unknown) 2 times. Patient dies approximately 5 months after the vaccination. Primary cause or death has not been specified and it is unknown whether an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness of the events retained as per Regulatory Authority reporting.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of FATIGUE (Fatigue), HEADACHE (Headache) and VOMITING (Vomit) in a 70-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 10-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 02-Oct-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 28-Jan-2022, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 07-Feb-2022, the patient experienced FATIGUE (Fatigue) (seriousness criterion death), HEADACHE (Headache) (seriousness criterion death) and VOMITING (Vomit) (seriousness criterion death). It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 10-Feb-2022, Computerised tomogram: lung tumors were found (abnormal) lung tumors were found. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication information was provided. The worldwide UID was reported as 4.1(b) [redacted]. Family reported a case of suspected COVID-19 vaccine related adverse reaction (death). His family said the patient had no chronic diseases. The patient had no discomfort after the first two doses. He had dizziness, chest distress, palpitations, joint pain, and other symptoms 5 days after vaccination. Later, he could not eat or walk steadily. On 07-Feb-2022, because the symptoms did not improve and he had urination issues, the patient came to Yuanlin Christian Hospital's ER for medical attention and returned home after examinations. On 09-Feb-2022, the symptoms remained, and he started to vomit. On 10-Feb-2022, the patient was sent to Changhua Christian Hospital's ER and his lung tumors were found in CT. The patient was immediately admitted and diagnosed as terminal adenocarcinoma of lung. Company comment: This regulatory case concerns a 70-year-old male patient with no medical history reported, who experienced the unexpected serious (death) events Fatigue, Headache, and Vomiting, 5 days after the third dose of mRNA-1273 vaccine (booster dose). The patient experienced, dizziness, chest distress, palpitations, and joint pain. Since the symptoms did not subside, he was taken to an ER. He also had urination symptoms and was shifted to another hospital. The symptoms remained and he also developed vomiting. A CT scan revealed lung tumours and he was diagnosed as having terminal Adenocarcinoma of lung. The patient died approximately a month later. An autopsy was not performed. Advanced age of the patient could be a risk factor and Adenocarcinoma of lung could be a confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of PULMONARY EMBOLISM (Acute pulmonary embolism) in a 95-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Hypertension and Dementia. On 15-Apr-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 16-Apr-2022, the patient experienced PULMONARY EMBOLISM (Acute pulmonary embolism) (seriousness criteria death and hospitalization). The patient was hospitalized on 18-Apr-2022 due to PULMONARY EMBOLISM. The patient was treated with ENOXAPARIN for Pulmonary embolism, at an unspecified dose and frequency; DOPAMINE for Pulmonary embolism, at an unspecified dose and frequency; CEFEPIME for Pulmonary embolism, at an unspecified dose and frequency and TEICOPLANIN for Pulmonary embolism, at an unspecified dose and frequency. The patient died on 18-Apr-2022. The reported cause of death was acute pulmonary embolism. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In April 2022, Angiogram: showed filling defects mainly in right main and ri showed filling defects mainly in right main and right lower lobar artery, suggesting pulmonary thromboemobolism & patchy consolidation in bilateral lower lobes. In April 2022, Blood creatine: 2.5 2.5 mg/dL. In April 2022, Blood gases abnormal: hypoxemia and metabolic acidosis in abg hypoxemia and metabolic acidosis in ABG. In April 2022, Blood pressure measurement: 98/50 98/50 mmHg. In April 2022, Blood urea: 44 44 mg/dL. In April 2022, Body temperature: 34.8 34.8 degree C. In April 2022, C-reactive protein: elevated elevated CRP.

Case ID	Narrative (Complete)
	In April 2022, Chest X-ray: cardiomegaly, rll consolidation Cardiomegaly, RLL consolidation. In April 2022, Electrocardiogram: junctional bradycardia Junctional bradycardia. In April 2022, Haemoglobin: 9.6 anemia (Hb: 9.6 g/dL). In April 2022, Heart rate: 48 48/min. In April 2022, Laboratory test: the lab data showed hyperglycemia, hyponatremia, h (abnormal) The lab data showed hyperglycemia, hyponatremia, hyperkalemia.. In April 2022, Oxygen saturation: 76 76%. In April 2022, Respiratory rate: 18 18/min. In April 2022, Urine analysis: pyuria with bacteria in u/a pyuria with bacteria in U/A. On 16-Apr-2022, Computerised tomogram: 1.filling defects mainly in right main and right l 1.Filling defects mainly in right main and right lower lobar artery, suggesting pulmonary thromboembolism. 2.Patchy consolidation in bilateral lower lobes, favoring inflammation.. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication provided by the reporter. On 16-Apr-2022, the patient came to hospital's ER for medical advice. Patient had a chief complaint of Gasping for breath and was partially dependent ADL. Was presented with shortness of breath in recent 2 days and was just vaccinated Moderna 2 days ago. Patient was presented with generalized weakness, night sweats, fatigue, poor appetite, and poor responsiveness and had no fever, chills, cold sweats, weight loss, skin rash, loss of consciousness, headache, dizziness, fainting, chest pain, palpitations, cough, sputum, hemoptysis, abdominal pain, nausea, vomiting, diarrhea, tarry or bloody stool, bowel, or bladder incontinence, decreased urine amount, urinary symptoms, flank pain, neck or back pain. Thus, patient was brought to ER. Due to acute pulmonary embolism, right main and right lower lobar artery, massive, PESI 165, class V, complicated with pulmonary infarction, pneumonia, and septic shock, admitted to ICU for further evaluation and management. On 18-April-2022 the patient was admitted due to acute pulmonary embolism, right main and right lower lobar artery, massive, PESI165, class V, complicated with pulmonary infarction, pneumonia, and septic shock. During hospitalization, vital signs was monitored regularly, arranged serial of examination, administered anticoagulant (enoxaparin), administered dopamine, and administered empiric antibiotics (cefepime, teicoplanin). The clinical symptoms were still deteriorated. She presented with acute respiratory failure and junctional bradycardia. The patient's families of related medical information, poor prognosis of acute pulmonary embolism and pneumonia with sepsis (septic shock, acute respiratory failure, multiple organ dysfunction syndrome, even death), and her families understood and accepted. They kept DNR, Do-Not-Attempt-Resuscitation (DNAR), Do-Not-Intubate (DNI), Do-Not-Defibrillate and Do-Not-Dialyse. The patient expired at 05:43 on 18-Apr-2022. The Worldwide UID was reported as 4.1(b) [redacted]. Company comment: This regulatory authority case concerns a 95 years old female patient with no relevant medical history reported, who experienced the unexpected fatal serious (seriousness criterion hospitalization) AESI event of pulmonary embolism, which occurred one day after third dose of mRNA-1273 vaccine. It is reported that patient went to emergency with 2 days history of shortness of breath, initial vital are Temperature: 34.8°C; Pulse: 48/min; RR: 18/min; BP: 98/50 mmHg, SpO2 76%. The lab data showed anemia (Hb: 9.6 g/dL), hyperglycemia, hyponatremia, hyperkalemia, renal impairment (BUN: 44 mg/dL, Cr.: 2.5 mg/dL), elevated CRP, hypoxemia and metabolic acidosis in ABG and pyuria with bacteria in urine and EKG showed junctional bradycardia. The CXR showed cardiomegaly, Right lower lobe consolidation. The CTA showed filling defects mainly in right main and right lower lobar artery, suggesting pulmonary thromboemobolism & patchy consolidation in bilateral lower lobes, patient also diagnosed with pulmonary infarction, pneumonia and septic shock, she was admitted to ICU for further evaluation and management, treated with anticoagulant (enoxaparin),dopamine and empiric antibiotics (cefepime, teicoplanin). Patient continue to deteriorate, went into acute respiratory failure and junctional bradycardia. Informed the patient's families members regarding poor prognosis, They kept DNR, Do-Not-Attempt-Resuscitation (DNAR), Do-Not-Intubate (DNI), Do-Not-Defibrillate and Do-Not-Dialyse. Patient died on 18-Apr-2022.Reported cause of death was acute pulmonary embolism. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. The event was assessed as serious as per Regulatory Authority´s report.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of THROMBOCYTOPENIA (Thrombocytopenia) in a 65-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 17-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 13-Apr-2022, the patient experienced THROMBOCYTOPENIA (Thrombocytopenia) (seriousness criteria death, hospitalization and medically significant). The patient was treated with METHYLPREDNISOLONE (MEPRON [METHYLPREDNISOLONE]) at a dose of 40 milligram and NYSTATIN (MYCOSTATIN) for Prophylaxis, at a dose of 4 milliliter four times per day. The patient died on 16-Apr-2022. The reported cause of death was Thrombocytopenia. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 13-Apr-2022, Chest X-ray: bilateral lung infiltration bilateral lung infiltration. On 13-Apr-2022, Platelet count decreased: 5000 5000 u/L. On 15-Apr-2022, Computerised tomogram: suspected pulmonary hemorrhage suspected pulmonary hemorrhage. On 16-Apr-2022, Chest X-ray: bilateral pulmonary infiltration bilateral pulmonary infiltration (suspected being caused by bleeding).. On 16-Apr-2022, Oxygen saturation: 99 99 % in the early hours of the morning., 67 67 % in the afternoon although it recovered to 94-95% after treatment.t and 70-73 70-73 dropped again in the evening (22:02).. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were reported. On 13-Apr-2022 patient went to ER in the hospital and described symptoms such as hematuria, systemic punctured petechiae, left eye bulbar hemorrhage, bruising and blisters in her tongue, without bloody stools or neurological symptoms. Patient was conscious when arrived at the hospital. Therefore, she received emergency blood transfusion with PH 2U and was hospitalized for observation. During hospitalization of April 14-15, 2022, another PLT 2U was transfused. On 15-Apr-22, IVIG 1 mg/kg/day was also given as the platelet value did not rise back.

Case ID	Narrative (Complete)
	On 16-April-22, In the early hours of the morning, the patient's oxygen demand increased, and NRM oxygen therapy (3 mL/min to 15 mL/min) was given. The patient coughed up blood, was restless, and said that could not get oxygen, so patient was hoped to remove the oxygen mask. After the doctor explained to the family the condition (blood pressure and heartbeat would slow down after the mask was removed), the family agreed to remove the oxygen mask and the patient was expired at 23:17. On 21-Apr-22, A phone call was made to the patient's son and informed about the vaccination relief process. The worldwide UID was reported as 4.1(b) . Company Comment - This case concerns a 65-year-old, female patient, with no relevant medical history who experienced the unexpected serious, fatal AESI event Thrombocytopenia (seriousness criteria hospitalization, death and medically significant) which occurred 2 months 28 days after the third dose of mRNA1273vaccine. The patient was treated with METHYLPREDNISOLONE (MEPRON [METHYLPREDNISOLONE]) at a dose of 40 milligram and NYSTATIN (MYCOSTATIN) for Prophylaxis, at a dose of 4 milliliter four times per day. The patient died on 16-Apr-2022. The reported cause of death was Thrombocytopenia. The investigation done between 13-16 -Apr-2022 revealed, Chest X-ray with bilateral lung infiltration, Platelet count decreased was 5000 u/Computerized tomogram with suspected pulmonary hemorrhage, Chest X-ray with bilateral pulmonary infiltration (suspected being caused by bleeding) and Oxygen saturation was 99 99 % in the early hours of the morning, 67 % in the afternoon although it recovered to 94-95% after treatment and 70-73 % dropped again in the evening. It is unknown if an autopsy was performed. The benefit-risk relationship of the vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in a 69-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048M21A_1110504) for COVID-19 vaccination. No Medical History information was reported. On 11-Apr-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on 11-Apr-2022 The patient died on 11-Apr-2022. The cause of death was not reported. An autopsy was not performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. The Worldwide UID was reported as 4.1(b) . April 19, 2022: Patient's daughter said patient had dyspnea in the evening after being vaccinated with Dose 3 (Moderna) vaccine on April 11, 2022. When the ambulance arrived, it was too late to rescue patient so patient was not sent to hospital. No concomitant medication was reported. No treatment information was provided. Company comment. This fatal regulatory case concerns a 69 – year – old, male patient with no medical history reported, who experienced the unexpected, serious event of death. The event occurred the same day after the administration of a dose of mRNA-1273 vaccine, reported as third dose of his COVID – 19 immunization schedules. The report stated that the patient experienced dyspnea in the evening after being vaccinated, and when the ambulance arrived the patient had died. The cause of death was unknown. Autopsy was not performed. No further details were provided for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Non-Significant correction was performed on 12-May-2022. Updated date of death to 11-Apr-2022.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 06-May-2022 and was forwarded to Moderna on 06-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (cause of death unknown) in an 80-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004962) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Prophylactic vaccination: Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax on 15-May-2021 and Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax on 26-Jun-2021. Past adverse reactions to the above products included No adverse event with Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax and Spikevax COVID-19 mRNA Vaccine (nucleoside modified)COVID-19 Vaccine Moderna dispersion for injectionSpykeVax. On 15-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. On 16-Dec-2021, the patient experienced INFLUENZA (Persistent fatigue, tiredness, persistent feeling of illness). The patient died on 22-Apr-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, INFLUENZA (Persistent fatigue, tiredness, persistent feeling of illness) had not resolved. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. Concomitant products were not provided. Treatment medication was not reported. The patient had no old age diseases and no long-term medication. Senders comment: Are you or the person concerned aware of allergies? If yes, which one? No Information on risk factors or pre-existing conditions Absolutely none! /An increasing feeling of illness with each vaccination, especially after the 3rd vaccination. Fell at home and died without warning on 22.04.2022. No old age diseases, none long-term medication.

Case ID	Narrative (Complete)
	Company Comment: This regulatory case concerns an 80-year-old, female patient with past drug history of administration of two doses of Spikevax (Moderna mRNA-1273 vaccine), who experienced the unexpected, serious event of death and the unexpected, non-serious event of influenza (persistent fatigue, tiredness, persistent feeling of illness). The event influenza occurred 1 day after receiving the third dose of the mRNA-1273 vaccine. The event death occurred approximately 4 months after receiving the third dose of the mRNA-1273 vaccine. It was reported that the patient experienced an increasing feeling of illness after each vaccination, especially after receiving the third dose. Treatment information was not provided. The event influenza had not resolved and no further details were provided until approximately 4 months after vaccination, it was reported that the patient fell at home and 'died without warning' on 22Apr2022. The cause of death was unknown. It is also unknown if an autopsy was performed. The history of administration of two doses of Spikevax (Moderna mRNA-1273 vaccine) remains a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of NAUSEA (Nausea), VOMITING (Vomit) and VACCINATION SITE PAIN (Pain at inoculation site) in an 86-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048M21A_1110509-CDC) for COVID-19 vaccination. No Medical History information was reported. On 20-Apr-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 milliliter. On 22-Apr-2022, the patient experienced NAUSEA (Nausea) (seriousness criterion death), VOMITING (Vomit) (seriousness criterion death) and VACCINATION SITE PAIN (Pain at inoculation site) (seriousness criterion death). The patient died on 22-Apr-2022. The reported cause of death was Nausea, vomit and pain at inoculation site. An autopsy was not performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Relevant concomitant medications were not reported. The patient received first dose of Moderna COVID-19 vaccine on 20-Apr-2022 and no discomfort on that day. On 21-Apr-2022, In the morning, the inoculation site began to swell, and in the evening, her face began to swell. On 22-Apr-2022, she experienced nausea and vomiting in the morning and fell down. On 22-Apr-2022, the patient was died. On 22-Apr-2022, The family wants to apply for VICP (picked up application form the health center). However, they were still considering whether to allow the autopsy (indicating that it must be discussed again) and were awaiting the judicial examination. Treatment information was not provided. Worldwide UID is reported as 4.1(b) [redacted] Company Comment: This is a Regulatory Authority case concerning an 86-year-old female patient, with no medical history reported, who experienced the unexpected and fatal events of Nausea, Vomiting and Vaccination site pain. Fatal events and patient´s death occurred 2 days after the first dose of mRNA-1273 vaccine. It was also reported that one day after vaccination the inoculation site and patient´s face began to swell. The reported cause of death was nausea, vomit and pain at inoculation site. An autopsy was not performed. Patient´s elderly age could be a confounder for fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] on 06-May-2022 and was forwarded to Moderna on 06-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of MALNUTRITION (Prolonged nutrient deficiency), CARDIAC ARREST (Advanced age with concomitant cardiac arrest), MOBILITY DECREASED (Inferior mobility), DECREASED APPETITE (Do not want to eat, do not drink), PERSONALITY CHANGE (Personality-changed (dropped a little of his good temper and mischievousness)), COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine), FATIGUE (Wearers and need to bed earlier, just want to sleep), GENERAL PHYSICAL HEALTH DETERIORATION (Tackled by) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiorgan failure) in a 94-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 016G21A) for COVID-19 vaccination. Co-suspect products included non-company products INFLUENZA VACCINE INACT SPLIT 4V (EFLUELDA) for an unknown indication, TOZINAMERAN (COMIRNATY) for an unknown indication and TOZINAMERAN (COMIRNATY) for an unknown indication. The patient's past medical history included Arm fracture, Colon cancer and Diarrhoea (as an allergic reaction after a penicillin cure after urinary tract infections.). Concurrent medical conditions included Penicillin allergy and Angina pectoris. On 04-Jun-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 21-Jul-2021, the patient received second dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 04-Nov-2021, the patient received dose of INFLUENZA VACCINE INACT SPLIT 4V (EFLUELDA) (unknown route) .7 milliliter. On 28-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. In 2021, the patient experienced FATIGUE (Wearers and need to bed earlier, just want to sleep) (seriousness criteria death and medically significant). In December 2021, the patient experienced MOBILITY DECREASED (Inferior mobility) (seriousness criteria death and medically significant), DECREASED APPETITE (Do not want to eat, do not drink) (seriousness criteria death and medically significant), PERSONALITY CHANGE (Personality-changed (dropped a little of his good temper and mischievousness)) (seriousness criteria death and medically significant) and GENERAL PHYSICAL HEALTH DETERIORATION (Tackled by) (seriousness criteria death and medically significant). On 28-Dec-2021, the patient experienced COVID-19 IMMUNISATION (Revaccination with different covid-19 vaccine) (seriousness criteria death and medically significant). On an unknown date, the patient experienced MALNUTRITION (Prolonged nutrient deficiency) (seriousness criteria death and medically significant), CARDIAC ARREST (Advanced age with concomitant cardiac arrest) (seriousness criteria death and medically significant) and MULTIPLE ORGAN DYSFUNCTION SYNDROME (Multiorgan failure) (seriousness criteria death and medically significant). The patient died on 15-Jan-2022. The reported cause of death was Unspecified nutritional deficiency, Cardiac arrest and Multi organ failure. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Spikevax) (Unknown) was unknown. No concomitant medications were provided. No treatment information was provided.

Case ID	Narrative (Complete)
	COMPANY COMMNET: This regulatory authority case concerns a 94 years old female patient with relevant past medical history of colon cancer, who experienced unexpected fatal serious events of malnutrition, cardiac arrest, mobility decreased, decreased appetite, personality change, fatigue, general physical health deterioration, multiple organ dysfunction, which occurred unspecified days after third dose of mRNA-1273 vaccine. Additionally Covid-19 immunization is also reported. The patient was noted to have received two doses with COMINARTY 5 months 7 days prior to mRNA-1273 (Interchange of vaccine products). Patient died on 15-Jan-2022. Reported cause of death was Unspecified nutritional deficiency, Cardiac arrest and Multi organ failure. It is unknown if an autopsy was performed. past medical history of colon cancer remains as confounding for the events malnutrition, decreased appetite, fatigue. The benefit-risk relationship of mRNA-1273 is not affected by this report. The event was assessed as serious as per Regulatory Authority´s report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 06-May-2022. The most recent information was received on 16-May-2022 and was forwarded to Moderna on 16-May-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of CORONARY ARTERY DISEASE (Coronary artery disease) in an 85-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 216035) for COVID-19 vaccination. No Medical History information was reported. On 14-Apr-2022, the patient received fourth dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. In April 2022, the patient experienced CORONARY ARTERY DISEASE (Coronary artery disease) (seriousness criterion death). The patient died on 16-Apr-2022. The reported cause of death was Coronary artery disease. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No concomitant products were reported. No treatment drugs were reported This is a regulatory, fatal, case concerning an 85-year-old male patient with no reported medical history, who experienced the unexpected serious (fatal) event of CORONARY ARTERY DISEASE which occurred on an unknown date after receiving the fourth dose of mRNA-1273 Vaccine. The patient died on April 2022. The cause of death was not reported. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 16-May-2022: Significant follow-up received: Event found death was deleted and new event Coronary artery disease was added. Patient age and date of death updated
4.1(b)	This regulatory authority case was reported by a physician and describes the occurrence of DYSPNOEA (Acute dyspnea), SUDDEN DEATH (Sudden death unexplained) and CARDIAC ARREST (Heart arrest) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005696) for COVID-19 vaccination. Patient received first three vaccinations with Comirnaty. On 07-Apr-2022, the patient received fourth dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 10-Apr-2022, the patient experienced DYSPNOEA (Acute dyspnea) (seriousness criterion death), SUDDEN DEATH (Sudden death unexplained) (seriousness criterion death) and CARDIAC ARREST (Heart arrest) (seriousness criterion death). The patient died on 10-Apr-2022. The reported cause of death was no resuscitation. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not provided. Treatment information was not provided. Company Comment: This regulatory case concerns an 80-year-old, male patient with past drug history of administration of three doses of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine), who experienced the unexpected, serious (fatal) events of dyspnoea (acute dyspnea), cardiac arrest and sudden death (sudden death unexplained). The events occurred 3 days after receiving a dose (second booster dose) of the mRNA-1273 vaccine. The patient expired on 10Apr2022 (3 days after vaccination). It was reported that there was 'no resuscitation' and the reported cause of death was sudden, unexplained death. No further details were provided. It is unknown if an autopsy was performed. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 06-May-2022 and was forwarded to Moderna on 06-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of PULMONARY OEDEMA (Lung edema) and PULMONARY EMBOLISM (Pulmonary embolism) in an 85-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 092F3AA) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 08-Apr-2021 and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca on 01-Jul-2021. Past adverse reactions to the above products included No adverse event with Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca and Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca. On 18-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Dec-2021, the patient experienced PULMONARY OEDEMA (Lung edema) (seriousness criterion death) and PULMONARY EMBOLISM (Pulmonary embolism) (seriousness criterion death). The patient died on 21-Dec-2021. The reported cause of death was Lung embolism. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medications were provided. No treatment medications were reported. Company comment: This is a regulatory authority case concerning a 85-year-old, male patient with no reported medical history and with vaccine history of receiving 2 doses of Covid-19 ChAdOx1-S (recombinant), who experienced the unexpected serious (death according to regulatory authority) AESI events of pulmonary edema and pulmonary embolism. The events occurred the same day with the booster dose of mRNA-1273 vaccine administration. The patient died approximately 3 days after the booster dose of mRNA-1273 vaccine administration. The reported cause of death is pulmonary embolism. It is unknown if autopsy was performed. No other information surrounding the events was reported. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 10-May-2022 and was forwarded to Moderna on 10-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of AORTIC DISSECTION (AORTITIS SECTION), COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) and PULMONARY EMBOLISM (LUNG EMBOLISM) in a 75-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3003659) for COVID-19 vaccination. The patient's past medical history included COVID-19 immunisation (Vaxzevria dose 2) on 14-Jul-2021, Pulmonary embolism, COVID-19 immunisation (Vaxzevria dose 1) on 27-Apr-2021 and Stroke. Concurrent medical conditions included Oxygen therapy, Muscle weakness left-sided, Respiratory insufficiency and Hypertension. On 27-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Feb-2022, after starting mRNA-1273 (Spikevax), the patient experienced PULMONARY EMBOLISM (LUNG EMBOLISM) (seriousness criterion death). On 06-Feb-2022, the patient experienced AORTIC DISSECTION (AORTITIS SECTION) (seriousness criterion death). On an unknown date, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) (seriousness criterion death). The patient died on 06-Feb-2022. The reported cause of death was 10037377 and 10002895. An autopsy was performed. The autopsy-determined cause of death was Aortic dissection and Pulmonary embolism. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication reported. No treatment medication reported. Company comment: This regulatory authority case concerns a 75-year-old male patient with Concurrent medical conditions of Oxygen therapy, Muscle weakness left-sided, Respiratory insufficiency and Hypertension, who experienced the unexpected serious events of Aortic dissection and Pulmonary embolism (AESI) (seriousness criteria Death) which occurred 9 days after the third dose of mRNA-1273 vaccine. COVID-19 immunisation was reported as additional event as patient received doses with Vaxzevria 9 months prior to current vaccination (inter change of vaccine product).The patient died on 06-Feb-2022. An autopsy was performed. The autopsy-determined cause of death was Aortic dissection and Pulmonary embolism. Patient’s Concurrent medical conditions of Oxygen therapy, Muscle weakness left-sided, Respiratory insufficiency and Hypertension remains a confounder.The benefit-risk relationship of mRNA-1273 is not affected by this report. Seriousness assessment has been retained as per Regulatory Authority reporting.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 09-May-2022 and was forwarded to Moderna on 09-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of ASTHENIA (Strength loss of), DEMENTIA ALZHEIMER'S TYPE (Alzheimer's disease), ASPIRATION (Aspiration), DYSPHAGIA (Dysphagia), DYSARTHRIA (Dysarthria), ATONIC SEIZURES (Drop seizures), DYSPNOEA (Dyspnoea), QUADRIPLEGIA (Tetraplegia) and PALLIATIVE CARE (Palliative care) in an 88-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for Prophylactic vaccination. The patient's past medical history included Depressive episode. Concurrent medical conditions included Polyneuropathy in 2014, Hyperlipoproteinemia and Arterial hypertension. On 16-Mar-2021, the patient received first dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 19-Apr-2021, received second dose of TOZINAMERAN (COMIRNATY) (unknown route) dosage was changed to 2 dosage form. On 09-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 05-Jan-2022, the patient experienced ASTHENIA (Strength loss of) (seriousness criteria death, hospitalization and life threatening), DEMENTIA ALZHEIMER'S TYPE (Alzheimer's disease) (seriousness criteria death, hospitalization and life threatening), ASPIRATION (Aspiration) (seriousness criteria death, hospitalization and life threatening), DYSPHAGIA (Dysphagia) (seriousness criteria death, hospitalization and life threatening), DYSARTHRIA (Dysarthria) (seriousness criteria death, hospitalization and life threatening), ATONIC SEIZURES (Drop seizures) (seriousness criteria death, hospitalization and life threatening) and DYSPNOEA (Dyspnoea) (seriousness criteria death, hospitalization and life threatening). On 04-Mar-2022, the patient experienced QUADRIPLEGIA (Tetraplegia) (seriousness criteria death, hospitalization and life threatening). On 21-Apr-2022, the patient experienced PALLIATIVE CARE (Palliative care) (seriousness criteria death, hospitalization and life threatening). The patient died on 27-Apr-2022. The reported cause of death was progression of alzheimer's disease. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant product use was provided. No treatment medication was provided. Company Comment: This regulatory case concerns an 88-year-old, female patient with pre-existing arterial hypertension, polyneuropathy and hyperlipoproteinemia, who experienced the unexpected, serious (fatal, life-threatening, hospitalized) events of Dementia Alzheimer's type, along with the

Case ID	Narrative (Complete)
	AESI Atonic seizures, events Dysarthria, Dysphagia, Aspiration, Dyspnoea, Asthenia, and with Quadriplegia. Palliative care was reported as an additional event which was provided to the patient during the last week of life. The events of dementia Alzheimer's type, dysarthria, dysphagia, aspiration, dyspnoea and asthenia occurred approximately a month after receiving mRNA-1273, given as booster dose; while quadriplegia started 3 months post-vaccination. The patient also received Tozinameran COVID-19 vaccine as primary series approximately 8 months prior to mRNA-1273. Course during hospital stay, diagnostic procedures conducted and treatment details were not provided in the case. The patient died 4.5 months after receiving mRNA-1273, with progression of Alzheimer's disease as reported cause of death. It is unknown if autopsy was performed. The patient's hypertension and hyperlipoproteinemia could be risk factors to the occurrence of a cerebrovascular event which in turn, could be a confounder to the dysarthria, dysphagia, aspiration, dyspnoea, asthenia and quadriplegia; while polyneuropathy could be a confounder to dysphagia, dyspnoea and asthenia. Additionally, the patient's hypertension could have contributed to a faster progression of Alzheimer's. Quadriplegia, asthenia, dysphagia and dysarthria can be clinical presentations in late-stage Alzheimer's. Tozinameran vaccine was also cited as co-suspect in this case. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
4.1(b) [redacted]	This spontaneous case was reported by a consumer and describes the occurrence of DEATH (she passed /death), PULMONARY MASS (mass on her lungs), METASTASES TO CENTRAL NERVOUS SYSTEM (lesion in the lungs metastasized to the brain / mass on her brain), THROMBOSIS (blood clots in the shin to the hip), HERPES ZOSTER (Shingles developed and the lesions were found on her left upper arm, shoulder and spread to her chest and back left upper shoulder) and COVID-19 (Covid-19 after 2 doses of the vaccine) in a 75-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 037B21A and 006B21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Latex allergy. On 17-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 17-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. In March 2021, the patient experienced INJECTION SITE PAIN (sore arm at the injection site for a day or two). In 2021, the patient experienced PULMONARY MASS (mass on her lungs) (seriousness criteria hospitalization and medically significant), METASTASES TO CENTRAL NERVOUS SYSTEM (lesion in the lungs metastasized to the brain / mass on her brain) (seriousness criteria hospitalization and medically significant), THROMBOSIS (blood clots in the shin to the hip) (seriousness criteria hospitalization and medically significant), HERPES ZOSTER (Shingles developed and the lesions were found on her left upper arm, shoulder and spread to her chest and back left upper shoulder) (seriousness criterion medically significant) and PAIN (a lot of pain from the lesions of the shingles). In February 2022, the patient experienced COVID-19 (Covid-19 after 2 doses of the vaccine) (seriousness criterion medically significant) and DRUG INEFFECTIVE (Covid-19 after 2 doses of the vaccine). The patient was treated with VALACYCLOVIR [VALACICLOVIR] for Shingles, at an unspecified dose and frequency. The patient died on 23-Mar-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, PULMONARY MASS (mass on her lungs), METASTASES TO CENTRAL NERVOUS SYSTEM (lesion in the lungs metastasized to the brain / mass on her brain), THROMBOSIS (blood clots in the shin to the hip), HERPES ZOSTER (Shingles developed and the lesions were found on her left upper arm, shoulder and spread to her chest and back left upper shoulder), COVID-19 (Covid-19 after 2 doses of the vaccine), DRUG INEFFECTIVE (Covid-19 after 2 doses of the vaccine), PAIN (a lot of pain from the lesions of the shingles) and INJECTION SITE PAIN (sore arm at the injection site for a day or two) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. It was reported that all hell broke loose after the 2nd dose. Caller reported that her bother who lived on and off with their mother noticed that she was having several falls. Her sister also noticed that when she spoke with her on the phone she was not making sense, could not complete her sentences, could not remember things, would mumble and not speak clearly and they were surprised because she was a very sharp lady. Everyone suspected that she might have a stroke. Her mother withheld this information from her until one day in Jul2021, she fell and no one was around to help her. Caller had to call the police to do a welfare check on her and they found her lying on the bathroom floor. She was taken to the hospital where they found a mass on her brain and her lungs. They were told that the mass needed to be removed immediately. They moved her to another state where caller would be able to take care of her. She was prescribed with Valacyclovir for Shingles developed around that time. The lesions on her left upper arm, shoulder and spread to her chest and back left upper shoulde were eventually scabbed over but she was still in a lot of pain. Brain surgery was done in another hospital. They were told that the lesion was from the mass in her lungs and it had metastasized to the brain. She underwent radiation after the brain surgery. This was somewhere in Sep2021 or Oct2021. She was hospitalized 3 more times due to blood clots that were seen on her shin to the hip. The patient spent more days in various hospitals than out after getting the 2nd dose of the vaccine. She did not have any concomitant vaccination with the Covid-19 vaccine. She contracted Covid-19 approximately 6 weeks (feb2022) before she passed on 23Mar2022 in a hospice across the hospital where she was confined last. No concomitant product use was provided by the reporter. Company comment- This spontaneous case concerns a 75-year-old female patient with no relevant medical history, who experienced Fatal, unexpected, serious (Hospitalization) events of Pulmonary mass, Metastases to brain, unexpected, serious (Medically significant) event of Herpes zoster and unexpected, serious (Hospitalization, Medically significant) adverse event of special interest Thrombosis and unexpected, serious (Medically significant) adverse event of special interest Covid-19. After getting the 2nd dose of vaccination, the patient complained that she could not walk and talk. She was noted to have several falls, was not making sense when she speaks, could not complete her sentences, and could not remember things. She would mumble and could not speak clearly. In July 2021, the patient fell, and no one was around to help her. She was found lying on the bathroom floor. She was taken to the hospital where they found a mass on her brain and lungs. They were told that the mass needed to be removed immediately. Shingles developed around this time. It was severe and the lesions were found on her left upper arm, shoulder and spread to her chest and back left upper shoulder. She was prescribed with Valacyclovir, and it eventually scabbed over but she was still in a lot of pain due to the lesions. Brain surgery was done in another hospital and they were told that the lesion was from the mass in her lungs and it had metastasized to the brain. She underwent radiation after the brain surgery. She was hospitalized 3 more times due to blood clots that were seen on her shin to the hip. The patient contracted Covid-19 approximately 6 weeks before she passed on in a hospice across the hospital where she was confined last. No autopsy result was disclosed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) [redacted] (Patient Link).
4.1(b) [redacted]	This spontaneous case was reported by an other health care professional and describes the occurrence of FALL (falling face first on the floor/collapsed) in a 77-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Multiple myeloma (IgG multiple myeloma) on 01-Mar-2008, Hypertension (HTN) on 09-Aug-2015, Gait abnormal (Impaired Gait) on 11-Jul-2010, Cardiac arrhythmia (Cardiac arrhythmia- Pacemaker dependent) on 09-Aug-2015, DVT on 09-Aug-2015 and Pacemaker insertion (cardiac) (Cardiac arrhythmia- Pacemaker dependent). Concomitant products included POMALIDOMIDE from 21-May-2021 to an unknown date, DEXAMETHASONE from 21-May-2021 to an unknown date, GABAPENTIN (NEURONTIN) from 21-May-2021 to an unknown date and LACTULOSE for an unknown indication.

Case ID	Narrative (Complete)
	On 25-Oct-2021 at 8:49 AM, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 30-Apr-2022, the patient experienced FALL (falling face first on the floor/collapsed) (seriousness criterion death). The patient died on 30-Apr-2022. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter considered FALL (falling face first on the floor/collapsed) to be not related. No treatment medication was reported by reporter. It was reported that patient was involved in a study with Protocol no- MCC 21536 and Subject number-4.1(b) Patient took third dose of Moderna vaccine on 25-Oct-2021. It was reported that study staff contacted patient on 3-May-2022 for month 6 blood withdraw per protocol and came to know that patient passed away on 30-Apr-2022. Patient wife already informed clinical team of her husband at medical center. patients wife reported that she left the patient home alone for few hours, when she retuned she found that patient had fallen face first in the bathroom. she called EMT for assistance but first responder did not proceed with any intervention. she stated that the cause of death had not yet been released. she reported that the death certificate was pending. Company comment: This spontaneous case concerns a 77 year old male patient with relevant medical history of Multiple myeloma, Hypertension, Cardiac arrhythmia, Cardiac pacemaker insertion and Deep vein thrombosis who met with the unexpected fatal (seriousness criteria-death) event of Fall, about 6 months, 4 days after receiving the third dose with mRNA-1273 vaccine in the COVID-19 vaccination series. Patient was at home and collapsed falling face first on the floor; could not be revived by the rescue team. The cause of death was not known. No further information on autopsy details and details pertaining to the previous doses was available in the report. Elderly age of the patient and multiple co morbidities could be risk factors for the fatal outcome. The causality for the fatal event was 'not related' as per the report. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number:4.1(b)) on 12-May-2022 and was forwarded to Moderna on 12-May-2022. This regulatory authority case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CARDIOGENIC SHOCK (Cardiogenic shock), ACUTE CORONARY SYNDROME (Acute coronary syndrome) and ACUTE CORONARY SYNDROME (Non ST segment elevation acute coronary syndrome) in a 74-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 214029 and 000138A) for COVID-19 vaccination. No medical history. On 11-Jan-2022, the patient received first dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 01-Feb-2022, received second dose of mRNA-1273 (Spikevax) (Intramuscular) dosage was changed to 1 dosage form. On 14-Mar-2022, the patient experienced ACUTE CORONARY SYNDROME (Acute coronary syndrome) (seriousness criterion life threatening). On an unknown date, the patient experienced CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criterion death). an unknown date, the patient experienced ACUTE CORONARY SYNDROME (Non ST segment elevation acute coronary syndrome) (seriousness criterion life threatening). The patient died on an unknown date. The reported cause of death was Cardiogenic shock. It is unknown if an autopsy was performed. At the time of death, ACUTE CORONARY SYNDROME (Acute coronary syndrome) had not resolved and ACUTE CORONARY SYNDROME (Non ST segment elevation acute coronary syndrome) had resolved with sequelae. Concomitant product use was not provided by the reporter. Treatment information was not provided. Company comment- This is a fatal regulatory authority case concerning a 74-year-old male patient with no medical history reported who experienced the unexpected and serious (death) AESI cardiogenic shock along with the serious (life threatening) AESI acute coronary syndrome within 23-62 days after a second dose of mRNA-1273 vaccine was administered. First and second doses of mRNA-1273 were administered in an inappropriate schedule of vaccination (21 days interval). It is not known if an autopsy was performed. The date of death is unknown. No further details were provided for medical reviewing. Patient´s age and gender remain as a possible contributory risk factor for the events. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of CARDIOGENIC SHOCK (Cardiogenic shock), ACUTE KIDNEY INJURY (Acute renal failure), ISCHAEMIC CARDIOMYOPATHY (ischemic cardiomyopathy), MYOCARDIAL INFARCTION (Two heart attacks/Leg stents failed after hearth attacks) and COVID-19 (tested positive for Covid 19) in a 69-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 052C21A and 050C21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Stent placement (stent put in her leg) on 16-Jun-2021, Stent placement (she also had stents put in her legs and because suffered the 2 heart attacks) in July 2021, Bypass surgery (leg bypass surgery) in September 2021 and Amputation above knee on 24-Dec-2021. Concurrent medical conditions included Penicillin allergy, Allergy to antibiotic (Amoxicillin), Allergy (Aspirin) and Diabetes. Concomitant products included INSULIN for Diabetes. On 16-Jun-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 14-Jul-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 18-Jul-2021, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced MYOCARDIAL INFARCTION (Two heart attacks/Leg stents failed after hearth attacks) (seriousness criteria hospitalization and medically significant). On 31-Dec-2021, the patient experienced COVID-19 (tested positive for Covid 19) (seriousness criterion medically significant). On an unknown date, the patient experienced CARDIOGENIC SHOCK (Cardiogenic shock) (seriousness criteria death and medically significant), ACUTE KIDNEY INJURY (Acute renal failure) (seriousness criteria death and medically significant), ISCHAEMIC CARDIOMYOPATHY (ischemic cardiomyopathy) (seriousness criteria death and medically significant), PRODUCTIVE COUGH (Phlegm/Cough) and DRUG INEFFECTIVE (Lack of drug effect). The patient was treated with SACUBITRIL, VALSARTAN (ENTRESTO) at an unspecified dose and frequency; RANOLAZINE at an unspecified dose and frequency; METOPROLOL at an unspecified dose and frequency; CLOPIDOGREL at an unspecified dose and frequency and ATORVASTATIN at an unspecified dose and frequency. The patient died on 23-Feb-2022. The reported cause of death was Ischemic cardiomyopathy, Cardiogenic shock and Acute renal failure. An autopsy was not performed. At the

Case ID	Narrative (Complete)
	time of death, MYOCARDIAL INFARCTION (Two heart attacks/Leg stents failed after hearth attacks), COVID-19 (tested positive for Covid 19), PRODUCTIVE COUGH (Phlegm/Cough) and DRUG INEFFECTIVE (Lack of drug effect) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Dec-2021, SARS-CoV-2 test: positive (Positive) positive. This spontaneous case concerns a 69-year-old old female patient with relevant medical condition of diabetes mellitus and medical history of stent placement, who experienced the fatal, unexpected, serious (medically significant) adverse events of special interest of Cardiogenic shock, Ischaemic cardiomyopathy and Acute kidney injury and twice reported unexpected, serious (hospitalization, medically significant) adverse event of special interest of Myocardial infarction and unexpected, serious (medically significant) adverse event of special interest of COVID-19 which occurred after receiving the second dose of mRNA-1273 vaccine. Patient developed chest pain a day after the second dose. She was admitted in hospital and diagnosed to have two episodes of Myocardial infarction. She was discharged and prescribed with Entresto, Ranolazine, Metoprolol, Clopidogrel and Atorvastatin. Her leg stents failed on the same month of vaccination thus she underwent peripheral vascular bypass surgery two months after. Approximately 5 months after vaccination, she underwent above the knee leg amputation for unknown indication. She started physical rehabilitation since then. Patient developed COVID-19 (with a positive SARS-CoV-2 test) approximately five months after the second dose of mRNA-1273 vaccine. Drug ineffective was also considered. It was mentioned that COVID-19 is contributory to the patient demise however clinical presentation, diagnostic evaluation and treatment details were not reported. Death occurred approximately7 months after second dose of mRNA-1273 vaccine. The cause of death was reported as Cardiogenic shock, Ischemic cardiomyopathy and Acute renal failure. It is unknown if an autopsy was performed. Patient´s advanced age and medical condition remain confounders for Myocardial infarction, Cardiogenic shock, Ischaemic cardiomyopathy and Acute kidney injury and the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report This case was linked to 4.1(b) (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 12-May-2022: Upon internal Review on 19-May-2022, non-significant correction was made to update event stop date.
4.1(b)	This case was received via United Kingdom MHRA (Reference number: 4.1(b)) on 12-May-2022 and was forwarded to Moderna on 12-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of DEATH (Death) in an 82-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included IHD and CRT/ICD insertion (ICD in situ). On 10-May-2022, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. Death occurred on 10-May-2022 The cause of death was not reported. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medication use information was not provided by reporter. It was reported that unsure if related to spikevax which was administered on same day. Patient had ICD in situ. No reaction occurred as a result of a mistake made in the administration of the vaccine. Treatment medication use information was not provided by reporter. Company Comment: This is a regulatory case concerning an 82-year-old male patient with relevant medical history of IHD and ICD in situ, who had a fatal outcome with unexpected serious event of Death (reported as viral encephalitis versus autoimmune in etiology), which occurred on the same day after receiving a dose of mRNA-1273 vaccine. The clinical course leading to demise and the cause of death were not reported. It is unknown whether an autopsy was performed. No further details about the diagnostic procedures and treatments were provided. The medical history of IHD and ICD in situ could be contributory factors for the event. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness assessed as per Regulatory Authority reporting.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 13-May-2022 and was forwarded to Moderna on 13-May-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and DRUG INEFFECTIVE (Drug ineffective) in a 69-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 057G12A) for COVID-19 vaccination. Co-suspect product included non-company product CASIRIVIMAB, IMDEVIMAB (RONAPREVE) for COVID-19 prophylaxis. The patient's past medical history included Lymphoma and Ischaemic heart disease. On 15-Nov-2021, the patient received dose of CASIRIVIMAB, IMDEVIMAB (RONAPREVE) (Intravenous) 1 dosage form once per month. On 06-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 26-Dec-2021, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criteria death and hospitalization) and DRUG INEFFECTIVE (Drug ineffective) (seriousness criteria death and hospitalization). The patient died on 16-Feb-2022. The reported cause of death was pneumopathie covid-19. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication was not provided.

Case ID	Narrative (Complete)
	Treatment information was not provided. Company comment: This is a regulatory Fatal and serious (due to hospitalization) case concerning a 69 year-old, male patient with a history of Lymphoma, Myocardial ischaemia and concomitant use of casirivimab, imdevimab (reported as suspect drug), with vaccination failure and drug ineffective reported 20 days after the mRNA-1273 vaccine, dose number not provided (reported as R1), although no information on additional doses was available. The patient died 2 months 10 days after vaccination, the reported cause of death was COVID-19 pneumonitis. It is unknown whether an autopsy was performed. The mentioned medical history remains a contributory risk factor for the fatal outcome. Casirivimab, imdevimab was reported as COVID-19 prophylaxis, with start date one month prior to the onset of the events reported in the case. No further clinical information was available for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 21-Jun-2022: Follow-up information included no new information.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 11-May-2022 and was forwarded to Moderna on 13-May-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a nurse, was received via the PMDA (Ref. 4.1(b)). On 14-Jun-2021, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 05-Jul-2021, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 27-Feb-2022, at 10:15, the patient received the 3rd vaccination with this vaccine. From immediately after the vaccination, the patient continued to have no symptoms including adverse reactions. At 22:00, the patient went to bed. On 28-Feb-2022, around 00:55, while in bed, the patient suddenly complained of chest discomfort and was raced to the emergency outpatient department of the reporting hospital. At 01:10, when the ambulance team arrived, the patient had depressed level of consciousness with about 3 of JCS. However, poor oxygenation with Sp02 of 87% was noted under administration of 10 L of oxygen, and assisted ventilation was started. At 01:25, the patient got into in a state of unrest immediately before the arrival at the reporting hospital. Immediately after visiting the hospital, the condition worsened, including decreased blood pressure, bradycardia, and dilated pupils. There was no spontaneous respiration, and the carotid artery was impalpable; thus, the patient was diagnosed with cardio-respiratory arrest. Chest compressions was started, and BVM ventilation were continued. Effective cardiopulmonary resuscitation was continued, but the family member requested discontinuation of the cardiopulmonary resuscitation. At 01:40, the patient was confirmed dead. CT was performed, but the cause of death was unknown. An autopsy was recommended to determine the cause, but it was declined, and it was concluded that the direct cause of death was acute cardiac death. The outcome of chest discomfort, depressed level of consciousness, poor oxygenation, state of unrest, decreased blood pressure, bradycardia, dilated pupils, and cardio-respiratory arrest was reported as fatal. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 13-May-2022 and was forwarded to Moderna on 13-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of SUDDEN DEATH (21/07/2021 pain at the injection site and asthenia. Sudden death on the 24th), INJECTION SITE PAIN (21/07/2021 pain at the injection site and asthenia. Sudden death on the 24th) and ASTHENIA (21/07/2021 pain at the injection site and asthenia. Sudden death on the 24th) in a 66-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004499) for COVID-19 vaccination. Concurrent medical conditions included Hypoadrenocorticism. On 21-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 24-Jul-2021, the patient experienced SUDDEN DEATH (21/07/2021 pain at the injection site and asthenia. Sudden death on the 24th) (seriousness criterion death), INJECTION SITE PAIN (21/07/2021 pain at the injection site and asthenia. Sudden death on the 24th) (seriousness criterion death) and ASTHENIA (21/07/2021 pain at the injection site and asthenia. Sudden death on the 24th) (seriousness criterion death). The patient died on 24-Jul-2021. The reported cause of death was Sudden death, Injection site pain and Asthenia. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications was not provided by the reporter. Treatment information was not provided. Company comment: This regulatory case concerns a 66-year-old, male patient with medical history of Hypoadrenocorticism, who experienced the unexpected, fatal outcome of Sudden death, Injection site pain and Asthenia. The events occurred 3 days after administration of an unknown dose of mRNA-1273. The patient's medical condition of Hypoadrenocorticism could be a confounder to the event Sudden death. Details of concomitant medications and clinical course were not provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority's report.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 13-May-2022. The most recent information was received on 24-May-2022 and was forwarded to Moderna on 24-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of GUILLAIN-BARRE SYNDROME (Progressive ascending paresis, acute respiratory failure) and ACUTE RESPIRATORY FAILURE (Progressive ascending paresis, acute respiratory failure) in a 76-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 000060a) for COVID-19 vaccination. The patient's past medical history included Atheromatosis, Difficulty in walking and Renal dialysis. Concurrent medical conditions included Artificial cardiac pacemaker wearer, Type 2 diabetes mellitus, Diabetic neuropathy, Chronic renal failure and Chronic atrial fibrillation. Concomitant products included WARFARIN SODIUM (COUMADIN), BISOPROLOL FUMARATE, LINAGLIPTIN (TRAJENTA), SILODOSIN (UROREC), FUROSEMIDE (LASIX [FUROSEMIDE]), DUTASTERIDE (AVODART) and LANSOPRAZOLE (LANSOX) for an unknown indication. On 12-Apr-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 13-Apr-2022, the patient experienced GUILLAIN-BARRE SYNDROME (Progressive ascending paresis, acute respiratory failure) (seriousness criterion death) and ACUTE RESPIRATORY FAILURE (Progressive ascending paresis, acute respiratory failure) (seriousness criterion death). The patient died on 27-Apr-2022. The cause of death was not reported. An autopsy was not performed.

Case ID	Narrative (Complete)
	DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Apr-2022, Specialist consultation: inconclusive (Inconclusive) Inconclusive. On 21-Apr-2022, Computerised tomogram head: negative (Negative) Negative. On 22-Apr-2022, Electromyogram: inconclusive (Inconclusive) Inconclusive. On 22-Apr-2022, Specialist consultation: inconclusive (Inconclusive) Inconclusive. On 25-Apr-2022, Computerised tomogram head: inconclusive (Inconclusive) Inconclusive. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Patient was hospitalized on 19.04.22 with suspicion of Guillain Barr's syndrome, symptoms that arose a few days after the third dose of Covid Pfizer vaccine. On 21.04, due to worsening of the motor picture, he was transferred to resuscitation, where he was intubated by progressive tetraparesis. Meanwhile, there was a picture of septic shock with hypotension and persistent fever, high inflammation indices. The clinical picture worsened further on 25.04.22 with compars. Treatment information was not reported. Company Company Comment: This regulatory case concerns a 76-year-old male patient, with relevant medical history of cardiac assistance device user, type 2 diabetes mellitus, chronic kidney disease, and atrial fibrillation, who experienced the unexpected serious fatal AESIs Guillain-Barre syndrome and Acute respiratory failure that occurred 1 day after receiving the dose of mRNA-1273 vaccine. Patient was hospitalized on the 6th day (from events onset) with suspicion of Guillain-Barre syndrome. The motor function worsened and progressed to tetraparesis, and was then intubated. As reported, there was picture of septic shock with hypotension and persistent fever, high inflammation indices. Cranial CT scan and electromyogram were reported inconclusive, as well as neurological consult. Patient's condition worsened and was then eventually died after 14 days from events onset (15 days post vaccination). It was reported that no autopsy was performed. The multiple co-morbidities could be considered as risk factors for the event acute respiratory failure and fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 24-May-2022: Follow-up information received included: updated autopsy information and lab date results. On 14-Jun-2022: Follow-up contains no new information.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 16-May-2022. The most recent information was received on 01-Jun-2022 and was forwarded to Moderna on 01-Jun-2022. This regulatory authority case was reported by a physician and describes the occurrence of CIRCULATORY COLLAPSE (Going down on toilet, diarrhoea, resuscitation setting on arrival, can start from going out on the toilet within minutes, already aystolie did not succeed, madam deceased), DIARRHOEA (Going down on toilet, diarrhoea, resuscitation setting on arrival, can start from going out on the toilet within minutes, already aystolie did not succeed, madam deceased) and RESUSCITATION (Going down on toilet, diarrhoea, resuscitation setting on arrival, can start from going out on the toilet within minutes, already aystolie did not succeed,madam deceased) in a 69-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Diverticulitis, Hypothyroidism (no medication now), Polymyalgia rheumatica (polymalgic rheumatics, March 2022, polyarthrosis without underlying Rheumatic disease) in March 2022, Type 2 diabetes mellitus (no medication now), CVA in 2021, Gastric bypass and Lichen sclerosus. Previously administered products included for Product used for unknown indication: Pfeizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 31-Mar-2021, Pfeizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST on 01-Jul-2021, Moderna COVID-19 VACCIN MODERNA INJVLST 0 and25MLCOVID-19 VACCIN MODERNA INJVLST on 01-Dec-2021. Past adverse reactions to the above products included No adverse event with Moderna COVID-19 VACCIN MODERNA INJVLST 0,25MLCOVID-19 VACCIN MODERNA INJVLST, Pfeizer COVID-19 VACCIN PFIZER INJVLST 0,3MLCOVID-19 VACCIN PFIZER INJVLST, Pfeizer COVID-19 VACCIN PFIZER INJVLST 0 and3MLCOVID-19 VACCIN PFIZER INJVLST. Concurrent medical conditions included COPD (class 2), Polyarthritis, High cholesterol, Hypertension and Shoulder prosthesis user (shoulder prosthesis straight). Concomitant products included CLOPIDOGREL (CLOPIDOGREL TEV), HYDROCHLOROTHIAZIDE, LISINOPRIL (LISINOPRIL/HYDROCHLOORTHIAZIDE), QUETIAPINE FUMARATE (QUETIAPINE GH), CALCIUMCARBONAAT, ATORVASTATIN CALCIUM (ATORVASTATINE EG), BECLOMETASONE DIPROPIONATE (APO-BECLOMETHASONE) and PANTOPRAZOLE SODIUM SESQUIHYDRATE (PANTOPRAZOLO) for an unknown indication. On 07-Apr-2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 09-Apr-2022, the patient experienced EAR HAEMORRHAGE (Blood from the right ear) and INFLUENZA LIKE ILLNESS (From 9 april flu, ie cold and headache, no coughing, ﷺnot fit﷽). 09-Apr-2022, the patient experienced MALAISE (Don't feel good). On 12-Apr-2022, the patient experienced INSOMNIA (Night from 12 to 13 and from 13 to 14 not slept well). On 13-Apr-2022, the patient experienced NAUSEA (Night 13 to 14 not slept well because of heavy arms, nauseous, not good) and LIMB DISCOMFORT (Night 13 to 14 not slept well because of heavy arms, nauseous, not good). On 14-Apr-2022, the patient experienced CIRCULATORY COLLAPSE (Going down on toilet, diarrhoea, resuscitation setting on arrival, can start from going out on the toilet within minutes, already aystolie did not succeed, madam deceased) (seriousness criterion death), DIARRHOEA (Going down on toilet, diarrhoea, resuscitation setting on arrival, can start from going out on the toilet within minutes, already aystolie did not succeed, madam deceased) (seriousness criterion death), HAEMATOMA (At death also some bruises on the arms that are also edematous) and OEDEMA PERIPHERAL (At death also some bruises on the arms, which are also edematous.). 14-Apr-2022, the patient experienced RESUSCITATION (Going down on toilet, diarrhoea, resuscitation setting on arrival, can start from going out on the toilet within minutes, already aystolie did not succeed,madam deceased) (seriousness criterion death). The patient died on 14-Apr-2022. The reported cause of death was suspicion myocardial infarction (registered as primary cause of death). An autopsy was not performed. At the time of death, NAUSEA (Night 13 to 14 not slept well because of heavy arms, nauseous, not good), INSOMNIA (Night from 12 to 13 and from 13 to 14 not slept well), EAR HAEMORRHAGE (Blood from the right ear), LIMB DISCOMFORT (Night 13 to 14 not slept well because of heavy arms, nauseous, not good), MALAISE (Don't feel good) and INFLUENZA LIKE ILLNESS (From 9 april flu, ie cold and headache, no coughing, ﷺnot fit﷽) had not resolved and HAEMATOMA (At death also some bruises on the arms that are also edematous) and OEDEMA PERIPHERAL (At death also some bruises on the arms, which are also edematous.) outcome was unknown.

Case ID	Narrative (Complete)
	For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No treatment details were reported. Company Comment: This regulatory case concerns a 69-year-old female patient with relevant medical history of Hypertension, High cholesterol, Chronic obstructive pulmonary disease, Type 2 diabetes mellitus who experienced the serious fatal unexpected events of Circulatory collapse, Diarrhoea and Resuscitation 7 days after a dose of mRNA-1273 vaccine. It was reported patient going down on toilet, with diarrhoea, tried resuscitation within minutes, but asystole, could not succeed and patient died. The reported cause of death was Myocardial infarction (reported as suspicion myocardial infarction (registered as primary cause of death)). Patient died 7 days after mRNA-1273 vaccine. Autopsy was not performed. Patient also had experienced non-serious events of nausea, Insomnia, Haematoma, Ear haemorrhage, Limb discomfort, Oedema peripheral, Malaise and Influenza like illness few days (2 to 6 days) after mRNA-1273 vaccine. Patient has received initial schedule of vaccinations with TOZINAMERAN (interchange of vaccine products) noted. Elderly age and mentioned medical history could be confounder for the event Circulatory collapse and the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes: On 01-Jun-2022: Follow up document received contains medical history and events onset date were updated. Concomitant dugs and events were added. On 01-Jun-2022: Follow up document received contains event verbatim and concomitant drug (Pantoprazolo) were updated.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 16-May-2022. The most recent information was received on 13-Jun-2022 and was forwarded to Moderna on 13-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (My father suffered a severe stroke one week (on 06.04.22) after vaccination with Spikevax (31.3.22), from which he passed away on 14.4.22.) in an 80-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. Previously administered products included for COVID-19 immunisation: VAXZEVRIA. Past adverse reactions to the above products included Apoplectic fit with VAXZEVRIA. Concurrent medical conditions included Atrial fibrillation, Diabetes mellitus and Fruit allergy (Allergic to KIWI). On 31-Mar-2022, the patient received fourth dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 06-Apr-2022, after starting mRNA-1273 (Spikevax), the patient experienced CEREBROVASCULAR ACCIDENT (My father suffered a severe stroke one week (on 06.04.22) after vaccination with Spikevax (31.3.22), from which he passed away on 14.4.22.) (seriousness criterion death). The patient died on 14-Apr-2022. The reported cause of death was Apoplectic fit. It is unknown if an autopsy was performed. No concomitant medications were reported. No treatment information was reported. Patient was an old, sick but self-reliant man. It was reported that during the first vaccination in 2021 with AstraZeneca he already suffered a serious stroke. Company Comment: This regulatory case concerns an 80-year-old male patient, with relevant medical history of atrial fibrillation and diabetes mellitus, past history of Cerebrovascular accident after vaccination with CHADOX1 NCOV-19 in 2021, who experienced the unexpected serious and fatal AESI of Cerebrovascular accident that occurred 6 days after receiving the mRNA-1273 vaccine as 4th dose in covid 19 vaccination series. No further clinical course, lab results or treatment details were reported. Patient died 8 days from the event onset (14 days post vaccination). The reported cause of death was cerebrovascular accident. It is unknown if an autopsy was performed. Patient had received a dose of vaccination with CHADOX1 NCOV-19 on unknown date (Interchange of vaccine products). Relevant medical history of atrial fibrillation and diabetes mellitus, past history of Cerebrovascular accident after vaccination with CHADOX1 NCOV-19 in 2021 could be possible confounders and elderly age as risk factor to the event. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 13-Jun-2022: Causality updated to possible.
4.1(b)	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b)) on 17-May-2022. The most recent information was received on 09-Jun-2022 and was forwarded to Moderna on 09-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CHOKING (choking), DELIRIUM (delerium), AGITATION (Agitation), CONFUSIONAL STATE (Confusion), FALL (Fall), PSYCHOMOTOR HYPERACTIVITY (Hyperactivity), PERSONALITY CHANGE (Personality change), SEIZURE (Seizure), PRODUCTIVE COUGH (Sputum), MALAISE (Feeling sick), HYPOTENSION (Blood pressure low), CARDIAC ARREST (Cardiac arrest) and AGONAL RESPIRATION (Agonal respiration) in a 90-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for COVID-19 vaccination, TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) for COVID-19 vaccination. Patient had a long history of being treated for hyperparathyroidism, anxiety, depression, arthritis (possibly ankylosing spondylitis), and blood pressure variation, as well as problems with persistent redness round her eyelids. She had a few hospital admissions for fainting (over a period of several years) and then one for the fall and broken femur- partly caused because she was agitated. The patient's past medical history included Prolonged periods (Occasional more elevated periods - but none to the reporter knowledge for years before the first COVID vaccine.), Hyperparathyroidism, Blood pressure fluctuation, Fainting, Eyelid rash, Sarcoma (lost an arm to a sarcoma in the 1980s) and Femur fracture (broken femur). Concurrent medical conditions included Depression (Chronic), Arthritis (Patient had arthritis (possibly ankylosing spondylitis)) and Anxiety (Chronic).

Case ID	Narrative (Complete)
	On 22-Jan-2021, the patient received first dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (unknown route) 1 dosage form. On 29-Jul-2021, the patient received second dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENECA) (unknown route) 1 dosage form. On 11-Jan-2022, the patient received third dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (unknown route) 1 dosage form. On 28-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 08-Mar-2021, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced DELIRIUM (delerium) (seriousness criteria death and hospitalization). In March 2021, the patient experienced CHOKING (choking) (seriousness criteria death and hospitalization). On 14-May-2022, the patient experienced SEIZURE (Seizure) (seriousness criteria death and hospitalization), MALAISE (Feeling sick) (seriousness criteria death and hospitalization) and HYPOTENSION (Blood pressure low) (seriousness criteria death and hospitalization). On an unknown date, the patient experienced AGITATION (Agitation) (seriousness criteria death and hospitalization), CONFUSIONAL STATE (Confusion) (seriousness criteria death and hospitalization), FALL (Fall) (seriousness criteria death and hospitalization), PSYCHOMOTOR HYPERACTIVITY (Hyperactivity) (seriousness criteria death and hospitalization), PERSONALITY CHANGE (Personality change) (seriousness criteria death and hospitalization), PRODUCTIVE COUGH (Sputum) (seriousness criteria death and hospitalization), CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and hospitalization) and AGONAL RESPIRATION (Agonal respiration) (seriousness criteria death and hospitalization). The patient died on 14-May-2022. The reported cause of death was Delirium, Choking and Cardiac arrest. It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. It was reported that A few weeks after the first dose of the vaccine (22 January 2021), she started to have choking fits. She then had to be admitted to hospital (29 March) with a variety of symptoms including agitation, personality change, confusion and delirium. Patient's second dose had been delayed due to the concerns about the possible adverse reaction to the first dose. After partial recovery and stays in care homes and at home, she had a second dose,of AZ vaccine. A few weeks after the second dose she was again hyper-active, and fell and broke her femur and was hospitalized. Patient had a booster dose of another COVID vaccine during her time in hospital, possibly an mRNA, possibly Pfizer. She improved gradually but a few weeks after that booster she again became agitated and confused. This had partially subsided when she had her 4th COVID vaccine, possibly Moderna, a few days ago. She again became more agitated and confused. she had a choking problem with whitish sputum, and she had a fit.She died at home with paramedics in attendance. The reported mentioned that no post mortem was performed. It was reported that reaction did not occurred as a result of a mistake made in the administration of the vaccine. Company Comment: This regulatory authority case concerns a 90-year-old female patient with a medical history of Depression, Anxiety and Blood pressure fluctuation, who experienced the fatal unexpected serious events of Seizure (AESI), Choking, Delirium, Agitation, Confusional State, Fall, Psychomotor Hyperactivity, Personality Change, Productive Cough, Malaise, Hypotension, Cardiac Arrest and Agonal Respiration, that led to hospitalization and death. Few weeks after receiving the first dose of COVID-19 vaccine AstraZeneca, the patient started to have choking fits and was admitted to a hospital approximately 2 months after the first dose with symptoms of agitation, personality change, confusion and delirium. The patient partially recovered and stayed in care home and the second dose of AstraZeneca vaccine was given. Few weeks after the second dose, the patient again became hyper-active, fell and broke her femur and was hospitalized. A booster dose of AstraZeneca was given while the patient was in the hospital. The patient improved gradually but again became agitated and confused. The patient became more agitated and confused after partially subsiding few days after receiving a dose of mRNA-1273 vaccine. The patient had choking and died at home with paramedics in attendance on 14-May-2022. Diagnostic tests and treatment details were not provided in the case. The reported cause of death was Delirium, Choking and Cardiac arrest. It is unknown if an autopsy was performed. At the time of the last observation, the outcome of chocking, delirium had not recovered, cardiac arrest was fatal and the rest unknown. Patient's medical history of depression and anxiety could be confounders for the events Delirium, Agitation, Confusional state, Psychomotor hyperactivity, and Personality change. Blood pressure fluctuation could be contributory to the event Hypotension. Patient's advanced age could be a contributory risk factor for the event cardiac arrest. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as reported. Most recent FOLLOW-UP information incorporated above includes: On 24-May-2022: Medical history, event and narrative updated. On 09-Jun-2022: Significant follow-up received contains cause of death,additional events, event stop date removed (Delirium), event outcome, co-suspect product,suspect product start and stop date details and case narrative were updated.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 18-May-2022. The most recent information was received on 19-May-2022 and was forwarded to Moderna on 19-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of SYNCOPE (Relapsing syncope) in a 76-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005884 sc 08/05/22) for COVID-19 vaccination. The patient's past medical history included Hypertension pulmonary on 09-Dec-2021. Previously administered products included for COVID-19 immunisation: COMIRNATY on 14-Apr-2021 and COMIRNATY on 05-May-2021. Past adverse reactions to the above products included No adverse event with COMIRNATY and COMIRNATY. Concurrent medical conditions included Diabetes. Concomitant products included PANTOPRAZOLE for Acid reflux (oesophageal), TICAGRELOR and ATORVASTATIN for Atherothrombosis, INSULIN ASPART (NOVORAPID), DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE, METFORMIN HYDROCHLORIDE (XIGDUO) and INSULIN GLARGINE (TOUJEO) for Diabetes mellitus, ACETYLSALICYLIC ACID (CARDIOASPIRIN) for Hypertension. On 19-Nov-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 16-Apr-2022, after starting mRNA-1273 (Spikevax), the patient experienced SYNCOPE (Relapsing syncope) (seriousness criterion death). The patient died on 16-Apr-2022. The reported cause of death was Syncope. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment was reported. Report was suggested by spouse Company comment: This regulatory authority case concerns 76-years-old, male patient with past medical history of Hypertension pulmonary from 09-Dec-2021 to 16-Apr-2022, who experienced the unexpected Fatal event of Syncope (relapsing syncope) (seriousness criteria death). Patient died after 4 month 28 days after

Case ID	Narrative (Complete)
	the dose of mRNA-1273 vaccine (dose number not specified). Cause of death was reported as Syncope. However, autopsy report was not provided. It was reported that patient had received 2 doses with COMIRNATY vaccine 6 months 14 days prior to current vaccination (Interchange of vaccine products). Patient's elderly age, Interchange of vaccine products and past medical history of Hypertension pulmonary from 09-Dec-2021 to 16-Apr-2022 remains a confounder. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority's reporting. Most recent FOLLOW-UP information incorporated above includes: On 19-May-2022: Follow-up received is significant. Medical History was updated, Suspect drug information was updated and Concomitant medications were added. On 31-May-2022: Follow up document received contains non significant information(senders comment were updated and historical vaccine term were translated) On 06-Jun-2022: Follow-up received included no new information.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of TACHYPNOEA (Polypnea) in an 81-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. SP2110-CDC) for COVID-19 vaccination. The patient's past medical history included Polypnea (in recent 2 months, her condition was better recently). Concurrent medical conditions included Hypertension (with long-term medication). On 29-Apr-2022, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 03-May-2022, the patient experienced TACHYPNOEA (Polypnea) (seriousness criterion death). The patient died on 03-May-2022. The reported cause of death was Polypnea. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No concomitant medication information was provided. The patient presented with polypnea in recent 2 months, her condition was better recently, so she received the Medigen vaccine on 29-April, she felt fatigue, and polypnea also occurred. On 03-May, family members found, she had no spontaneous respiratory and heartbeat in the night, she was sent to hospital and died. No treatment medication was provided. The worldwide UID was reported as 4.1(b) [redacted]. Company Comment:This is a fatal, regulatory case concerning an 81-year-old female patient with past medical history of Polypnea, who experienced the unexpected serious event of Tachypnea which led to the eventual demise of the patient as reported by the regulatory authority and occurred 4 days after receiving the second dose of mRNA-1273 Vaccine. As reported, after patient received the vaccine, she experienced fatigue, and polypnea. Four days later, the family members found that she had no spontaneous respiratory and heartbeat, she was then sent to hospital and died. The reported cause of death was Polypnea. It is unknown if an autopsy was performed. The medical history of Polypnea remains a confounder. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report.
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of CEREBRAL HAEMORRHAGE (Cerebral hemorrhage) in an 86-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 2100686_1110427-CDC) for COVID-19 vaccination. Concurrent medical conditions included Diabetes (Patient had diabetes for many years and received treatment with insulin in hospital.). On 13-Apr-2022, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-Apr-2022, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced CEREBRAL HAEMORRHAGE (Cerebral hemorrhage) (seriousness criterion death). The patient died on 02-May-2022. The reported cause of death was Cerebral hemorrhage. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant Medication use information was not provided by reporter. On 13 April 2022, the patient felt uncomfortable immediately after vaccination, but without clear symptoms. on 17 April 2022, the patient suddenly not able to stand up on Sunday, was rushed to the Hospital and diagnosed as cerebral hemorrhage. On 2 May 2022, patient was declared dead. Treatment Medication use information was not provided by reporter. The Worldwide UID was reported as 4.1(b) [redacted]. Company comment: This regulatory authority case concerns an 86 year old male patient with relevant medical history of diabetes mellitus who experienced the unexpected fatal (seriousness criterion-death) AESI of Cerebral haemorrhage, about 4 days after receiving the second dose with mRNA-1273 vaccine in the COVID-19 vaccination series. The event had a fatal outcome with death occurring about 19 days after vaccine administration. The patient felt uncomfortable immediately after vaccination but without clear symptoms. About 4 days later, he suddenly could not stand up and was rushed to hospital where he was diagnosed with Cerebral haemorrhage. He was declared dead after 15 days. No further information on clinical course, management of the event, details pertaining to the first dose and autopsy findings was available in the report. Advanced age of the patient and concurrent diabetes mellitus could be risk factors for the event. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness retained as per Regulatory Authority reporting.
4.1(b) [redacted]	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 09-May-2022 and was forwarded to Moderna on 11-May-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of SEPSIS (Sepsis) and IMMUNE SYSTEM DISORDER (Immune system storm due to Macrophage virus induced by vaacine) in a 72-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 939599-CDC) for COVID-19 vaccination. Concurrent medical conditions included Hypertension.

Case ID	Narrative (Complete)
	On 02-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 29-Sep-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to .5 milliliter. On 15-Nov-2021, the patient experienced SEPSIS (Sepsis) (seriousness criteria death and medically significant) and IMMUNE SYSTEM DISORDER (Immune system storm due to Macrophage virus induced by vaacine) (seriousness criterion death). The patient died on 13-Apr-2022. The reported cause of death was Sepsis, immune system storm due to macrophage virus induced by vaacine, Respiratory failure, Pneumonia and Septic shock. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Bacterial test: no growth in blood bacterial culture no growth in blood bacterial culture. On an unknown date, Blood test: no abnormalities seen No abnormalities seen. On an unknown date, Chest X-ray: pulmonary infiltrates pulmonary infiltrates, nodules and swollen lymph nodes in neck and axilla nodules and swollen lymph nodes in neck and axilla and no abnormalities no abnormalities. On an unknown date, Computerised tomogram: nodules and swollen lymph nodes in neck and axilla nodules and swollen lymph nodes in neck and axilla. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. The worldwide UID was reported as 4.1(b) [redacted] Concomitant medication was not reported. This fatal regulatory case concerns an 72-year-old male patient with medical history of hypertension for many years who experienced the serious unexpected events of SEPSIS and IMMUNE SYSTEM DISORDER The events occurred 48 days after 2nd dose of mRNA-1273 vaccine The patient died on13-Apr-2022, 197 days after vaccination. It is Unknown if Autopsy was performed, The benefit-risk relationship of drug is not affected by this report Terms and onset dates were captured as provided The case was assessed as serious by the Regulatory Authority´s report due to Death On 02-JUL-2021, Vaccination with the first dose of Moderna vaccine, the patient suffered from bone pain and discomfort, restless after returning to home, which was considered by himself to be ischialgia, and he went to a drugstore to purchase some painkillers and went to the Chung Po Folk Therapy for osteopathic manipulation. 29- SEP-2021, Vaccination with the second dose of Moderna vaccine, patent was unable to get out of bed to walk due to ache after 3 weeks of Vaccination. 15- NOV-2021 he went to the Healthcare Service for medical treatment, thereafter, he had joint pain and discomfort and limbs swelling successively. 29-DEC-2021, patient went to the Healthcare Service for medical treatment due to successive asthma and discomfort, slight fever. CXR examination showed pulmonary infiltrates, so the referral form was provided to the hospital, then the patient visited the Rheumatology of Changgung Hospital with the help of family due to unimproved symptoms, and blood test was performed, no abnormalities seen, and the patient was transferred to the Chest Medicine for treatment. F/UCXR and CT: nodules and swollen lymph nodes in neck and axilla, the patient was admitted into the hospital for observation and treatment, it was recommended to conduct a pathological section examination, but the patient
4.1(b) [redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of LOSS OF CONSCIOUSNESS (Unresponsiveness) in a 74-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 068F21A) for COVID-19 vaccination. No Medical History information was reported. On 12-Jan-2022, the patient received third dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 12-Jan-2022 at 8:47 AM, the patient experienced LOSS OF CONSCIOUSNESS (Unresponsiveness) (seriousness criterion death). The reported cause of death was unresponsiveness. It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medication were not provided. The patient had received his booster dose of COVID-19 Vaccine Moderna. One to two hours post vaccination while watching the online burial mass of his sister in their home, patient was found by his son, laying on the floor, unconscious, with urine flowing down his pants. Patient was brought and admitted to hospital. At the ER, patient had woke up with slurring of speech. He was then managed and was seen by the doctor on duty. Treatment medication were not provided. The Worldwide UID was reported as 4.1(b) [redacted]. Company comment: This regulatory case concerns a 74-year-old, male patient with no reported medical history, who experienced the unexpected, fatal outcome of Loss of consciousness. The event occurred on the same day of administration of third dose of mRNA-1273. There was no information provided regarding the initial two doses. It has been reported that 1-2 hours after vaccination, the patient was found lying unconscious on the floor, the patient was then brought to an institution and was subsequently admitted where he regained consciousness but has slurring of speech. Details of concomitant medications, medical history, clinical course, treatment and outcome were not provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority's report.
4.1(b) [redacted]	This case was received via United Kingdom MHRA (Reference number: 4.1(b) [redacted]) on 19-May-2022 and was forwarded to Moderna on 19-May-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of LOWER RESPIRATORY TRACT INFECTION (chest infection) and PNEUMONIA (Pneumonia) in an 87-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000081A) for COVID-19 vaccination.

Case ID	Narrative (Complete)
	No Medical History information was reported. On 27-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 28-Apr-2022, the patient experienced LOWER RESPIRATORY TRACT INFECTION (chest infection) (seriousness criteria death and medically significant) and PNEUMONIA (Pneumonia) (seriousness criteria death and medically significant). The patient died on 04-May-2022. The reported cause of death was Pneumonia. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 04-May-2022, SARS-CoV-2 test: negative (Negative) Negative. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medication list was not provided. Treatment information was not provided. Patient admitted to hospital on 28-Apr-2022 with chest infection/ pneumonia where patient passed away on the 4-May-2022. Patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. This report did not relate to possible blood clots or low platelet counts. This report did not relate to possible myocarditis or pericarditis. This fatal regulatory case concerns an 87-year-old male patient with no reported medical history who experienced the serious unexpected events of LOWER RESPIRATORY TRACT INFECTION and PNEUMONIA The events occurred 6 days after 4th dose of mRNA-1273 vaccine The patient died on 4-May-2022, 6 days after vaccination. On 04-May-2022, SARS-CoV-2 test: negative It is Unknown if Autopsy was performed, The benefit-risk relationship of drug is not affected by this report Terms and onset dates were captured as provided The case was assessed as serious by the Regulatory Authority´s report due to Death and medically significant
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of PNEUMONIA (Pneumonia) in an 87-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000081A) for COVID-19 vaccination. The patient's past medical history included Left ventricular dysfunction, Aortic stenosis and Ischaemic heart disease. Concurrent medical conditions included Chronic kidney disease stage 3 and Pulmonary hypertension secondary. Concomitant products included APIXABAN, HYDROXOCOBALAMIN, TAMSULOSIN, FINASTERIDE, ATORVASTATIN, LANSOPRAZOLE and EPOETIN NOS for an unknown indication. On 27-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 11-May-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PNEUMONIA (Pneumonia) (seriousness criteria death and medically significant). The reported cause of death was Aortic stenosis, Chronic kidney disease, Pneumonia, Heart failure and Frailty. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In October 2021, Echocardiogram: mild left ventricular impairment (abnormal) mild left ventricular impairment. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient not had symptoms associated with COVID-19. Not had a COVID-19 test. Patient recent cardiology concerns including HF. Patient had not tested positive for COVID-19 since having the vaccine. Patient was not enrolled in clinical trial. The report did not relate to possible blood clots or low platelet counts. The report did not relate to possible myocarditis or pericarditis. The reported cause of death was pneumonia/ aortic stenosis with heart failure, chronic kidney disease, frailty of old age. If performed, please provide a copy of the post-mortem report: NA Any symptoms the patient experienced following vaccination: no immediate symptoms post vaccination. The relevant past medical or past drug history included Echo Oct 2021- mild left ventricular impairment. mod/severe aortic stenosis, ischaemic heart disease, CKD stage 3 and secondary pulmonary hypertension. COVID-19 infection status included: recent test unavailable. No treatment medication were provided. Company Comment: This regulatory case concerns an 87-year-old male patient, with no relevant medical history, who experienced the unexpected serious medically significant fatal event of Pneumonia that occurred 14 days after receiving the mRNA-1273 vaccine as a 4th dose. Patients Echocardiogram showed abnormal results. The reported cause of death was Aortic stenosis, Chronic kidney disease, Pneumonia, Heart failure and Frailty. An autopsy was not performed. There was no information provided regarding the first 3 doses of vaccination. The past medical history of Left ventricular dysfunction, Aortic stenosis and Ischaemic heart disease and concurrent medical conditions of Chronic kidney disease stage 3 and Pulmonary hypertension secondary remains a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report.

Case ID	Narrative (Complete)
	Most recent FOLLOW-UP information incorporated above includes: On 02-Jun-2022: Follow-up received included, added medical history, death details (cause of death and autopsy detail), concomitant medications, suspect drug action taken updated and narrative was updated
4.1(b)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 20-May-2022. The most recent information was received on 14-Jun-2022 and was forwarded to Moderna on 20-Jun-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician who performed postmortem examination, was received via the PMDA (Ref, 4.1(b)). On 14-Jun-2022, follow-up information was received from the physician who performed postmortem examination. On an unknown date, the patient received the 1st dose of a COVID-19 vaccine (product name unknown). On an unknown date, the patient received the 2nd dose of a COVID-19 vaccine (product name unknown). On an unknown date, body temperature before the vaccination: 35.8 degrees Celsius. On 18-May-2022, at 14:41, the patient received the 3rd vaccination with this vaccine. Around 23:00, a family member saw the patient watching TV in the living room. On 19-May-2022, around 01:00, the patient died. Around 07:40, in the living room, a family member found the patient was lying in a prone position and had already been in a state of cardio-respiratory arrest. A postmortem examination was performed, and based on the circumstances and detection of troponin T, the cause of death was considered to be cardiac death. No autopsy was conducted. No follow-up investigation will be made. Reporter comments continuation: The patient had cardiac diseases shown below, which may have had some influence; therefore, the occurrence of the adverse event is related to pathological factors of underlying diseases and complications. Since the patient died within 12 hours after the vaccination with this vaccine, the cause of death is related to the adverse event. The patient had cardiac diseases including history of myocardial infarction, chronic cardiac failure, and atrial fibrillation, and thus it is considered possible that this vaccine had some effect on the heart. Other factors may include history of myocardial infarction and chronic cardiac failure. Follow-up received on 14-JUN-2022 Updated: Patient Information, Other Relevant History, Lab Data, Event Information, Narrative, Reporter Comments Company Comment: The event developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 23-May-2022 and was forwarded to Moderna on 24-May-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 27-Feb-2022, the patient received the 3rd vaccination with this vaccine. On an unknown date, the patient experienced severe vasculitis. On 01-Mar-2022, diffuse alveolar haemorrhage and respiratory failure developed. Pyrexia of 38.3 degrees Celsius was noted. On 02-Mar-2022, the patient was referred to a nearby physician with a diagnosis of severe pneumonia. Computed tomography (CT) on admission showed diffuse infiltrative shadows mainly in the upper lung fields of both lungs. On 03-Mar-2022, the respiratory status was rapidly deteriorated. Since SpO2 became 70% to 80% even with oxygen of 15 L/min, intubation was performed, and artificial respiration was started. A large amount of foamy bloody sputum was aspirated via the intubation tube. The patient was diagnosed with diffuse alveolar hemorrhage. Steroid pulse therapy was started. On 15-Mar-2022, the mechanical ventilation was removed. On 22-Mar-2022, respiratory status worsened again, and the patient was intubated again. Pneumonia in both lower lobes was shown on the image. MRSA was detected by culture. Bacterial infection was observed. Antibiotic treatment was performed. On an unknown date, the patient suffered multiple organ failure. On 11-Apr-2022, the patient died. The outcome of severe pneumonia, and vasculitis was unknown. The outcome of diffuse alveolar hemorrhage, respiratory failure, multi-organ failure, and bacterial infection was reported as fatal. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This spontaneous case was reported by a consumer and describes the occurrence of PARKINSON'S DISEASE (Parkinson's disease), DEMENTIA (Dementia due to Parkinson's disease) and SEIZURE (Seizures) in a 75-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 065K21A and 030H21B) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect products included non-company products CARBIDOPA, LEVODOPA (DUOPA) for Parkinson's disease and TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) for COVID-19 vaccination. The patient's past medical history included Alcohol use in 2012 and Arterial stent insertion NOS. Concurrent medical conditions included Penicillin allergy, Non-smoker and Parkinson's disease. Concomitant products included LORAZEPAM for Anxiety, QUETIAPINE FUMARATE (SEROQUEL) for Anxiety and Prophylaxis, PARACETAMOL (TYLENOL) for Pain, TRAZODONE for Prophylaxis, VENLAFAXINE, MIDODRINE, MACROGOL 3350 (MIRALAX), VITAMIN D2 and LANSOPRAZOLE (PREVACID) for an unknown indication. On 16-Oct-2017, the patient started CARBIDOPA, LEVODOPA (DUOPA) (Percutaneous) at an unspecified dose. On 06-Feb-2021, the patient received first dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (Intramuscular) 1 dosage form. On 27-Feb-2021, received second dose of TOZINAMERAN (PFIZER BIONTECH COVID-19 VACCINE) (Intramuscular) dosage was changed to 1 dosage form. On 12-Dec-2021, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 03-May-2022, received fourth dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 04-May-2022, the patient experienced SEIZURE (Seizures) (seriousness criteria death and medically significant) and PYREXIA (Fever). On an unknown date, the patient experienced PARKINSON'S DISEASE (Parkinson's disease) (seriousness criteria death and medically significant), DEMENTIA (Dementia due to Parkinson's disease) (seriousness criteria death and medically significant) and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products). The patient was treated with Hospice care for Parkinson's disease; Hospice care for Dementia; Hospice care for Seizure and Hospice care for Pyrexia. The patient died on 12-May-2022. The reported cause of death was parkinson's disease and dementia due to parkinson's disease. It is unknown if an autopsy was performed. At the time of death, PYREXIA (Fever) had not resolved and INTERCHANGE OF VACCINE PRODUCTS (Interchange of vaccine products) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Body temperature: 104.3 f 104.3 F. Company Comment: This spontaneous case concerns a 75-year-old old male patient with concurrent condition of Parkinson’s Disease and relevant medical history of Arterial stent insertion who experienced the fatal unexpected, serious (medically significant) adverse event of special interest of Seizure and fatal, unexpected (medically significant) events of Parkinson’s disease and Dementia which occurred after receiving a dose of mRNA-1273 vaccine taken as fourth dose of COVID-19 immunization. He previously received mRNA-1273 approximately five months prior to the current dose but with no information on adverse event. Interchange of vaccine products is noted in this case as he received Pfizer BIONTECH COVID-19 vaccine as primary series of COVID-19 immunization. Patient has been taking several central nervous system medications and was admitted to hospice care 10

Case ID	Narrative (Complete)
	months prior to the events. Two days after the last dose of mRNA-1273 administration, he developed high grade fever (104.7 degrees Fahrenheit) and seizure. The clinical course was not provided but reported that patient died at home 8 days after the onset of seizure. Death occurred 9 days after second dose of mRNA-1273 vaccine. The cause of death was reported as Parkinson's disease and Dementia due to Parkinson's disease. It is unknown if an autopsy was performed. Dementia is a common manifestation of Parkinson's disease. Concomitant use of Venflaxine and Trazodone and occurrence of high grade fever are confounders for the event Seizure. Advanced age, medical history and low body mass index are also considered confounders for the fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b) [redacted]	This case was received via United Kingdom MHRA (Reference number: 4.1(b) [redacted]) on 24-May-2022 and was forwarded to Moderna on 24-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of VOMITING (vomiting), ABDOMINAL PAIN (tummy pain), FATIGUE (tiredness), COVID-19 (SARS-CoV-2 infection), DEATH (Death) and THIRST (Thirst) in a 98-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Suspected COVID-19 from 11-Apr-2022 to 18-Apr-2022. Previously administered products included for COVID-19 vaccination: SARS-COV-2 VIRUS since an unknown date, SARS-COV-2 VIRUS since an unknown date and SARS-COV-2 VIRUS since an unknown date. Past adverse reactions to the above products included No adverse reaction with SARS-COV-2 VIRUS, SARS-COV-2 VIRUS and SARS-COV-2 VIRUS. Concomitant products included PARACETAMOL for Gut pain. On 09-May-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 11-May-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced COVID-19 (SARS-CoV-2 infection) (seriousness criterion hospitalization) and DEATH (Death) (seriousness criteria death and hospitalization). On an unknown date, the patient experienced VOMITING (vomiting) (seriousness criterion hospitalization), ABDOMINAL PAIN (tummy pain) (seriousness criterion hospitalization), FATIGUE (tiredness) (seriousness criterion hospitalization) and THIRST (Thirst) (seriousness criterion hospitalization). The patient died on 14-May-2022. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, VOMITING (vomiting), ABDOMINAL PAIN (tummy pain), FATIGUE (tiredness) and THIRST (Thirst) outcome was unknown and COVID-19 (SARS-CoV-2 infection) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: no - negative covid-19 test (Negative) No - Negative COVID-19 test. The patient experienced Tummy pain, vomiting fluids, tiredness and thirsty Patient is not enrolled in clinical trial. The patient report doesn't relate to possible myocarditis or pericarditis. The treatment history was not provided. Company Comment: This regulatory authority case concerns a 98-year-old male patient, with no relevant medical history reported, who experienced unexpected, serious fatal events (death, hospitalization) AESI Covid19 (not laboratory confirmed) with vomiting, abdominal pain, fatigue and thirst, around 2 days after receiving a fourth dose of mRNA-1273. Clinical course and treatment, and circumstances surrounding death were not reported. The cause of death was also not reported. It is not known if an autopsy was performed. The patient's advanced age could be a contributory factor for the fatal outcome. The ongoing Covid-19 pandemic could be a contributory factor for Covid19. The benefit risk relationship of mRNA-1273 is not affected by this report. Event seriousness is assessed as per regulatory authority's report. Most recent FOLLOW-UP information incorporated above includes: On 26-May-2022: Follow-up information received on 26-May-2022 contains no new information.
4.1(b) [redacted]	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b) [redacted]) on 24-May-2022. The most recent information was received on 01-Jun-2022 and was forwarded to Moderna on 01-Jun-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of PNEUMONIA (Pneumonia) in an 82-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000018A) for COVID-19 vaccination. The patient's past medical history included Living in residential institution. Previously administered products included for COVID-19 vaccination: SARS-COV-2 VIRUS, SARS-COV-2 VIRUS and SARS-COV-2 VIRUS. Past adverse reactions to the above products included No adverse reaction with SARS-COV-2 VIRUS, SARS-COV-2 VIRUS and SARS-COV-2 VIRUS. Concurrent medical conditions included Hypertension, Vascular dementia, Atrial fibrillation, Type 2 diabetes mellitus and Chronic kidney disease stage 3. Concomitant products included BENPERIDOL, BISOPROLOL, GLICLAZIDE, LINAGLIPTIN and MIRTAZAPINE for an unknown indication. On 11-May-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 14-May-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PNEUMONIA (Pneumonia) (seriousness criteria death, hospitalization and medically significant). The patient was hospitalized on 14-May-2022 due to PNEUMONIA. The patient died on 15-May-2022. The reported cause of death was Pneumonia. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Covid-19 infection status was negative.. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient was generally well before receiving the vaccine. On 14-May-2022, a 999 ambulance was called, the emergency department provisional diagnosis was sepsis and the patient was admitted to the hospital. The patient's medicine was obtained in a care home.

Case ID	Narrative (Complete)
	The patient thought that this reaction did not occurred as a result of a mistake made in the administration of the vaccine. The patient's death occurred following administration of the fourth dose (2nd Booster). A post mortem of patient was not performed. No treatment information was provided by the reporter. Company Comment: This regulatory authority case concerns a 82 year male patient with history of living in residential institution, and having concurrent illness with type 2 Diabetes mellitus, CKD Stage 3, hypertension , Vascular dementia , atrial fibrillation (Past medical) , who experienced Serious (fatal , hospitalization , medically significant) , unexpected event of Pneumonia which occurred 3 days post vaccination with 4 dose of mRNA-1273 vaccine in the covid 19 vaccination series. Patient previously received 3 doses of SARS-COV-2 VIRUS vaccine (brand not provided) on an unknown date. The patient was hospitalized on 14-May-2022 due to pneumonia. The patient died on 15-May-2022. The reported cause of death was Pneumonia. A post mortem of patient was not performed. On an unknown date, SARS-CoV-2 test was negative. Details of treatment medications and results of other laboratories/diagnostic procedures were not reported. Patient was generally well before receiving the vaccine. The age of this patient plus living in residential institution with the above mentioned multiple medical conditions are considered confounders for the event. The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 01-Jun-2022: Follow-up received include : Historical vaccine (SARS COV-2 Vaccine) added, Cause of death (Pneumonia) added, Suspect Moderna Vaccine (Indication, action taken) updated, iNarrative updated.
4.1(b)	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) on 23-May-2022 and was forwarded to Moderna on 25-May-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (Ref, 4.1(b)). The vaccine recipient made regular visits to a respiratory clinic for interstitial pneumonia and pulmonary fibrosis, was being given oxygen at home, and was taking anticoagulants. On an unknown date, the patient received the 1st dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On an unknown date, the patient received the 2nd dose of non-company coronavirus modified uridine RNA vaccine (SARS-CoV-2). On 24-Mar-2022, the patient received the 3rd vaccination with this vaccine. On 29-Mar-2022, around 06:00, the patient suddenly experienced dyspnea and was raced to a medical institution. At 13:00, the patient was in a state of severe respiratory failure and was transferred urgently to the reporting hospital with NIPPV. On admission, the patient was intubated because Sp02 was 25.4. During intubation, bloody foamy sputum was discharged from the tube. The artificial respiration was started, and Sp02 was 44 torr even under 100% of oxygen. At 18:00, diffuse pulmonary alveolar haemorrhage was noted. Adverse reactions to this vaccine caused vasculitis at the pulmonary capillary level, and since the patient was taking anticoagulants, diffuse pulmonary alveolar haemorrhage was considered to develop. On 30-Mar-2022, at 16:15, the patient died. The outcome of respiratory failure and diffuse pulmonary alveolar haemorrhage was reported as fatal. The outcome of vasculitis was unknown. Follow-up investigation will be made. Company Comment: The events developed after the administration of ELASOMERAN and there is temporal relationship.
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) on 25-May-2022. The most recent information was received on 27-Jun-2022 and was forwarded to Moderna on 27-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of SEPSIS (sepsis rare bacteria,), PULMONARY EMBOLISM (longembolie), HYPOXIA (decline oxygen 63 percent), PNEUMONIA (died within 4 weeks of pneumonia), PYREXIA (hoge koorts), ARRHYTHMIA (cardiac arrhythmias, was super healthy before) and CHILLS (rillingen) in an 80-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3005789BS) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Product used for unknown indication: PFIZER BIONTECH COVID-19 VACCINE on 03-May-2021 and PFIZER BIONTECH COVID-19 VACCINE on 06-Jul-2021. Past adverse reactions to the above products included No adverse event with PFIZER BIONTECH COVID-19 VACCINE and PFIZER BIONTECH COVID-19 VACCINE. Concurrent medical conditions included Hypertension (No family history of hypertension) and Bronchitis (No family history of bronchitis). Concomitant products included DOPAMINE HYDROCHLORIDE (SEMINIET) for an unknown indication. On 04-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 18-Dec-2021, the patient experienced SEPSIS (sepsis rare bacteria,) (seriousness criterion death), PULMONARY EMBOLISM (longembolie) (seriousness criterion death), PNEUMONIA (died within 4 weeks of pneumonia) (seriousness criterion death), ARRHYTHMIA (cardiac arrhythmias, was super healthy before) (seriousness criterion death) and FEBRILE CONVULSION (febrile seizures). On 19-Dec-2021, the patient experienced HYPOXIA (decline oxygen 63 percent) (seriousness criterion death), PYREXIA (hoge koorts) (seriousness criterion death) and CHILLS (rillingen) (seriousness criterion death). The patient died on 02-Jan-2022. The reported cause of death was no more oxygen and lungs full of scars, no more alveoli. An autopsy was not performed. At the time of death, FEBRILE CONVULSION (febrile seizures) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-Dec-2021, Oxygen saturation: 63 63 %. On 18-Dec-2021, longfoto: it turned out there were a lot of scars in his lun it turned out there were a lot of scars in his lungs. On 19-Dec-2021, SARS-CoV-2 test: negative (Negative) Negative. Concomitant medication was not provided. Treatment information was not provided. Company Comment: This regulatory case concerns an 80-year-old, male patient with current medical history of Hypertension and Bronchitis, who experienced the unexpected, fatal AESI of Pulmonary embolism and Arrhythmia, unexpected, fatal outcome of Sepsis, Hypoxia, Pneumonia, Pyrexia and Chills and unexpected, non-serious AESI of Febrile convulsion. The event Sepsis, Pulmonary embolism, Pneumonia, Arrhythmia and Febrile convulsion occurred 14 days after administration of an unknown dose of mRNA-1273. The event Hypoxia, Pyrexia and Chill occurred 15 days after administration of an unknown dose of mRNA-1273. The patient had two initial doses of Pfizer approximately 5 months prior, the interval between the two doses is 64 days. The patient expired 29 days after vaccination of mRNA-1273, the reported cause of death was hypoxia and absence of alveoli in the lungs with multiple scarring, no autopsy was performed. On December 19, 2021, SARS-CoV-2 test was done which yielded a negative result. The patient's medical history of Hypertension and Bronchitis could be confounders to the events Pneumonia, Pulmonary embolism and Hypoxia. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness retained as per Regulatory Authority's report.

Case ID	Narrative (Complete)
	Most recent FOLLOW-UP information incorporated above includes: On 27-Jun-2022: Significant follow up appended, Updated autopsy from Unknown to No. Laboratory data added.
4.1(b)	This spontaneous case was reported by a patient family member or friend and describes the occurrence of HEPATIC CIRRHOSIS (The callers Mother passed away from Cirrhosis of the Liver and Dementia) and DEMENTIA (The callers Mother passed away from Cirrhosis of the Liver and Dementia) in an 87-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Dementia and Liver cirrhosis. On 29-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On 30-Aug-2021, received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced HEPATIC CIRRHOSIS (The callers Mother passed away from Cirrhosis of the Liver and Dementia) (seriousness criteria death and medically significant) and DEMENTIA (The callers Mother passed away from Cirrhosis of the Liver and Dementia) (seriousness criteria death and medically significant). The reported cause of death was cirrhosis of the liver and Dementia. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not provided. Treatment information was not provided. Company comment: This is a spontaneous case concerning a 87-year-old, female patient with concurrent medical conditions of cirrhosis of the liver and dementia and with vaccine history of receiving first, second and third dose of mRNA-1273 vaccine, who experienced the unexpected serious (medically significant and death) AESI event of hepatic cirrhosis and the unexpected serious (medically significant and death) event of dementia. The events hepatic cirrhosis and dementia occurred before the patient received first, second and third dose of mRNA-1273 vaccine administration. It was reported that the patient died from cirrhosis of the liver and dementia approximately 66 days after the patient received third dose of mRNA-1273 vaccine administration. It was unknown if autopsy was performed and if the cause of death was determined by a physician. The patient's age remain confounder for the event dementia. The concurrent medical conditions of cirrhosis of the liver and dementia remain confounders for the events. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) (Patient Link).
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 27-May-2022 and was forwarded to Moderna on 27-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PLEURAL EFFUSION (Respiratory difficulty, massive left pleural effusion of heteroplastic genesis. Left pleural biopsy reveals non-small cell lung cancer. Subsequent clinical worsening up to death), NON-SMALL CELL LUNG CANCER (Respiratory difficulty, massive left pleural effusion of heteroplastic genesis. Left pleural biopsy reveals non-small cell lung cancer. Subsequent clinical worsening up to death) and DYSPNOEA (Respiratory difficulty, massive left pleural effusion of heteroplastic genesis. Left pleural biopsy reveals non-small cell lung cancer. Subsequent clinical worsening up to death) in an 89-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214024 sc 09/02/2022) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Comirnaty ((lotto ET1831 sc 30/06/21)) on 20-Mar-2021 and Comirnaty ((lotto EW2246 sc 31/07/21)) on 10-Apr-2021. Past adverse reactions to the above products included No adverse event with Comirnaty and Comirnaty. On 27-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 10-Dec-2021, the patient experienced PLEURAL EFFUSION (Respiratory difficulty, massive left pleural effusion of heteroplastic genesis. Left pleural biopsy reveals non-small cell lung cancer. Subsequent clinical worsening up to death) (seriousness criterion death), NON-SMALL CELL LUNG CANCER (Respiratory difficulty, massive left pleural effusion of heteroplastic genesis. Left pleural biopsy reveals non-small cell lung cancer. Subsequent clinical worsening up to death) (seriousness criterion death) and DYSPNOEA (Respiratory difficulty, massive left pleural effusion of heteroplastic genesis. Left pleural biopsy reveals non-small cell lung cancer. Subsequent clinical worsening up to death) (seriousness criterion death). The reported cause of death was Non-small cell lung cancer, Dyspnea and Unilateral pleural effusion. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In 2021, Blood test: normal (normal) was in good health with blood tests without any altered values. No concomitant medication information was provided. No treatment medications were provided Company Comment: This is a regulatory case concerning an 89-year-old female patient with no medical history reported, who had a fatal outcome with unexpected serious events of Non-small cell lung cancer confirmed by left pleural biopsy, Dyspnoea, and Pleural effusion, which occurred 13 days after receiving a dose of mRNA-1273 as the third dose of COVID-19 vaccine. Patient had received 2-dose primary series of Comirnaty COVID-19 vaccine with no reported adverse event, approximately 8 months prior to mRNA-1273 vaccination (Interchange of vaccine products). It was reported that the patient had was in good health with unremarkable blood tests before vaccination. Then, patient experienced respiratory difficulty and noted to have massive left pleural effusion of heteroplastic genesis. Patient underwent left pleural biopsy which revealed non-small cell lung cancer. However, patient's clinical condition worsen and led to death. It was unknown whether an autopsy was performed. The cause of death was not reported. No further details about the treatments were provided. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness assessed as per Regulatory Authority reporting. Most recent FOLLOW-UP information incorporated above includes:

Case ID	Narrative (Complete)
	On 02-Jun-2022: Follow up contains non significant information. On 06-Jun-2022: Follow-up contains non-significant information.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 30-May-2022 and was forwarded to Moderna on 30-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBRAL HAEMORRHAGE (cerebral hemorrhage) in a 68-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 042G21A) for COVID-19 vaccination. Previously administered products included for COVID-19 immunisation: Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca. Past adverse reactions to the above products included No adverse event with Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])COVID-19 Vaccine AstraZeneca suspension for injectionCOVID-19 Vaccine AstraZeneca. Concurrent medical conditions included Arterial hypertension and Disease Parkinson's. On 16-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 19-Dec-2021, the patient experienced CEREBRAL HAEMORRHAGE (cerebral hemorrhage) (seriousness criteria death and medically significant). The patient died on 18-May-2022. The reported cause of death was Cerebral haemorrhage. It is unknown if an autopsy was performed. No allergies was reported.No concomitant information was provided. On 16-DEC-21 patient had 3rd vaccination with Moderna and previously had Astra Zeneca twice.On 19-DEC-21 Stem ganglia hemorrhage occurred extending into the right thalamus and right crus cerberi with subfalxial herniation, followed by coma GCS 6, surgery with hematoma evacuation on 19-DEC-21.Patient had hemiplegia left, neglect left. Neurogenic dysphagia, unable to speak, communication partly due to Head nodding possible during the course, then also awake for weeks. Patient had Food PEG. Rez. Aspiration pneumonias until death on 18-MAY-22Treatment medication details was not provided. Company comment: This regulatory authority case concerns a 68 years old male patient with concurrent medical history of Arterial hypertension, who experienced the unexpected fatal serious (seriousness criterion death) event of cerebral hemorrhage, which occurred 3 days after third dose of mRNA-1273 vaccine. The patient was noted to have received two doses with VAXZEVRIA COVID-19 VACCINE (COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) prior to mRNA-1273 (Interchange of vaccine products). It is reported that On 19-DEC-21 patient had Stem ganglia hemorrhage occurred extending into the right thalamus and right crus cerberi with subfalxial herniation and patient GCS is 6, on same day surgery with hematoma evacuation was done, Patient had hemiplegia left. Neurogenic dysphagia, unable to speak, communication partly due to Head nodding possible during the course, then also awake for weeks. Patient had Food PEG. Patient had Aspiration pneumonias until death. The patient died on 18-May-2022. The reported cause of death was Cerebral hemorrhage. It is unknown if an autopsy was performed. Concurrent medical condition Arterial hypertension is confounding for the event. The benefit-risk relationship of mRNA-1273 is not affected by this report. The event was assessed as serious as per Regulatory Authority´s report.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in an 81-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Renal dialysis (long-term renal dialysis). Previously administered products included for Product used for unknown indication: ASTRAZENECA COVID-19 VACCINE (first dose) on 16-Jun-2021 and ASTRAZENECA COVID-19 VACCINE (Second dose) on 01-Oct-2021. Past adverse reactions to the above products included No adverse event with ASTRAZENECA COVID-19 VACCINE and ASTRAZENECA COVID-19 VACCINE. Concurrent medical conditions included Hypertension. On 29-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 22-Apr-2022, received fourth dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. Death occurred on 23-Apr-2022 The patient died on 23-Apr-2022. The reported cause of death was suspected adverse reaction. An autopsy was not performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Patient age was reported as 81.3. The patient did not go for medical consultations, diagnosis and treatments. No concomitant medication information was reported.No treatment medication was reported.On 11 May 2022, a family member reported a case of death due to suspected adverse reaction after COVID-19 vaccination.The patient received the first and second doses of AZ and Moderna Basic Booster in hospital. There was no discomfort after inoculation. On 22 April 2022, patient was vaccinated with the fourth dose of Moderna (Booster) after renal dialysis in Hospital. There was no discomfort after administration, and returned home and moved and took rest normally. In the morning on 23 April 23, the next day, when the family member called the patient to have breakfast, it was found that the patient was cold and had no breathing and heartbeat. The patient was not dissected. The WWID number was reported as 4.1(b) Company comment: This regulatory authority case concerns a 81 years old male patient with no relevant medical history reported, who experienced the unexpected fatal serious (seriousness criterion death) event of death , which occurred one day after fourth dose of mRNA-1273 vaccine. The patient was noted to have received two doses with ASTRAZENECA COVID-19 VACCINE (COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) 6 months 21 days prior to mRNA-1273 (Interchange of vaccine products).It is reported that after renal dialysis in Hospital, vaccinated with fourth dose of Moderna (Booster), there was no discomfort after administration, and returned home and moved and took rest normally. In the morning on 23 April 23, the next day, when the family member called the patient to have breakfast, it was found that the patient was cold and had no breathing and heartbeat. The reported cause of death was suspected adverse reaction. An autopsy was not performed. The patient died on April 23, 2022. Patient funeral affairs have been completed smoothly. Past medical history of Renal dialysis (long-term renal dialysis) is risk factor for the event death. .The benefit-risk relationship of mRNA-1273 is not affected by this report. The event were assessed as serious as per Regulatory Authority´s report.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DECREASED APPETITE (Loss of appetite) in an 88-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination.

Case ID	Narrative (Complete)
	The patient's past medical history included Renal dialysis (for 14 years with no diabetes or hypertension.). On 29-Apr-2022 at 9:30 AM, the patient received fourth dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 12-May-2022, the patient experienced DECREASED APPETITE (Loss of appetite) (seriousness criterion death). The patient died on 12-May-2022. The reported cause of death was loss of appetite. It is unknown if an autopsy was performed. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. The patient had no diabetes or hypertension. The patient was inoculated with a half dose of Moderna Booster, and later his body was normal. In the morning on May 12, there was no abnormality too. But from noon, patient was unable to eat. At 2:30 p.m., patient had shortness of breath. However, the caregiver said that sometimes the patient had such problem previously, so no action was taken. At 4:30 p.m., it was found that the patient sprayed foams from the mouth and could not be woken up. Granddaughter of the patient was carried out CPR immediately and the patient was sent to the hospital, but with OHCA. The first aid was ineffective, and the patient was declared dead. On 17-May-2022: At 14:30, a phone call was made to the family member, and currently the funeral affairs are being processed. It is planned to make an application for relief for harm from drug, and the family member was told to prepare the documents, and the application can be accepted within 2 years, and the family member can accept it. The death certificate is to be made up and uploaded. No treatment medications were reported. The Worldwide UID was reported as T[redacted]. Company Comment: This regulatory case concerns an 88-year-old, male patient on long-term renal dialysis, who experienced the unexpected, fatal event of Decreased appetite. The event occurred 13 days after receiving mRNA-1273 as fourth COVID-19 vaccine dose. The patient had shortness of breath on the same day, but no action done at the time since according to the caregiver this would usually be observed on the patient. Two hours after, the patient had foaming at the mouth and could not be awakened. Cardiopulmonary resuscitation was administered by a relative and the patient was immediately brought to a hospital. Upon arrival, he was declared dead from out-of-hospital cardiac arrest. It is unknown if autopsy was performed. The patient's advanced age and long-term renal dialysis, suggestive of chronic kidney disease, could be a confounder for the event and for the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event's seriousness was assessed as per Regulatory Authority's report.
[redacted]	This regulatory authority case was reported by an other health care professional and describes the occurrence of DYSPNOEA (Dyspnea and low saturation) and OXYGEN SATURATION DECREASED (Dyspnea and low saturation) in an 85-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Hypertension, Gout, Tuberculosis since 05-May-2022 and Cerebellar embolism since 12-Apr-2022. On 17-May-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-May-2022, the patient experienced DYSPNOEA (Dyspnea and low saturation) (seriousness criterion death) and OXYGEN SATURATION DECREASED (Dyspnea and low saturation) (seriousness criterion death). The patient was treated with HYDROCORTISONE at a dose of 2 vials ST IVP and IPRATROPIUM BROMIDE, SALBUTAMOL SULFATE (COMBIVENT) at a dose of Combivent UDV Inhalation Solution 2.5mg/bot 2 bots INHL.21:15:. The reported cause of death was Dyspnea and Oxygen saturation low. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Oxygen saturation: 93% (Low) 93% At that time, the HPO2 was 93%, and after check-in., 95% (normal) 95% it slowly rose to about 95%. and 82% (Low) 82% HPO2 was 82%.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant medications were not reported. On May 17, 2022 first dose of Moderna vaccine was inoculated in the morning. Due to dyspnea and low Saturation, the patient went to the emergency room of Hospital at 20:50 for consultations and treatments. After consultations and diagnosis. The patient died of respiratory failure. On May18, 2022: The patient came to the emergency room on April 12, 2022 for consultations and treatments due to dizziness. The patient was diagnosed with cerebellar embolism and was admitted to ICU. On April 30, the patient was transferred to the general ward. It was originally planned to transfer the patient to a long-term care center for follow-up and care, but on May 4, TB was suspected and medication was started. On May 5, the TB was diagnosed and confirmed. The patient was discharged in the morning on May 17. The family member first took the patient to Hospital to receive the first dose of Medena, and went to Care Center at about 11AM. The patient was a little asthmatic at the time of check-in, but the family member said that it was needed to send the patient to the hospital for consultations and treatment first. In the evening, the patient began to have asthma again. Therefore, the institution sent the patient to the emergency room of Hospital at 20:00 for consultations and treatments. The patient died of respiratory failure at 21:15. No first aid was carried out (with DNR signed). With regard to VICP, the family member was under consideration, and currently there was the intention that no dissection will be carried out. It is expected that the funeral will be held next week. Certificate of death diagnosis: Respiratory failure/pneumonia. The Worldwide UID was reported as [redacted] Company comment: This regulatory case concerns an 85-year-old male patient, with reported medical history of Hypertension, Cerebellar embolism and Tuberculosis who experienced unexpected, serious, fatal events of Dyspnoea, and Oxygen saturation decreased, the same day after receiving mRNA-1273 vaccine as a first dose. In the evening of the vaccination date, the patient was reported to have Dyspnoea and Low Oxygen saturation prompting ED consult. The patient was started with Solu-Cortef (Hydrocortisone) 100 mg/vial injection 2 vials ST IVP and Combivent UDV Inhalation Solution 2.5 mg/bottle 2 bottles via inhalation. Few hours after, the patient died due to respiratory failure. No first aid was carried out since a DNR was signed. The reported cause of death was dyspnea and oxygen saturation low, however, there is no intention that an autopsy will be carried out. The patient's past medical history of

Case ID	Narrative (Complete)
	Cerebellar embolism and concurrent medical history of Hypertension and Tuberculosis could be considered as confounders for the events. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of HEADACHE (Headache), MYALGIA (Muscle pain), PYREXIA (Fever), VACCINATION SITE ERYTHEMA (Reddening vaccination site), VACCINATION SITE SWELLING (Vaccination site swelling) and VACCINATION SITE PAIN (Vaccination site pain) in an 81-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Chronic kidney disease, Pneumoconiosis, Pneumothorax and Gout. On 03-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 06-Jul-2021, the patient experienced HEADACHE (Headache) (seriousness criterion death), MYALGIA (Muscle pain) (seriousness criterion death), PYREXIA (Fever) (seriousness criterion death), VACCINATION SITE ERYTHEMA (Reddening vaccination site) (seriousness criterion death), VACCINATION SITE SWELLING (Vaccination site swelling) (seriousness criterion death) and VACCINATION SITE PAIN (Vaccination site pain) (seriousness criterion death). The patient died on 23-Apr-2022. The reported cause of death was Pneumonia, Headache, Muscle pain, Fever, reddening vaccination site, Vaccination site swelling and Vaccination site pain. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant product was not provided by the reporter. The patient received vaccine on July 3, 2021 and later developed redness, swelling, heat, pain and general soreness at the vaccination site, and on July 6, respiratory asthma and fever occurred, and the patient went to Hospital for consultations and treatments, and later was referred to Hospital and hospitalized for 16 days. On September 20, the patient was hospitalized again till October 6. During the period, the patient was hospitalized in Hospital from December 5 to December 9. All of hospitalizations were due to respiratory distress. The patient was hospitalized between January 14 and January 26, 2022 and on April 8. The patient died of pneumonia on April 23, 2022. On 10-May-2022 the son of the patient said that the patient died on April 23 and he wanted to report the case and apply for relief for harm from drug, and assistance was given. Treatment information was not provided. The Worldwide UID number was reported as 4.1(b) Company Comment: This fatal regulatory authority case concerns 81-year-old male patient, with medical history of pneumoconiosis and pneumothorax, who experienced the unexpected, serious (due to death) events of HEADACHE, MYALGIA, PYREXIA, VACCINATION SITE ERYTHEMA, VACCINATION SITE SWELLING and VACCINATION SITE PAIN, 3 days after the first dose of mRNA-1273 vaccine. As per narrative of the source document, he experienced redness, swelling, heat, pain and general soreness at the vaccination site, and after 3 days he consulted due to respiratory asthma and fever. He was hospitalized for 16 days, and during the following 5 months he had 4 hospitalizations due to respiratory distress. The cause of death was pneumonia and it occurred approximately 10 months after vaccination. It is unknown if an autopsy was performed. The history of pneumoconiosis and pneumothorax remain as confounders for the cause of death The benefit-risk relationship of mRNA-1273 is not affected by this report. Event´s seriousness assessed as per Regulatory Authority's report.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in an 80-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 2100696_1110525) for COVID-19 vaccination. The patient's past medical history included Renal dialysis (history of chronic renal dialysis). Previously administered products included for Product used for unknown indication: AZ vaccine on 17-Jun-2021 and AZ vaccine on 23-Sep-2021. Past adverse reactions to the above products included No adverse event with AZ vaccine and AZ vaccine. On 20-Jan-2022, the patient received third dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 05-May-2022, received fourth dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. Death occurred on 05-May-2022 The patient died on 05-May-2022. The cause of death was not reported. An autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medication information was provided. On 05-May-2022, the patient received the fourth dose of vaccine when she went to undergo renal dialysis. After returning home, she had physical discomfort and weak legs and vomited water, but she was still conscious. After she lied in bed for rest, the family member found that she had no vital signs. No visible cause of trauma leading to death was found in autopsy and there was a renal dialysis tube on the right shoulder. The family member suspected that it was associated with the vaccination. In order to clarify the cause of death and mode of death, it was requested for anatomical anatomy and examination. On May 13, preliminary investigation report in judicial anatomy was showed intracranial hemorrhage, head injury and possible fall). The worldwide UID was reported as 4.1(b) No treatment was provided. Company Comment: This regulatory case concerns an 80-year-old female patient on Renal dialysis, who experienced the unexpected serious event of Death on the same day after receiving mRNA-1273 vaccine given as fourth dose in the COVID-19 vaccination series. Patient was administered with the vaccine when she had her dialysis. Upon returning home, she presented with physical discomfort, weak legs, and vomiting. She then went for bed rest and was later found without vital signs. Autopsy report showed no visible cause of trauma leading to death. Judicial anatomy evaluation revealed preliminary findings of intracranial hemorrhage, head injury and a possible fall. Patient previously received 2 doses of non-company brand COVID-19 vaccine from AstraZeneca and an mRNA-1273 vaccine given as third dose in the series prior to current mRNA-1273 vaccine. Concurrent Renal dialysis possibly in the presence of complications could be considered as a confounder. The benefit-risk relationship of mRNA-1273 is not affected by this report. Case seriousness was assessed as per Regulatory Authority report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 26-May-2022 and was forwarded to Moderna on 26-May-2022.

Case ID	Narrative (Complete)
	This regulatory authority case was reported by a pharmacist and describes the occurrence of COVID-19 PNEUMONIA (COVID-19 pneumonia) and VACCINATION FAILURE (Vaccine failure) in a 77-year-old male patient who received mRNA-1273 (Spikevax) (batch nos. 3001532 and 3002339) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Co-suspect product included non-company product TOZINAMERAN (COMIRNATY) for COVID-19 vaccination. The patient's past medical history included Hypertensive retinopathy, Paroxysmal atrial fibrillation (ANTICOAGULATED), Type 2 diabetes mellitus, Chronic kidney disease stage 4, Hypertension arterial, Stroke and Dyslipidaemia. On 09-Apr-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 20-May-2021, received dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to 1 dosage form. On 28-Jan-2022, the patient received third dose of TOZINAMERAN (COMIRNATY) (unknown route) 1 dosage form. On 13-Feb-2022, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria death, hospitalization and medically significant), VACCINATION FAILURE (Vaccine failure) (seriousness criteria death, hospitalization and medically significant) and COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine). The patient died on 16-Feb-2022. The reported cause of death was COVID-19 pneumonia and vaccine failure. It is unknown if an autopsy was performed. At the time of death, COVID-19 IMMUNISATION (Revaccination with different COVID-19 vaccine) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 31-Jan-2022, SARS-CoV-2 test positive: positive (Positive) Positive. On 08-Feb-2022, SARS-CoV-2 test positive: positive (Positive) Positive. On 13-Feb-2022, Chest X-ray: cardiomegaly, pinched scf, interstitial infiltrate cardiomegaly, pinched SCF, interstitial infiltrate with increased vascular pattern, congestive hilia.. On 14-Feb-2022, Chest X-ray: infiltrates and signs of pulmonary congestion infiltrates and signs of pulmonary congestion. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication information was reported. No treatment medication was reported. Company Comment: This is a Regulatory Authority case concerning a 77-year-old male patient, with relevant medical history of paroxysmal atrial fibrillation, type 2 diabetes mellitus, chronic kidney disease stage 4, hypertension arterial, stroke and dyslipidaemia, who experienced the unexpected, serious (due to medically significant and hospitalization) fatal events of COVID-19 pneumonia (AESI) and Vaccination failure, fatal events and patient´s death occurred approximately 8 months and 3 weeks after a dose (probably second dose) of mRNA-1273 vaccine. Probable first and second dose of mRNA-1273 vaccine were administered with an interval of 40 days (Inappropriate schedule of vaccine administered). Revaccination with different COVID-19 vaccine is also reported, as third dose of COVID-19 vaccination schedule was administered with Pfizer vaccine, 8 months after a dose of mRNA-1273, and 16 days before the events. Comirnaty remains as a co-suspect product. The reported cause of death was COVID-19 pneumonia and vaccine failure. It is unknown if an autopsy was performed. Patient´s medical history could be a confounder for fatal outcome. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 30-May-2022 and was forwarded to Moderna on 30-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of HYPOXIC-ISCHAEMIC ENCEPHALOPATHY (Cerebral hypoxic encephalopathy) and CARDIAC ARREST (Cardiac arrest) in a 79-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000037A) for COVID-19 vaccination. The patient's past medical history included COVID-19 immunisation (Spikevax dos 3) on 27-Nov-2021, COVID-19 immunisation (Spikevax dos 2) on 23-Mar-2021 and COVID-19 immunisation (Spikevax dos 1) on 23-Feb-2021. Concurrent medical conditions included Cervical dystonia and Depression. On 28-Apr-2022, the patient received fourth dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 28-Apr-2022, the patient experienced HYPOXIC-ISCHAEMIC ENCEPHALOPATHY (Cerebral hypoxic encephalopathy) (seriousness criteria death and life threatening) and CARDIAC ARREST (Cardiac arrest) (seriousness criteria death and life threatening). The patient died on 06-May-2022. The reported cause of death was cerebral hypoxic encephalopathy and Cardiac arrest. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was reported. No treatment medications was reported. Company comment This regulatory authority fatal case concerns a 79-year-old female patient, with medical history of Cervical dystonia and Depression, who experienced the unexpected serious fatal and life-threatening events of HYPOXIC-ISCHAEMIC ENCEPHALOPATHY (AESI) and CARDIAC ARREST, which started on the same day after receiving the fourth dose of mRNA-1273 vaccine. Patient died 8 days after receiving dose and those events started. The reported cause of death was cerebral hypoxic encephalopathy and Cardiac arrest. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 31-May-2022 and was forwarded to Moderna on 31-May-2022. This regulatory authority case was reported by a physician and describes the occurrence of LUNG INFILTRATION (LUNG COMPLICATION (LUNG CHANGES AS IN VIRAL INFECTION)) in a 78-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3001177) for COVID-19 vaccination.

Case ID	Narrative (Complete)
	The patient's past medical history included Progressive multifocal leukoencephalopathy (PML after Twice Infusions Mabthera 2008) in 2008, COVID-19 immunisation (Spikevax dose 1, batch number: 300042722) on 23-Feb-2021, Pneumonitis (Suspected pneumonitis during Methotrexate about 20 years ago,), Breast cancer and Radiation therapy. Concurrent medical conditions included Rheumatoid arthritis, Cognitive disorder and Ulcerative colitis. On 23-Mar-2021, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 08-Apr-2021, the patient experienced LUNG INFILTRATION (LUNG COMPLICATION (LUNG CHANGES AS IN VIRAL INFECTION)) (seriousness criterion death). The patient died on 08-Apr-2021. The reported cause of death was 10035742. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) negative. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. No concomitant medication reported. No treatment medication reported. Company Comment: This regulatory authority case concerns a 78-year-old, female patient with relevant current condition of Rheumatoid arthritis, and medical history of Pneumonitis, Breast cancer, Radiation therapy and Progressive multifocal leukoencephalopathy after Rituximab treatment who experienced the unexpected, fatal event of Lung infiltration which occurred 16 days after administration of second dose of mRNA-1273. Patient has received the first dose of mRNA-1273, 28 days prior to the second dose with no reported information on adverse event. Lung infiltration was further described as lung complication with lung changes seen in viral infection. A COVID-19 test was performed on unspecified date which yielded a negative result. Patient died on the same day that the event started. It is unknown if an autopsy was performed however the cause of death was reported as Pneumonitis. Patient´s advanced age, concurrent condition and medical history remain as confounders for the event Pneumonitis and the fatal outcome. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per regulatory authority's report.
4.1(b) [redacted]	This literature-non-study case was reported in a literature article and describes the occurrence of RESPIRATORY FAILURE (Respiratory failure) and INTERSTITIAL LUNG DISEASE (Interstitial lung disease (ILD) exacerbation) in a 72-year-old male patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. LITERATURE REFERENCE: Ehteshami-Afshar S, Raj R. COVID-19 mRNA vaccines and ILD exacerbation: causation or just a temporal association?. Am J Respir Crit Care Med. 2022 Concurrent medical conditions included Interstitial lung disease and Pleuroparenchymal fibroelastosis (Patient had slowly progressive pleuro-parenchymal fibroelastosis). On an unknown date, the patient received second dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced RESPIRATORY FAILURE (Respiratory failure) (seriousness criteria death, medically significant and life threatening) and INTERSTITIAL LUNG DISEASE (Interstitial lung disease (ILD) exacerbation) (seriousness criteria death and medically significant). The patient was treated with TOCILIZUMAB for Adverse event, at an unspecified dose and frequency. The reported cause of death was Respiratory failure and interstitial lung disease (ild) exacerbation. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Bronchoscopy: normal (normal) Workup including bronchoscopy did not reveal any causes for the exacerbation. On an unknown date, Computerised tomogram: diffuse ground glass opacities with patchy areas Diffuse ground glass opacities with patchy areas of consolidation was found.. On an unknown date, Physical examination: normal (normal) did not reveal any causes for the exacerbation. For mRNA-1273 (Spikevax) (Unknown), the reporter considered RESPIRATORY FAILURE (Respiratory failure) and INTERSTITIAL LUNG DISEASE (Interstitial lung disease (ILD) exacerbation) to be related. Patient presented with symptoms like cough, dyspnea, and hypoxia, 5 days after the vaccination. Patient progressed rapidly to respiratory failure requiring invasive mechanical ventilation. No response was found upon high dose corticosteroids and tocilizumab and eventually experienced death. No concomitant medications were reported. Company comment: This is a fatal literature non-study case concerning a 72-year-old, male patient with slowly progressive pleuro-parenchymal fibroelastosis, who experienced the unexpected, serious events of respiratory failure (fatal, life – threatening and medically significant) and interstitial lung disease (fatal and medically significant). The events occurred 5 days after the administration a dose of mRNA-1273 vaccine, reported as second dose of his COVID – 19 immunization schedules; no information about previous vaccination schedule was provided. The report stated that the patient experienced cough, dyspnoea and hypoxia. CT showed new diffuse ground glass opacities with patchy areas of consolidation. A detailed history, physical exam, and workup including bronchoscopy did not reveal any causes for the exacerbation. He progressed rapidly to respiratory failure requiring invasive mechanical ventilation. He did not respond to high dose corticosteroids and tocilizumab, and eventually died. It is unknown if an autopsy was performed and death date. No further details were provided for medical review. Patient´s mentioned medical history remains as confounder. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 03-Jun-2022: Follow up received by safety on 03-Jun-2022 has Email with FTA and contains significant information reporters information, literature information, additional event, seriousness criteria and death details updated.
4.1(b) [redacted]	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b) [redacted]) on 02-Jun-2022. The most recent information was received on 14-Jun-2022 and was forwarded to Moderna on 14-Jun-2022.

Case ID	Narrative (Complete)
	This regulatory authority case was reported by an other health care professional and describes the occurrence of AORTIC STENOSIS (Aortic stenosis), CHRONIC KIDNEY DISEASE (Chronic kidney disease) and PNEUMONIA (Pneumonia) in an 87-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) (batch no. 000081A) for COVID-19 vaccination. Patient did not had symptoms associated with COVID-19 and not had COVID-19 test. The patient's past medical history included Nose bleeds and Heart failure. Concurrent medical conditions included Ischaemic heart disease, Aortic stenosis (Moderate/severe aortic stenosis), Chronic kidney disease stage 3 and Pulmonary hypertension secondary. Concomitant products included APIXABAN from 01-May-2019 to an unknown date, ATORVASTATIN from 06-Dec-2021 to an unknown date, FINASTERIDE from 04-Feb-2016 to an unknown date, LANSOPRAZOLE from 06-Sep-2021 to an unknown date, TAMSULOSIN from 14-Apr-2015 to an unknown date, HYDROXOCOBALAMIN and EPOETIN NOS for an unknown indication. On 27-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 28-Apr-2022, after starting mRNA-1273 (Moderna CoviD-19 Vaccine), the patient experienced PNEUMONIA (Pneumonia) (seriousness criteria death, hospitalization and medically significant). On an unknown date, the patient experienced AORTIC STENOSIS (Aortic stenosis) (seriousness criteria death, hospitalization and medically significant) and CHRONIC KIDNEY DISEASE (Chronic kidney disease) (seriousness criteria death, hospitalization and medically significant). The patient died on 11-May-2022. The reported cause of death was Pneumonia, Elderly, Heart failure, Chronic kidney disease and Aortic stenosis. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In October 2021, Echocardiogram: mild lv impairment Mild LV Impairment. For mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. It was reported that the patient experienced no symptoms immediately post vaccination. Patient had been admitted in and out of hospital prior to vaccine with nose bleeds and heart failure. Patient was taken to hospital on 28-Apr-2022 and died on the 11-May-2022 from pneumonia/ aortic stenosis with heart failure, chronic kidney disease, frailty of old age. Patient was not enrolled in clinical trial. The report did not related to possible blood clots or low platelet counts, possible myocarditis or pericarditis. No immediate symptoms were experienced by the patient post vaccination. Recent test was unavailable for COVID-19 infection status. No treatment details were reported. Company comment: This Regulatory Authority case concerns an 87-year-old male patient with relevant medical history of Heart failure, Ischaemic heart disease, Aortic stenosis (Moderate/Severe aortic stenosis), Chronic kidney disease stage 3 (CKD stage 3) and Pulmonary hypertension secondary, who experienced the unexpected serious events of Aortic stenosis, Chronic kidney disease, and Pneumonia reported as medically significant and led to hospitalization and fatal outcome. The events Aortic stenosis, and Chronic kidney disease occurred on unknown dates after receiving mRNA-1273 vaccine given as 4th dose in the COVID-19 vaccination series while the event Pneumonia occurred 1 day after administration of the same vaccine. Patient had been admitted several times in the hospital prior to vaccination for nose bleeds and heart failure. Patient had no adverse event immediately post vaccination. However, the next day of vaccination, he was brought to the hospital and died 13 days later. Cause of death was reported as Pneumonia, Elderly, Heart failure, Chronic kidney disease and Aortic stenosis. An autopsy was not performed. No information was provided on any other doses of COVID-19 vaccination. The relevant medical history of Heart failure, Ischaemic heart disease, Aortic stenosis (Moderate/Severe aortic stenosis), Chronic kidney disease stage 3 (CKD stage 3), Pulmonary hypertension secondary and the advanced age of the patient could be considered as contributory risk factors for the events. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report. Most recent FOLLOW-UP information incorporated above includes: On 14-Jun-2022: Significant Follow-Up: Updated patient's medical history, action taken of suspect drug, seriousness of events, added cause of death, concomitant drugs and deleted events (Epistaxis, Aortic stenosis).
4.1(b) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 03-Jun-2022 and was forwarded to Moderna on 03-Jun-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of ASPIRATION (Vomit inhalation), VOMITING (Vomiting) and PNEUMONIA ASPIRATION (Pneumonia aspiration) in a 74-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000080A) for COVID-19 vaccination. The patient's past medical history included Emesis on 30-Sep-2021. Concurrent medical conditions included Acromegaly, Anxiodepressive syndrome, Arterial hypertension, Breast cancer in 2007, Tobacco user and Cognitive disorders. Concomitant products included HYDROCHLOROTHIAZIDE, VALSARTAN (VALSARTAN/HIDROCLOROTIAZIDA), ZOPICLONE (IMOVANE), PARACETAMOL (DAFALGAN) and OXAZEPAM (SERESTA) for an unknown indication. On 11-May-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) .25 milliliter. On 12-May-2022, the patient experienced ASPIRATION (Vomit inhalation) (seriousness criterion life threatening), VOMITING (Vomiting) (seriousness criterion life threatening) and PNEUMONIA ASPIRATION (Pneumonia aspiration) (seriousness criteria death and life threatening). The patient died on 12-May-2022. The reported cause of death was massive inhalation on several vomiting, inhalation pneumonia. An autopsy was not performed. At the time of death, ASPIRATION (Vomit inhalation) and VOMITING (Vomiting) had not resolved. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Dosage text: R2 No treatment information were reported by the reporter. Company Comment: This regulatory case concerns a 74-year-old female patient with concurrent acromegaly, and concomitant use of Valsartan and Oxazepam, who experienced the unexpected serious events of Aspiration (Vomit inhalation), Vomiting, and Pneumonia aspiration that occurred 1 day after receiving a dose of mRNA-1273 vaccine. All events were life-threatening; however, Pneumonia aspiration was reported with a fatal outcome. Patient died on the same day the events occurred. Cause of death was reported as massive inhalation on several vomiting, inhalation pneumonia. Autopsy was not performed. No information was provided on any other COVID-19 vaccination prior to current mRNA-1273 vaccine. People with

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	acromegaly may develop respiratory abnormalities including sleep apnea, and concomitant use of Valsartan and Oxazepam may cause trouble with swallowing and/or breathing that may be sudden. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Case seriousness was assessed as per Regulatory Authority report.
4.1(b)	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 02-Jun-2022 and was forwarded to Moderna on 03-Jun-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of DYSPNOEA (Dyspnea), ASTHENIA (General weakness) and COVID-19 (Positive rt pcr test) in an 81-year-old female patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. Co-suspect products included non-company products COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) for an unknown indication and COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) for an unknown indication. No medical history information was reported. On 13-May-2021, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) (unknown route) 1 dosage form. On 08-Aug-2021, the patient received dose of COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19) (ASTRAZENECA COVID-19 VACCINE) (unknown route) 1 dosage form. In January 2022, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 29-Mar-2022, the patient experienced COVID-19 (Positive rt pcr test) (seriousness criterion death). On an unknown date, the patient experienced DYSPNOEA (Dyspnea) (seriousness criterion death) and ASTHENIA (General weakness) (seriousness criterion death). The reported cause of death was positive rt pcr test, Dyspnea and general weakness. It is unknown if an autopsy was performed. Not Provided The action taken with mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown) was unknown. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. No concomitant medication was provided. No treatment medication was provided. Worldwide UID was reported as 4.1(b) . This fatal regulatory case concerns an 81-year-old female patient with medical history Of ASTRAZENECA COVID-19 VACCINE on 13-May and 8-August, 2021 who experienced the serious unexpected events of COVID-19 (AESI), DYSPNOEA and ASTHENIA. The events occurred unknown days after a dose of mRNA-1273 vaccine The reported cause of death was positive pcr positive test, Dyspnea and general weakness. It is unknown if an autopsy was performed. The benefit-risk relationship of drug is not affected by this report Terms and onset dates were captured as provided The case was assessed as serious by the Regulatory Authority´s report due to Death
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in a 72-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 06-Oct-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 03-Nov-2021, received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. Death occurred on 19-Mar-2022 The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. No concomitant medication information was reported. No treatment medication was reported. World wide UID reported as 4.1(b) Company comment: This case concerns a 72-year-old male patient with no medical history reported, who experienced the fatal event of death 1 month after a dose of mRNA-1273. Cause of death was reported as unknown. Information regarding clinical course, diagnostic tests and autopsy report has not been disclosed. Patient's age could be a confounding factor. The benefit-risk relationship of mRNA-1273 is not affected by this report.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of CHEST PAIN (Chest pain), HYPERHIDROSIS (diaphoresis), DYSPNOEA (shortness of breath) and VOMITING (vomiting) in a 70-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 22-Sep-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 27-Apr-2022, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion death), HYPERHIDROSIS (diaphoresis) (seriousness criterion death), DYSPNOEA (shortness of breath) (seriousness criterion death) and VOMITING (vomiting) (seriousness criterion death). The reported cause of death was Chest pain, Diaphoresis, Shortness of breath and Vomiting. It is unknown if an autopsy was performed.

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	For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. Three hours prior to admission, patient had onset of chest pain radiating to the back associated with diaphoresis and shortness of breath. Patient also vomited two episodes. Concomitant medications were not reported. No treatment information was provided by the reporter. Company Comment: This is a regulatory authority case concerning a 70-year-old, male patient with no reported medical history, who experienced the unexpected serious (fatal) events of Chest pain, Hyperhyrdrosis, Dyspnea, Vomiting. The events occurred 217 days after the unspecified dose of mRNA-1273 COVID 19 Vaccine. Three hours prior to admission, patient had onset of chest pain radiating to the back associated with diaphoresis and shortness of breath. Patient also vomited two episodes. The reported cause of death was Chest pain, Diaphoresis, Shortness of breath and Vomiting. It is unknown if an autopsy was performed. The rechallenge was unknown since no information about the first dose was disclosed. The reporter assessed the events as related to the product. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. Event terms, seriousness criteria and product information were captured as provided. The Worldwide UID was reported as 4.1(b)
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of DEATH (Death) in a 72-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 vaccination. No Medical History information was reported. On 10-Oct-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) 1 dosage form. On 13-Nov-2021, received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (unknown route) dosage was changed to 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. The Worldwide UID was reported as 4.1(b) No concomitant medications were reported. No treatment medications were reported. Company comment-This regulatory case concerns an elderly male patient aged 72 years with no medical history reported, who experienced the serious fatal unexpected event of Death on an unknown date after a dose of mRNA-1273 vaccine. No further information regarding the event and “cause” of death have been reported. It is unknown if an autopsy was performed. The reported cause of death was unknown. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Jun-2022 and was forwarded to Moderna on 07-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (Died in early May after a stroke), PANCREATIC CARCINOMA (Booster in April 2022 cancer diagnosis, lung, pancreas, brain; Died in early May after a stroke), BRAIN NEOPLASM MALIGNANT (Booster in April 2022 cancer diagnosis, lung, pancreas, brain; Died in early May after a stroke) and LUNG NEOPLASM MALIGNANT (Booster in April 2022 cancer diagnosis, lung, pancreas, brain; Died in early May after a stroke) in an 86-year-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The patient's past medical history included Tuberculosis (Preliminary lung damage TBC in childhood.). Previously administered products included for Prophylactic vaccination: SPIKEVAX on 01-Sep-2021. Past adverse reactions to the above products included Muscle twitch with SPIKEVAX. Concurrent medical conditions included Acute lung injury. In April 2022, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 4 dosage form. In April 2022, the patient experienced PANCREATIC CARCINOMA (Booster in April 2022 cancer diagnosis, lung, pancreas, brain; Died in early May after a stroke) (seriousness criteria hospitalization and life threatening), BRAIN NEOPLASM MALIGNANT (Booster in April 2022 cancer diagnosis, lung, pancreas, brain; Died in early May after a stroke) (seriousness criteria hospitalization and life threatening) and LUNG NEOPLASM MALIGNANT (Booster in April 2022 cancer diagnosis, lung, pancreas, brain; Died in early May after a stroke) (seriousness criteria hospitalization and life threatening). On 05-May-2022, the patient experienced CEREBROVASCULAR ACCIDENT (Died in early May after a stroke) (seriousness criterion death). The patient died on 05-May-2022. The reported cause of death was Accident cerebrovascular. It is unknown if an autopsy was performed. At the time of death, PANCREATIC CARCINOMA (Booster in April 2022 cancer diagnosis, lung, pancreas, brain; Died in early May after a stroke), BRAIN NEOPLASM MALIGNANT (Booster in April 2022 cancer diagnosis, lung, pancreas, brain; Died in early May after a stroke) and LUNG NEOPLASM MALIGNANT (Booster in April 2022 cancer diagnosis, lung, pancreas, brain; Died in early May after a stroke) had not resolved. No concomitant medication details was reported. No treatment medication details was reported. It was reported that none further medication until cancer diagnosis. Company Comment: This regulatory case concerns an 86-year-old female patient with concurrent acute lung injury, who experienced the unexpected serious (fatal) adverse event of special interest Cerebrovascular accident, and unexpected serious (Life-threatening and Hospitalization) events of Pancreatic carcinoma, Brain neoplasm malignant, and Lung neoplasm malignant. The events Pancreatic carcinoma, Brain neoplasm malignant, and Lung neoplasm malignant occurred on unknown dates after receiving booster dose of mRNA-1273 vaccine. The event Cerebrovascular accident that led to the death of the patient on the same day occurred the next month after administration of the same dose of vaccine. The reported cause of death was Accident

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	cerebrovascular. No autopsy report was provided. Patient previously received a dose of mRNA-1273 vaccine approximately 8 months prior to current mRNA-1273 vaccine. The concurrent acute lung injury is likely in association with Lung neoplasm malignant. Brain neoplasm malignant and the advanced age of the patient could be contributory to the fatal event of Cerebrovascular accident. The benefit-risk relationship of mRNA-1273 Vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Jun-2022 and was forwarded to Moderna on 07-Jun-2022. This regulatory authority case was reported by a physician and describes the occurrence of MYOCARDIAL INFARCTION (Infarct myocardial) in a 66-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 0001401) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 14-Jun-2021 and Comirnaty BNT162b2 on 27-Jul-2021. Past adverse reactions to the above products included No adverse reaction with Comirnaty BNT162b2 and Comirnaty BNT162b2. On 23-Jan-2022, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 24-Jan-2022, the patient experienced MYOCARDIAL INFARCTION (Infarct myocardial) (seriousness criteria death and life threatening). The patient died on 24-Jan-2022. The reported cause of death was Infarct myocardial. An autopsy was performed, but no results were provided. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Concomitant medication was not reported. No treatment information was provided. Company Comment: This is a regulatory authority case of interchange of vaccine products for this 66-year-old, female patient with past drug history of administration of two doses of Comirnaty (Pfizer/BioNTech COVID-19 mRNA vaccine), who experienced the unexpected, serious (fatal and life-threatening) AESI of myocardial infarction. The event occurred 1 day after receiving the booster dose of the mRNA-1273 vaccine. No details were provided regarding the event. Treatment information was also not provided. The patient expired on 24Jan2022 (1 day after vaccination). An autopsy was performed, however, the result was not provided. The reported cause of death was Myocardial infarction. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 07-Jun-2022: Significant live follow up - Autopsy details updated.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 07-Jun-2022 and was forwarded to Moderna on 07-Jun-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of VACCINATION FAILURE (Vaccination failure) and COVID-19 PNEUMONIA (COVID-19 pneumonitis) in a 96-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 214005) for COVID-19 vaccination. Co-suspect product included non-company product COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (COVID-19 VACCINE JANSSEN) for COVID-19 vaccination. The patient's past medical history included AFib, Gastric ulcer, Dyslipidemia, Stroke in June 2015, Arterial hypertension, Senile macular degeneration, Cardiac failure, Fracture femur in 2018, Bilateral cataracts and Haemorrhage of digestive tract. Concomitant products included AMIODARONE HYDROCHLORIDE (CORDARONE) for AFib, LINEZOLID (LOXENIL) for Arterial hypertension, CLOPIDOGREL BISULFATE (PLAVIX) for Cardiovascular event prophylaxis, METOPIMAZINE (VOGALENE) for Emesis, PANTOPRAZOLE for Gastric ulcer, IOPODATE CALCIUM (CALCIUM IPODATE) for Mineral supplementation, MIRTAZAPINE (NORSET) for Mood disorder, PARACETAMOL (DOLIPRANE) for Pain, POVIDONE (FLUIDABAK), TIMOLOL MALEATE (TIMOLOLO) and BRINZOLAMIDE for Senile macular degeneration, COLECALCIFEROL and COLECALCIFEROL for Vitamin D supplementation, HYDROXYZINE HYDROCHLORIDE, PREDNISOLONE (ATARAXOID) and DICLOFENAC SODIUM (VOLTARENE LP) for an unknown indication. On 20-Jul-2021, the patient received dose of COVID-19 VACCINE NRVV AD26 (JNJ 78436735) (COVID-19 VACCINE JANSSEN) (Intramuscular) 1 dosage form. On 17-Sep-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced VACCINATION FAILURE (Vaccination failure) (seriousness criteria death and hospitalization) and COVID-19 PNEUMONIA (COVID-19 pneumonitis) (seriousness criteria death and hospitalization). The patient died on 08-May-2022. The reported cause of death was Hemorrhagic shock. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 14-Mar-2022, SARS-CoV-2 test: positive (Positive) Positive. On 15-Mar-2022, Computerised tomogram: abnormal (abnormal) bibasal endobronchial filling with a focus of pneumonitis downstream at the bases, and multiple stable vertebral fractures. On 16-Mar-2022, SARS-CoV-2 test: positive (Positive) Positive. On 17-Mar-2022, SARS-CoV-2 antibody test: 84.2 (Positive) 84.2. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. No treatment medication reported. Patient had COVID pneumonitis due to the omicron variant despite a complete vaccination schedule with JANSSEN (D1) and SPIKEVAX (D2) vaccines less than 6 months before. Concomitant therapies included oxygen therapy, antibiotic therapy and corticotherapy. Company Comment: This is a regulatory case concerning a 96-year-old, female patient with reported medical history of Atrial fibrillation, Gastric ulcer, Dyslipidemia, Stroke, Arterial hypertension, Cardiac failure and Haemorrhage of digestive tract, who had a fatal outcome with unexpected serious

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	(hospitalization) adverse event of special interest of COVID-19 pneumonia. The patient tested positive for SARS-CoV-2 and Computerized tomogram showed bibasal endobronchial filling with a focus of pneumonitis downstream at the bases approximately 6 months after receiving a dose of mRNA-1273 vaccine. The patient was treated with oxygen therapy, antibiotic therapy and corticotheraphy. The patient died approximately 8 months after receiving the said mRNA-1273 (2 months after the positive test) with Hemorrhagic shock as the cause of death. The clinical course leading to demise was not reported. Medical history of Atrial fibrillation, Gastric ulcer, Dyslipidemia, Stroke, Arterial hypertension, Cardiac failure and Haemorrhage of digestive tract remain as risk factor for the COVID-19 pneumonia. Medical history of Gastric ulcer and Haemorrhage of digestive tract remain as risk factors for the cause of Death (Hemorrhagic shock). Vaccination failure was also reported as an additional event. It should be noted the patient received other COVID-19 vaccine (Janssen) as first dose (Interchange of vaccine products) approximately 59 days prior to mRNA-1273. The benefit-risk relationship of mRNA-1273 is not affected by this report. Event retained as serious as per Regulatory Authority.
4.1(b) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted]) on 08-Jun-2022. The most recent information was received on 13-Jun-2022 and was forwarded to Moderna on 13-Jun-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of INJECTION SITE ERYTHEMA (After the I dose involuntary muscle contractions, redness and pain during inoculation for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia kidney necrosis. Deaths on 28/02/2022.), VOMITING (After the first dose involuntary muscle contractions, redness and pain at the injection site for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia, renal necrosis. Deaths on 28/02/2022.), ABDOMINAL PAIN (After the first dose involuntary muscle contractions, redness and pain at the injection site for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia, renal necrosis. Deaths on 28/02/2022.), INJECTION SITE PAIN (After the first dose involuntary muscle contractions, redness and pain at the injection site for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia, renal necrosis. Deaths on 28/02/2022.), MUSCLE CONTRACTIONS INVOLUNTARY (After the first dose involuntary muscle contractions, redness and pain at the injection site for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia, renal necrosis. Deaths on 28/02/2022.), INTESTINAL ISCHAEMIA (After the first dose involuntary muscle contractions, redness and pain at the injection site for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia, renal necrosis. Deaths on 28/02/2022.) and RENAL NECROSIS (After the first dose involuntary muscle contractions, redness and pain at the injection site for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia, renal necrosis. Deaths on 28/02/2022.) in an 86-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000054A) for COVID-19 vaccination. No Medical History information was reported. On 28-Jan-2022, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 31-Jan-2022, the patient experienced INJECTION SITE ERYTHEMA (After the I dose involuntary muscle contractions, redness and pain during inoculation for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia kidney necrosis. Deaths on 28/02/2022.) (seriousness criterion death), VOMITING (After the first dose involuntary muscle contractions, redness and pain at the injection site for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia, renal necrosis. Deaths on 28/02/2022.) (seriousness criterion death), ABDOMINAL PAIN (After the first dose involuntary muscle contractions, redness and pain at the injection site for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia, renal necrosis. Deaths on 28/02/2022.) (seriousness criterion death), INJECTION SITE PAIN (After the first dose involuntary muscle contractions, redness and pain at the injection site for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia, renal necrosis. Deaths on 28/02/2022.) (seriousness criterion death), MUSCLE CONTRACTIONS INVOLUNTARY (After the first dose involuntary muscle contractions, redness and pain at the injection site for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia, renal necrosis. Deaths on 28/02/2022.) (seriousness criterion death), INTESTINAL ISCHAEMIA (After the first dose involuntary muscle contractions, redness and pain at the injection site for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia, renal necrosis. Deaths on 28/02/2022.) (seriousness criterion death) and RENAL NECROSIS (After the first dose involuntary muscle contractions, redness and pain at the injection site for 30 days. Biliary vomiting and abdominal pain. Intestinal ischemia, renal necrosis. Deaths on 28/02/2022.) (seriousness criterion death). The patient died on 28-Feb-2022. The reported cause of death was Renal necrosis, Abdominal pain, Injection site redness, Pain injection site, Bilious vomiting, Intestinal ischaemia and Muscle contractions involuntary. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter did not provide any causality assessments. Hospital discharge letter and death certificate were attached. No concomitant medication reported. No treatment medication reported. Company comment: This regulatory authority case concerns an 86-year-old female patient with no reported medical history, who experienced unexpected, fatal events of Injection site erythema, Vomiting, Abdominal pain, Injection site pain, Muscle contractions involuntary, Intestinal ischaemia and Renal necrosis which started 3 days after vaccination with a first dose of mRNA-1273. The patient died 28 days after. The cause of death was noted as Renal necrosis, Abdominal pain, Injection site erythema, Injection site pain, Vomiting, intestinal ischemia and Muscle contractions involuntary however, it is unknown if autopsy was performed. The age of the patient could be a contributory factor to the events. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report. Most recent FOLLOW-UP information incorporated above includes: On 13-Jun-2022: Significant follow up appended- New event added- Injection site redness and event onset date updated for- Bilious vomiting, Abdominal pain, Pain injection site, Muscle contractions involuntary, Intestinal ischaemia and Renal necrosis
4.1(b) [redacted]	This spontaneous case was reported by a consumer and describes the occurrence of ISCHAEMIC STROKE (In the brain, he was having little/mini ischemic strokes (Dysarthria, Balance disorder, Gait disturbance and Cognitive disorder)), CEREBRAL HAEMORRHAGE (Got a brain bleed) and FALL (started falling multiple times a day,Started falling, patient fell) in a 79-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 018B21A and 011A21A) for COVID-19 prophylaxis. The patient's past medical history included Short-term memory loss (Short term memory problems even before the 1st dose for about 2 years.). Concurrent medical conditions included Seasonal allergy. On 05-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Apr-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced ISCHAEMIC STROKE (In the brain, he was having little/mini ischemic strokes (Dysarthria, Balance disorder, Gait disturbance and Cognitive disorder)) (seriousness criteria death and medically significant), CEREBRAL HAEMORRHAGE (Got a brain bleed) (seriousness criteria death, hospitalization and medically significant) and FALL (started falling multiple times a day,Started falling, patient fell) (seriousness criterion death). The patient was hospitalized for 3 days due to CEREBRAL HAEMORRHAGE. The patient died on 24-Sep-2021. The reported cause of death was Ischemic stroke, Hemorrhage brain, Slurred speech, Balance difficulty, Gait disturbance, Falling and Cognitive disturbance. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 07-Aug-2021, Magnetic resonance imaging: little/mini ischemic strokes in the brain Little/Mini ischemic strokes in the brain (Lungs were clear, carotid arteries were clear, but, in the brain, he was having "little/mini ischemic strokes). No Concomitant Medication provided. The patients slurred speech worsened within 4 to 5 hours, started having balance and gait issues and was leaning to the right and his balance was off and from that day forward, he started falling multiple times a day. The doctors did MRI to see if he was clotting, lungs were clear, carotid arteries were clear but, in the brain, he was having "little/mini ischemic strokes". Patient started having balance issues, he started falling and there was decline in cognitive function, decline in slurred speech, decline in balance. Eventually the patient fell and got a brain bleed and was hospitalized for the brain bleed as he was in ICU for 3 days and then was discharged to skilled nursing facility. Patient had treated with memory medication. Company Comment: This is a Spontaneous case concerning a 79-year-old male patient, with relevant medical history of short-term memory loss, who experienced the unexpected, fatal AESIs of Cerebral haemorrhage (also seriousness criteria of hospitalization) and Ischaemic stroke, and the unexpected and fatal event of Fall. Within 4 to 5 hours after the second dose of mRNA-1273 vaccine, the patient's slurred speech worsened, he started having balance and gait issues and was leaning to the right. His balance was off and from that day forward, he started falling multiple times a day. MRI was performed and showed that lungs were clear, carotid arteries were clear but, in the brain, he was having "little/mini ischemic strokes". Once started having balance issues, he started falling and there was decline in cognitive function, decline in slurred speech, decline in balance. Eventually the patient fell and got a brain bleed and was hospitalized as he was in ICU for 3 days and then was discharged to skilled nursing facility. Patient´s death occurred approximately 5 months and 2 weeks after the second dose of mRNA-1273 vaccine. The reported cause of death was ischemic stroke, hemorrhage brain and falling. It is unknown if an autopsy was performed. Patient´s elderly age, as well as relevant medical history of short-term memory loss, could be confounders for Ischaemic stroke, which could be a contributory factor for patient´s fall and consequent cerebral haemorrhage. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. This case was linked to 4.1(b) (Patient Link).
4.1(b)	This regulatory authority case was reported by a consumer and describes the occurrence of COVID-19 (severe COVID-19 disease) in an 84-year-old patient of an unknown gender who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On an unknown date, the patient experienced COVID-19 (severe COVID-19 disease) (seriousness criterion death) and DRUG INEFFECTIVE (vaccine ineffectiveness). The patient died on an unknown date. The reported cause of death was severe covid-19 disease. It is unknown if an autopsy was performed. At the time of death, DRUG INEFFECTIVE (vaccine ineffectiveness) outcome was unknown. No concomitant medication was reported. No treatment medication was reported. One report described a vaccine ineffectiveness (symptomatic COVID): 84 months after the boosterdose, an 84-year-old patient developed severe COVID-19 disease and died. Company comment: This is a regulatory authority case reported by a consumer. A 84-year-old patient of an unknown gender, with no reported medical history, experienced severe COVID-19 disease (AESI) and died 84 months after receiving mRNA-1273 vaccine, reported as booster dose. The patient died on an unknown date. It is unknown if an autopsy was performed. No further details regarding previous doses, clinical course, diagnostic tests or treatment performed were disclosed. In addition, drug ineffective was also reported. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 09-Jun-2022 and was forwarded to Moderna on 09-Jun-2022. This regulatory authority case was reported by a physician and describes the occurrence of BONE CANCER (Malignant neoplasm of maxilla) in an 88-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 092F21A) for COVID-19 vaccination. Previously administered products included for COVID-19 vaccination: Comirnaty BNT162b2 on 20-Apr-2021 and Comirnaty BNT162b2 on 08-Jun-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2. On 08-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 14-Jan-2022, the patient experienced BONE CANCER (Malignant neoplasm of maxilla) (seriousness criteria death, hospitalization and life threatening). The patient died on 05-Mar-2022. The reported cause of death was Neoplasm of maxilla. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Unknown), the reporter considered BONE CANCER (Malignant neoplasm of maxilla) to be not related. No concomitant medication was reported.

Case ID	Narrative (Complete)
	No treatment information was reported. CC: This regulatory authority case concerns an 88 year old female patient, with no medical history reported, who experienced the Serious (fatal, life-threatening, hospitalization), unexpected event of Malignant neoplasm of maxilla, which occurred 1 month, 6 days after a dose of mRNA-1273 vaccine administration, given as the third dose. The patient died 1 month, 19 days after the mRNA-1273 vaccine administration. The reported cause of death was Neoplasm of maxilla. It is unknown if an autopsy was performed. Patient was previously vaccinated with 2 doses of Comirnaty as primary series (Interchange of vaccine products). The details of the hospitalization and treatment information were not reported. The benefit -risk relationship of mRNA -1273 is not affected by this report. Events' seriousness assessed as per RA report.
4.1(b)	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b)) on 09-Jun-2022. The most recent information was received on 24-Jun-2022 and was forwarded to Moderna on 24-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (Stroke), STATUS EPILEPTICUS (Epileptic fit), GRIP STRENGTH DECREASED (Grip strength decreased) and MUSCULAR WEAKNESS (Weakness of limbs) in an 83-year-old male patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Vitamin B12 deficiency. Concurrent medical conditions included Blood pressure high (Taking medication for high blood pressure). Concomitant products included AMLODIPINE for Hypertension. On 19-Apr-2022, the patient received fourth dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 29-Apr-2022, the patient experienced CEREBROVASCULAR ACCIDENT (Stroke) (seriousness criteria death and hospitalization) and STATUS EPILEPTICUS (Epileptic fit) (seriousness criteria death and hospitalization). On an unknown date, the patient experienced GRIP STRENGTH DECREASED (Grip strength decreased) (seriousness criteria death and hospitalization) and MUSCULAR WEAKNESS (Weakness of limbs) (seriousness criteria death and hospitalization). The patient was hospitalized on 29-Apr-2022 due to CEREBROVASCULAR ACCIDENT, GRIP STRENGTH DECREASED, MUSCULAR WEAKNESS and STATUS EPILEPTICUS. The patient died on 09-May-2022. The reported cause of death was Stroke and Epileptic fit. An autopsy was not performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) test result = No - Negative COVID-19 test. It was reported that Moderna COVID-19 vaccine caused loss of used of his left arm and hand which the vaccine was given in. Ten days after having the vaccine patient had a stroke and epileptic fits (he never had a fit in his life before this). He was taken into hospital on 29-Apr-2022 and ten days later he died. Patient had not tested positive for COVID-19 since having the vaccine. Patient had not symptoms associated with COVID-19. The certified cause of death was given as Status Epilepticus, Multiple Cerebrovascular Accidents, Hypertension. Patient was taking medication for high blood pressure (prescribed daily medication) and was having injections for vitamin B12 deficiency. Patient had his last Covid vaccination in his left arm on 19-Apr-2022. About one week later he found that he could not use his left arm properly or grip anything with his left hand. He was walking as normal and had not lost the use of left leg. On 29-Apr-2022, patient was taken ill with what appeared to be a stroke and when admitted to Hospital, it was informed that he was having a series of fits. A post-mortem was not performed on the patient. Patient was not enrolled in clinical trial. It was reported that the report was not related to possible myocarditis or pericarditis. Company Comment: This regulatory authority case concerns an 83-year-old male patient, with relevant medical history of hypertension who experienced the fatal, unexpected, serious (due to death and hospitalization criteria) adverse events of special interest of Cerebrovascular accident and Status epilepticus, and fatal, unexpected, serious (due to death and hospitalization criteria) events of Grip strength decreased and Muscular weakness, which occurred after receiving the fourth dose of mRNA-1273 vaccine. No information was provided regarding previous doses of COVID-19 vaccination. Approximately a week after vaccination, patient noted left arm weakness with decreased in grip strength of the left hand. Patient was still able to ambulate with no noted weakness of the lower extremity. Ten days after vaccination, patient was admitted in a hospital due to stroke. Diagnostic evaluation was not provided but patient developed multiple episodes of seizures during the hospital stay. Death occurred 10 days after mRNA-1273 administration. Autopsy was not performed. The reported cause of death was Stroke and Epileptic fit. Patient's advanced age and concurrent hypertension are risk factors for stroke. Additionally, patient's age is a confounder for the fatal outcome. The benefit -risk relationship of mRNA -1273 is not affected by this report. Events' seriousness assessed as per RA report. Most recent FOLLOW-UP information incorporated above includes: On 24-Jun-2022: Significant Follow up received: Cause of death updated.
4.1(b)	This regulatory authority case was reported by an other health care professional and describes the occurrence of BLOOD PRESSURE INCREASED (Hypertension) in a 72-year-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) for COVID-19 prophylaxis. No Medical History information was reported. On 06-Oct-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On 13-Nov-2021, received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced BLOOD PRESSURE INCREASED (Hypertension) (seriousness criterion death). The reported cause of death was hypertension. It is unknown if an autopsy was performed. For mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided by the reporter. On 19-Mar-2021, the patient experienced BLOOD PRESSURE INCREASED (Hypertension) (seriousness criterion death). It was reported that patient was asymptomatic. No treatment information was provided by the reporter. The worldwide UID was reported as 4.1(b) Company Comment: This fatal regulatory case concerns an 72-year-old male patient with no medical history reported who experienced the fatal unexpected event of blood pressure increased. The patient received two doses of mRNA-1273 (COVID-19 Vaccine Moderna). There is unclear reported death date because it was

Case ID	Narrative (Complete)
	prior to the administration of Moderna vaccine, thus latency between vaccination and the event could not be assessed. The reported cause of death was blood pressure increased. It is unknown if an autopsy was performed. The benefit-risk relationship of drug is not affected by this report. The case was assessed as serious by the Regulatory Authority´s report due to Death.
4.1(b)	This case was received via European Medicines Agency (Reference number 4.1(b)) on 14-Jun-2022 and was forwarded to Moderna on 14-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of PULMONARY EMBOLISM (pulmonary embolism), DECREASED APPETITE (loss of appetite), FATIGUE (tired), COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE), CARDIAC FAILURE (heart failure), DYSPNOEA (shortness of breath) and ASTHENIA (powerless) in an 85-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 000037A) for COVID-19 vaccination. The patient's past medical history included COVID-19 immunisation (Dose 1 Vaxzevria 2021-03-15 batch number ABV5441) on 15-Mar-2021, COVID-19 immunisation (Dose 2 Vaxzevria 2021-05-17 batch number ABV5297.) on 17-May-2021 and COVID-19 immunisation (Dose 3 Comirnaty 2021-12-15 batch number) on 15-Dec-2021. Concurrent medical conditions included Diabetes mellitus and Hypertension. On 27-Apr-2022, the patient received fourth dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 28-Apr-2022, the patient experienced DECREASED APPETITE (loss of appetite) (seriousness criteria death and medically significant), FATIGUE (tired) (seriousness criteria death and medically significant), DYSPNOEA (shortness of breath) (seriousness criteria death and medically significant) and ASTHENIA (powerless) (seriousness criteria death and medically significant). On 01-May-2022, the patient experienced PULMONARY EMBOLISM (pulmonary embolism) (seriousness criteria death and medically significant) and CARDIAC FAILURE (heart failure) (seriousness criteria death and medically significant). On an unknown date, the patient experienced COVID-19 IMMUNISATION (REVACCINATION WITH DIFFERENT COVID-19 VACCINE) (seriousness criteria death and medically significant). The patient died on 08-May-2022. The reported cause of death was 10007554 and 10037377. It is unknown if an autopsy was performed. No concomitant medications were reported. No treatment medications were reported. Company comment: This regulatory case concerns an 85-year-old female with relevant medical history of Diabetes mellitus, hypertension, and interchange of vaccine products, who experienced the unexpected serious (death, medically significant) events of Pulmonary embolism (AESI), decreased appetite, Fatigue, Cardiac failure, Dyspnoea, and Asthenia, one day after receiving mRNA-1273 vaccine as 4th dose. Additionally, Covid-19 immunisation was also reported. Initially the patient experienced decreased appetite, fatigue, shortness of breath, and asthenia and 3 days later, Pulmonary embolism and Cardiac failure. A week later, she died. It is unknown if an autopsy was performed. Cause of death was reported as Pulmonary embolism and Cardiac failure. Details of concomitant medications, symptoms, clinical course, investigation reports and treatment were not provided. Five months prior to the Moderna dose, the patient had taken two doses of Vaxzevria AstraZeneca Covid-19 vaccine and one dose of Comirnaty Covid-19 vaccine. Advanced age of the patient could be a risk factor. Medical history of Diabetes mellitus and hypertension could be confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. The case seriousness was assessed as per Regulatory Authority report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 14-Jun-2022 and was forwarded to Moderna on 14-Jun-2022. This regulatory authority case was reported by a physician and describes the occurrence of ACUTE PULMONARY OEDEMA (ACUTE PULMONARY EDEMA) in a 75-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 057G21A) for COVID-19 vaccination. The patient's past medical history included Stroke, Carotid artery atheroma and Arterial hypertension. Concomitant products included TOZINAMERAN (COMIRNATY) from 05-May-2021 to 05-May-2021 for COVID-19 vaccination. On 17-Dec-2021, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On 23-Dec-2021, after starting mRNA-1273 (Spikevax), the patient experienced ACUTE PULMONARY OEDEMA (ACUTE PULMONARY EDEMA) (seriousness criterion death). The patient died on 26-Jan-2022. The reported cause of death was Acute pulmonary edema. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Company comment: This is a regulatory case concerning a 75-year-old male patient with medical history of carotid artery atheroma, arterial hypertension and stroke, who experienced the fatal event acute pulmonary edema, 6 days days after the third dose of COVID-19 vaccination with mRNA-1273 (previous primary vaccination with Tozineram - Comirnaty). The patient died 3 days after the event start date. Clinical course, diagnostic tests and treatment details were not provided. The reported cause of death was Acute pulmonary edema. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. The dosage text of suspect product reported as R1. Treatment information was not provided.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 15-Jun-2022 and was forwarded to Moderna on 15-Jun-2022. This regulatory authority case was reported by a pharmacist and describes the occurrence of DEATH (Death unexplained) in a 96-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 44A) for COVID-19 vaccination. No Medical History information was reported. On 24-May-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. Death occurred on 25-May-2022 The patient died on 25-May-2022. The cause of death was not reported. It is unknown if an autopsy was performed.

Case ID	Narrative (Complete)
	mRNA-1273 (Spikevax) (Intramuscular) was withdrawn on 24-May-2022. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. Suspect dosage text was reported as R1. No concomitant medications were reported. No treatment details were reported. Company comment: This is a regulatory authority case concerning a 96-year-old, female patient with no reported medical history, who experienced the unexpected serious (death according to regulatory authority) event of Death. The event occurred 1 day after the unknown dose number of mRNA-1273 vaccine administration. The reported cause of death was unexplained death. It is unknown if autopsy was performed. No other information surrounding the event was reported. The patient's age remain confounder for the event. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 16-Jun-2022 and was forwarded to Moderna on 16-Jun-2022. This regulatory authority case was reported by a physician and describes the occurrence of COVID-19 (COVID-19) and VACCINATION FAILURE (Vaccination failure) in an 84-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3005243) for COVID-19 vaccination. Concurrent medical conditions included Osteoporosis and Glaucoma. Concomitant products included ATORVASTATIN, COLECALCIFEROL (VITAMIN D 3) and CALCIUM for an unknown indication. On 23-Nov-2021, the patient received third dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 29-May-2022, the patient experienced COVID-19 (COVID-19) (seriousness criteria death and hospitalization) and VACCINATION FAILURE (Vaccination failure) (seriousness criteria death and hospitalization). The reported cause of death was extensive myocardial infarction associated with covid and Vaccination failure. It is unknown if an autopsy was performed. For mRNA-1273 (Spikevax) (Intramuscular), the reporter did not provide any causality assessments. It was reported that serious vaccine ineffectiveness report. However, the booster dose was done 6 months earlier, the effectiveness might have been reduced. No treatment medications were provided. Company comment. This fatal regulatory case concerns an 84 – year – old, female patient with no relevant medical history, who experienced the unexpected, serious (due to criteria of death and hospitalization) AESI of COVID – 19 that occurred approximately 6 months after receiving a booster dose of mRNA-1273. Vaccination failure was also reported, however, no information about previous vaccination schedule was provided. It was unspecified if an autopsy was performed. The report stated that the patient died by extensive myocardial infarction associated with COVID. Death date was not reported. No further clinical information was provided for medical reviewing. Patient´s age could be a confounding factor for serious illness from COVID-19 and for myocardial infarction. Patient´s concomitant medication atorvastatin could be suggestive of underlying hyperlipidemia, risk factor for myocardial infarction. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.
4.1(b)	This case was received via European Medicines Agency (Reference number: 4.1(b)) on 16-Jun-2022 and was forwarded to Moderna on 16-Jun-2022. This regulatory authority case was reported by a consumer and describes the occurrence of DEATH (Few weeks after booster vaccination died suddenly unexpectedly!) in a 67-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3004951) for COVID-19 vaccination. The person was not concerned to have known allergies. Information on risk factors or pre-existing conditions include shields hypofunction. Previously administered products included for Prophylactic vaccination: Comirnaty BNT162b2 on 29-Apr-2021 and Comirnaty BNT162b2 on 19-May-2021. Past adverse reactions to the above products included No adverse event with Comirnaty BNT162b2 and Comirnaty BNT162b2. Concurrent medical conditions included Hypothyreosis. On 02-Dec-2021, the patient received third dose of mRNA-1273 (Spikevax) (unknown route) 3 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant information was reported. It was reported that patient died suddenly a few weeks after the 3rd vaccination. No treatment information was provided. CC: This regulatory case concerns a 67-year-old, male patient with a relevant medical history of hypothyroidism, who had a fatal outcome with unexpected serious event of death. The event occurred unknown days after the third dose of vaccination of mRNA-1273. Patient was previously vaccinated with 2 doses of Comirnaty BNT162b2 as primary series (Interchange of vaccine products). The clinical course leading to demise and the cause of death were not reported. It was reported that patient died suddenly a few weeks after the third dose of mRNA-1273 vaccination. It is unknown if an autopsy was performed. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events' seriousness was assessed as per Regulatory Authority's report.
4.1(b)	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 17-Jun-2022 and was forwarded to Moderna on 20-Jun-2022. This regulatory authority case was reported by a nurse and describes the occurrence of TRAUMATIC HAEMATOMA (TRAUMATIC HAEMATOMA), PUPIL FIXED (PUPILS FIXED), BRADYCARDIA (BRADYCARDIA), SYNCOPE (SYNCOPE), ANISOCORIA (ANISOCORIA) and CRANIOCEREBRAL INJURY (TRAUMATIC CEREBRAL INJURY) in a 68-year-old female patient who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 prophylaxis.

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	Concomitant products included ATORVASTATIN, CARVEDILOL, SPIRONOLACTONE, ACETYLSALICYLIC ACID, ISOSORBIDE, HYDROCHLOROTHIAZID, LOSARTAN and INSULIN ISOPHANE BOVINE (INSULIN ISOPHANE) for an unknown indication. On an unknown date, the patient received dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced TRAUMATIC HAEMATOMA (TRAUMATIC HAEMATOMA) (seriousness criterion death), PUPIL FIXED (PUPILS FIXED) (seriousness criterion death), BRADYCARDIA (BRADYCARDIA) (seriousness criterion death), SYNCOPE (SYNCOPE) (seriousness criterion death), ANISOCORIA (ANISOCORIA) (seriousness criterion death) and CRANIOCEREBRAL INJURY (TRAUMATIC CEREBRAL INJURY) (seriousness criterion death). The reported cause of death was Traumatic haematoma, Pupils fixed, Bradycardia, Syncope, Anisocoria and traumatic cerebral injury. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown) was unknown. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. Outcome was reported as death not related to medicine. No treatment medications were reported. Company comment: This fatal regulatory case concerns an 68-year-old female patient with medical history of concomitant medications as atorvastatine, carvevidol, spironolactone, AAS, isosorbide, hydroclorotiazide, losartan, insuline NPH who experienced the fatal unexpected events of traumatic haematoma, pupil fixed, bradycardia, syncope, anisocoria and traumatic brain injury unknown days after a dose of mRNA-1273 (COVID-19 Vaccine Moderna). The reported cause of death was Traumatic haematoma, Pupils fixed, Bradycardia, Syncope, Anisocoria and traumatic cerebral injury. It is unknown if an autopsy was performed. The benefit-risk relationship of drug is not affected by this report. The case was assessed as serious by the Regulatory Authority´s report due to Death.