Appendix 11.29c Elderly: 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)	GERMANY	Acute pulmonary oedema, Pulmonary embolism	85.00	Female	VAXZEVRIA; VAXZEVRIA		4.1(b)	092F21A
4.1(b)	GERMANY	Sudden death	86.00	Male	SPIKEVAX; SPIKEVAX		4.1(b)	3004951
4.1(b)	AUSTRIA	Death	73.00	Male	Diabetes mellitus(C); Hypertension(C); COVID-19 VACCINE MODERNA(H); COVID-19 VACCINE MODERNA(H)		4.1(b)	
4.1(b)	CZECH REPUBLIC	Dyspnoea, Leukaemia, Pain, Pain in extremity, Rash macular, Spinal pain	72.00	Female	Cardiac disorder(C)		4.1(b)	
4.1(b)	THAILAND	Cerebral haemorrhage, Fall	85.00	Female		ASTRAZENECA COVID-19 VACCINE	4.1(b) 4.1(b)	
	GERMANY	Death	72.00	Male			4.1(b)	
4.1(b)	GERMANY	Cerebrovascular accident	82.00	Female			4.1(b)	
4.1(b)	GERMANY	Death	66.00	Male	Coronary artery disease(C); Coronary artery bypass		4.1(b)	
4.1(b)	GERMANY	Death, Loss of consciousness	89.00	Female			4.1(b)	
4.1(b)	GERMANY	Cardiac arrest	90.00	Male	Cardiac failure(C)		4.1(b)	000117A
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
4.1(b)	GERMANY	Cerebrovascular accident	96.00	Male			4.1(b)	
4.1(b)	PORTUGAL	Chills, Respiratory distress	85.00	Male	Chronic kidney disease(H); Cardiovascular disorder(H)		4.1(b)	3005885
4.1(b)	GERMANY	Myocardial infarction	66.00	Male			4.1(b)	216044
4.1(b)	GERMANY	Sudden death	81.00	Male			4.1(b)	
4.1(b)	UNITED KINGDOM	COVID-19, Ruptured cerebral aneurysm	76.00	Female			4.1(b)	000014A
4.1(b)	GREECE	Chills, Coronary artery occlusion, Death, Dyspnoea, Fatigue, Feeling cold, Myocardial infarction, Pyrexia	73.00	Male	Hypertension(H); Diabetes mellitus(H)		4.1(b)	
4.1(b)	JAPAN	Pneumonia aspiration, Respiratory failure	82.00	Male	Cardiac failure(C); Chronic obstructive pulmonary disease(C)		4.1(b)	3005700
4.1(b)	KOREA, REPUBLIC OF	Sudden death	66.00	Male			KR-MODERNATX, INC.- 4.1(b)	
	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]	4.1(b)	3004952

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	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	4.1(b) 4.1(b)	
	GERMANY	Asthenia, Death, Dehydration, Diarrhoea, Dizziness, Malaise, Nausea	78.00	Female	Adrenal insufficiency(H); Autoimmune thyroiditis(H); Vitamin B12 deficiency(H); VAXZEVRIA; COMIRNATY		4.1(b)	
4.1(b)	GERMANY	Cardiac arrest	79.00	Female	Hypertension(C); Hiatus hernia(C); B-cell small lymphocytic lymphoma(C); Hyperlipidaemia(C); Spinal osteoarthritis(C)		4.1(b)	3005291
4.1(b)	FINLAND	Brain injury, Myocardial ischaemia, Ventricular fibrillation	86.00	Male			4.1(b)	3006274
4.1(b)	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	4.1(b)	3005701
4.1(b)	GERMANY	Death, Fatigue, Influenza, Paraesthesia, Vomiting	81.00	Female	Heart valve calcification(C)		4.1(b)	000114AM
4.1(b)	JAPAN	Aortic dissection, Cardio-respiratory arrest, Dyspnoea	68.00	Female	COMIRNATY; COMIRNATY		4.1(b)	3005840
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)	
4.1(b)	GERMANY	Sudden death	65.00	Male	Coronary artery disease(H); Atrial fibrillation(H); Hypertension(H)		4.1(b)	000105A
4.1(b)	GERMANY	Sudden death	67.00	Male	VAXZEVRIA; COMIRNATY		4.1(b)	3004951
4.1(b)	SPAIN	COVID-19 pneumonia, Vaccination failure	65.00	Male		VAXZEVRIA	4.1(b)	216001
4.1(b)	GERMANY	Cerebral infarction, Cerebrovascular accident, Hemiparesis	80.00	Male	Atrial fibrillation(C); BNT162B2; BNT162B2		4.1(b)	092F21A
4.1(b)	JAPAN	Drowning, Listless, Somnolence	77.00	Female	Uterine cancer(C); Rectal cancer(C); Metastases to lymph nodes(C); COMIRNATY; COMIRNATY	TEGAFUR;URACIL	4.1(b)	3006279
4.1(b)	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	4.1(b)	3005840
4.1(b)	SPAIN	Death	68.00	Male		VAXZEVRIA	4.1(b)	031G21A
4.1(b)	TAIWAN, PROVINCE OF CHINA	Cardiac arrest	71.00	Female	Diabetes mellitus(C); Hypertension(C)		4.1(b) 4.1(b)	
	TAIWAN, PROVINCE OF CHINA	Fatigue, Myalgia, Vaccination site pain	71.00	Female			4.1(b) 4.1(b)	

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	Altered state of consciousness	77.00	Female			4.1(b) 4.1(b)	006K21A_1110208-CDC
4.1(b)	TAIWAN, PROVINCE OF CHINA	Chest discomfort	77.00	Male			4.1(b) 4.1(b)	
	TAIWAN, PROVINCE OF CHINA	Death	92.00	Female			4.1(b) 4.1(b)	
	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	4.1(b)	3005786
4.1(b)	TAIWAN, PROVINCE OF CHINA	Abdominal pain, Abdominal pain upper, Chest pain, Syncope	73.00	Female	Diabetes mellitus(C); Hypertension(C); Cardiac failure(H)		4.1(b) 4.1(b)	
	TAIWAN, PROVINCE OF CHINA	Headache, Syncope, Vomiting	72.00	Female	Diabetes mellitus(C); Dialysis; ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE		4.1(b) 4.1(b)	
	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		4.1(b) 4.1(b)	
	TAIWAN, PROVINCE OF CHINA	Death	70.00	Male			4.1(b) 4.1(b)	
	TAIWAN, PROVINCE OF CHINA	Chest pain	80.00	Female			4.1(b) 4.1(b)	
	TAIWAN, PROVINCE OF CHINA	Death	69.00	Male			4.1(b) 4.1(b)	
	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		4.1(b) 4.1(b)	050F21A_1110124-CDC
4.1(b)	TAIWAN, PROVINCE OF CHINA	Altered state of consciousness, Syncope	72.00	Female			4.1(b) 4.1(b)	006K21A_1110208-CDC
4.1(b)	TAIWAN, PROVINCE OF CHINA	Apnoea, Cardiac arrest, Loss of consciousness	72.00	Male			4.1(b)	050F21A-1110124-CDC
4.1(b)	TAIWAN, PROVINCE OF CHINA	Decreased appetite, Pyrexia	86.00	Female	Bronchiectasis(C); ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE		4.1(b) 4.1(b)	072F21A_1110129-CDC
4.1(b)	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	4.1(b)	

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	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)		4.1(b)	
4.1(b)	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]	4.1(b)	000008A
4.1(b)	JAPAN	Angina pectoris, Death	72.00	Male			4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Cardiac arrest	71.00	Female			4.1(b) 4.1(b)	
	TAIWAN, PROVINCE OF CHINA	Insomnia	66.00	Male			4.1(b) 4.1(b)	
	TAIWAN, PROVINCE OF CHINA	Cold sweat, Presyncope	84.00	Male	Hypertension(C); Diabetes mellitus(C)		4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Cardiac arrest	78.00	Female	Atrial fibrillation(C); Hypertensive heart disease(C)		4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Abdominal pain	65.00	Male			4.1(b) 4.1(b)	
	TAIWAN, PROVINCE OF CHINA	Death	67.00	Female			4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Pyrexia	83.00	Male	Cerebrovascular accident(C); Hypertension(C)		4.1(b) 4.1(b)	
	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)		4.1(b) 4.1(b)	
	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	4.1(b)	3006279
4.1(b)	JAPAN	Arrhythmia, Cardio-respiratory arrest, Visceral congestion	81.00	Female			4.1(b)	3006279
4.1(b)	GERMANY	Death	67.00	Male			4.1(b)	000128A
4.1(b)	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	4.1(b)	
4.1(b)	JAPAN	Death, Pyrexia, Respiratory arrest, Sputum increased	88.00	Male	Neoplasm malignant(C); Comirnaty; Comirnaty; Prostate cancer(C); Cerebral infarction(H)		4.1(b)	3006279

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	JAPAN	Acute myocardial infarction, Angiopathy, Cardio-respiratory arrest, Product storage error	90.00	Female	Hypertension(C)		4.1(b)	000009A
4.1(b)	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	4.1(b)	
4.1(b)	JAPAN	Cardiac failure, Death, Pallor	86.00	Male	Diabetes mellitus(C); Hypertension(C); Prostatism(C)	INSULIN	4.1(b)	000018A
4.1(b)	JAPAN	Drowning	69.00	Female	Schizophrenia(H)	SENNOSIDE A+B; PZC [PERPHENAZINE HYDROCHLORIDE]; SULPIRIDE; METOCLOPRAMIDE; ARTANE [ARTEMETHER]; MOSAPRIDE; GASMOTIN [LEVOSULPIRIDE]; PARIET	4.1(b)	3006279
4.1(b)	JAPAN	Cardio-respiratory arrest, Contusion, Epistaxis	85.00	Male	Hypertension(C); Cerebral infarction(H); COMIRNATY; COMIRNATY		4.1(b)	3005786
4.1(b)	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	4.1(b)	000021A
4.1(b)	JAPAN	Arrhythmia, Cardio-respiratory arrest	80.00	Male	Angina pectoris(C); COMIRNATY; COMIRNATY		4.1(b)	
4.1(b)	GERMANY	Pulmonary embolism, Resuscitation, Thrombophlebitis	67.00	Male	Tobacco user(C); Infection(C)		4.1(b)	
4.1(b)	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	4.1(b)	000020A
4.1(b)	JAPAN	Myocarditis, Shock	81.00	Male	COMIRNATY(H); COMIRNATY(H)		4.1(b)	000021A
4.1(b)	SWEDEN	Death, Interchange of vaccine products, Off label use	95.00	Female			4.1(b)	016G21A
4.1(b)	UNITED KINGDOM	Myocardial infarction, Thrombosis	66.00	Male			4.1(b)	
4.1(b)	JAPAN	Cardio-respiratory arrest, Death, Pyrexia	89.00	Female	Dementia(C); Femur fracture(C); Central venous catheterisation(H); Pneumonia aspiration(C)	FULCALIQ; MINERAMIC	4.1(b)	3005786
4.1(b)	JAPAN	Aortic arteriosclerosis, Cardiac failure acute, Lacunar infarction	81.00	Female	Gastric cancer(H); Gastrectomy; Cholelithiasis(H); Cholecystectomy; Uterine cancer(H); Hysterosalpingo-oophorectomy		4.1(b)	3006279
4.1(b)	JAPAN	Aortic dissection, Cardio-respiratory arrest, Fall, Headache, Loss of consciousness	102.00	Female	COMIRNATY; COMIRNATY		4.1(b)	000012A
4.1(b)	JAPAN	Cardio-respiratory arrest	86.00	Female	Hypertension(C); Hypercholesterolaemia(C)		4.1(b)	
4.1(b)	GERMANY	Meningitis, Multiple organ dysfunction syndrome	69.00	Male	COVID-19 VACCINE ASTRAZENECA; COMIRNATY		4.1(b)	
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	4.1(b)	
4.1(b)	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	4.1(b)	
4.1(b)	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)		4.1(b)	216045
4.1(b)	TAIWAN, PROVINCE OF CHINA	Decreased appetite, Incontinence, Muscular weakness	84.00	Male			4.1(b)	

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	Neuroleptic malignant syndrome	86.00	Female			4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Abdominal pain, Dyspnoea, Muscular weakness	83.00	Male			4.1(b)	006K21A_1110210-CDC
4.1(b)	TAIWAN, PROVINCE OF CHINA	Pyrexia	86.00	Male			4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Asthenia, Chest discomfort, Depressed level of consciousness, Dizziness	85.00	Female			4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Headache	65.00	Male	Diabetes mellitus(C)		4.1(b)	006K21A_1110214-CDC
4.1(b)	TAIWAN, PROVINCE OF CHINA	Cardiac failure, Respiratory failure	93.00	Male			4.1(b)	
4.1(b)	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	4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Myocarditis	84.00	Female			4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Feeling cold, Headache	93.00	Male			4.1(b) 4.1(b)	2100685_1110308-CDC
4.1(b)	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	4.1(b)	
4.1(b)	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	4.1(b)	3005785
4.1(b)	GERMANY	Brain injury, Encephalitis, Status epilepticus	69.00	Female			4.1(b)	
4.1(b)	JAPAN	Death	74.00	Female	COMIRNATY; COMIRNATY		4.1(b)	3005786
4.1(b)	JAPAN	Acute kidney injury, Altered state of consciousness, Cardiac arrest, Cyanosis, Gastrointestinal haemorrhage, Hyperkalaemia, Pyrexia	77.00	Female	Diabetes mellitus(C)		4.1(b)	000011A
4.1(b)	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	4.1(b)	000028A
4.1(b)	FINLAND	Purulent pericarditis	91.00	Male			4.1(b)	
4.1(b)	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	4.1(b)	
4.1(b)	LATVIA	Death, Nausea, Pyrexia	75.00	Female	Goitre(C); Hypertension(C); Hypercholesterolaemia(C)	MOXONIDIN; CONCOR; TRIPLIXAM; ROSULIP F; PREDNISOLONE V	4.1(b)	000027BA

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	JAPAN	Cardiac disorder	92.00	Female	Hypertension(C); Oedema(C)	VESICARE; EDIROL; OPALMON; SELARA	4.1(b)	000018A
4.1(b)	JAPAN	Drowning	87.00	Male	COMIRNATY; COMIRNATY		4.1(b)	
4.1(b)	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	4.1(b)	000005A
4.1(b)	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	4.1(b)	000025A
4.1(b)	TAIWAN, PROVINCE OF CHINA	Acute myocardial infarction	70.00	Male			4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Chest pain, Hypoaesthesia, Muscular weakness, Palpitations	66.00	Male	Hypertension(H); Polypectomy		4.1(b)	
4.1(b)	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	4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Asthma, Fatigue, Somnolence	89.00	Female	Osteoporosis(H); ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE		4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Sepsis, Syncope	78.00	Male			4.1(b)	2100685
4.1(b)	TAIWAN, PROVINCE OF CHINA	Fatigue	68.00	Male	Surgery; Hypertension(C)		4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Pyrexia	89.00	Male			4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Death	80.00	Male			4.1(b)	
4.1(b)	NORWAY	Cardiac arrest, COVID-19 immunisation, Pulmonary embolism	78.00	Male			4.1(b)	3004498
4.1(b)	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	4.1(b)	000211A
4.1(b)	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	4.1(b)	
4.1(b)	JAPAN	Diarrhoea, Myocardial infarction	75.00	Male	Hypertension(C); Diabetes mellitus(C); Atrial fibrillation(C)		4.1(b)	
4.1(b)	GERMANY	Cerebral haemorrhage	83.00	Female	Cardiac disorder(C)		4.1(b)	
4.1(b)	JAPAN	Cardio-respiratory arrest	75.00	Male	Hypertension(C); Benign prostatic hyperplasia(C); Hypertonic bladder(C)	LISINOPRIL; AMLODIPINE; NATRIX; BETANIS; CERNILTON N	4.1(b)	3006343
4.1(b)	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	4.1(b)	000028A
4.1(b)	JAPAN	Pneumonia	93.00	Female	Dementia(C)		4.1(b)	

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	GERMANY	Cerebral haemorrhage	84.00	Female			4.1(b)	3005690
4.1(b)	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)		4.1(b)	000009A
4.1(b)	JAPAN	Anaemia, Cardiac failure, Cardio-respiratory arrest, Depressed level of consciousness, Dyspnoea, Haematochezia, Polyp	86.00	Female	Cardiac failure congestive(C)		4.1(b)	3005786
4.1(b)	JAPAN	Death, Depressed level of consciousness	76.00	Male	Cerebral infarction(C); Diabetes mellitus(C); Cerebral infarction(H); COMIRNATY; COMIRNATY		4.1(b)	3005786
4.1(b)	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	4.1(b)	000025A
4.1(b)	GERMANY	Granulomatosis with polyangiitis	77.00	Female	Granulomatosis with polyangiitis(C); COMIRNATY; COMIRNATY		4.1(b)	000087A
4.1(b)	TAIWAN, PROVINCE OF CHINA	Asthma, Chest discomfort	87.00	Female	Diabetes mellitus(C); Hypoacusis(C)		4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Acute myocardial infarction	85.00	Female			4.1(b)	006K21A 1110210-CDC
4.1(b)	TAIWAN, PROVINCE OF CHINA	Fatigue, Headache, Myalgia, Pain in extremity	75.00	Male			4.1(b)	
4.1(b)	GERMANY	Pulmonary embolism	84.00	Female			4.1(b)	
4.1(b)	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)		4.1(b)	007G21A
4.1(b)	GERMANY	Cerebral haemorrhage	91.00	Female	COMIRNATY; COMIRNATY		4.1(b)	000125A
4.1(b)	JAPAN	Aortic dissection, Cardio-respiratory arrest	80.00	Female	Aortic dissection(H)		4.1(b)	000001A
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)	UNITED KINGDOM	Cardiac death	75.00	Male			4.1(b)	000074A
4.1(b)	JAPAN	Acute myocardial infarction, Arrhythmia, Cardiac arrest, Loss of consciousness, Pulmonary congestion	69.00	Female	Hypertension(C); Hyperlipidaemia(C); Back pain(C)		4.1(b)	
4.1(b)	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	4.1(b)	000076A
4.1(b)	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		4.1(b)	000114A
4.1(b)	JAPAN	Acute respiratory distress syndrome, Pneumonia	79.00	Male	Hypertension(C); Urticaria chronic(C)	LOSARTAN K; PREDONINE-1; ZOLPIDEM TARTRATE	4.1(b)	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)	
4.1(b)	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		4.1(b)	3006270
4.1(b)	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		4.1(b)	21046
4.1(b)	UNITED KINGDOM	Cardiac arrest	87.00	Male	Cerebrovascular accident(H); Cardiac pacemaker insertion		4.1(b)	000076A
4.1(b)	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	4.1(b)	0000768
4.1(b)	GREECE	Death, Dyspnoea	78.00	Female			4.1(b)	
4.1(b)	JAPAN	Cardio-respiratory arrest, Death, Decreased activity, Incontinence, Pyrexia	65.00	Male	Schizophrenia(C)		4.1(b)	3006278
4.1(b)	UNITED KINGDOM	Death	89.00	Female	Dementia Alzheimer's type(C); Asthenia(C)	COMIRNATY; NITROFURANTOIN	4.1(b)	000075A
4.1(b)	TAIWAN, PROVINCE OF CHINA	Death	72.00	Male	Hypertension(C); Diabetes mellitus(C)		4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Fatigue, Pyrexia	83.00	Male	Diabetes mellitus(C); Hypertension(C); Cerebrovascular accident(H); Myocardial infarction(H)		4.1(b)	
4.1(b)	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		4.1(b)	3006278
4.1(b)	TAIWAN, PROVINCE OF CHINA	Fatigue, Headache, Vomiting	70.00	Male			4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Pulmonary embolism	95.00	Female	Hypertension(C); Dementia(C)		4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Thrombocytopenia	65.00	Female			4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Death	69.00	Male			4.1(b)	048M21A_1110504
4.1(b)	GERMANY	Death, Influenza	80.00	Female	SPIKEVAX; SPIKEVAX		4.1(b)	3004962
4.1(b)	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)		4.1(b)	016G21A
4.1(b)	GERMANY	Cardiac arrest, Dyspnoea, Sudden death	80.00	Male			4.1(b)	3005696
4.1(b)	GERMANY	Pulmonary embolism, Pulmonary oedema	85.00	Male	VAXZEVRIA; VAXZEVRIA		4.1(b)	092F3AA

Case ID	Country	ALL PTs	Patient Age (Years)	Patient Gender	Medical History	Concomitant Medications	WW Identifier	Batch/Lot Number
4.1(b)	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)		4.1(b)	3003659
4.1(b)	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)		4.1(b)	092F21A
4.1(b)	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	4.1(b) 4.1(b)	
	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)		4.1(b)	
4.1(b)	GERMANY	Cerebrovascular accident	80.00	Male	Atrial fibrillation(C); Diabetes mellitus(C); VAXZEVRIA; Food allergy		4.1(b)	
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)	
4.1(b)	PHILIPPINES	Loss of consciousness	74.00	Male			4.1(b)	068F21A
4.1(b)	UNITED KINGDOM	Lower respiratory tract infection, Pneumonia	87.00	Male			4.1(b)	000081A
4.1(b)	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	4.1(b)	000081A
4.1(b)	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)		4.1(b)	000224A
4.1(b)	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		4.1(b)	
4.1(b)	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	4.1(b) 4.1(b)	065K21A; 030H21B
4.1(b)	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	4.1(b)	
4.1(b)	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	4.1(b)	000018A
4.1(b)	ITALY	Dyspnoea, Non-small cell lung cancer, Pleural effusion	89.00	Female	COMIRNATY; COMIRNATY		4.1(b)	214024 sc 09/02/2022
4.1(b)	GERMANY	Cerebral haemorrhage	68.00	Male	Hypertension(C); Parkinson's disease(C); VAXZEVRIA		4.1(b)	042G21A

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	Death	81.00	Male	Hypertension(C); Dialysis; ASTRAZENECA COVID-19 VACCINE; ASTRAZENECA COVID-19 VACCINE		4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Decreased appetite	88.00	Male	Dialysis		4.1(b)	
4.1(b)	TAIWAN, PROVINCE OF CHINA	Death	80.00	Female	Dialysis; COVID-19 VACCINE ASTRAZENECA; COVID-19 VACCINE ASTRAZENECA		4.1(b)	2100696_1110525
4.1(b)	SWEDEN	Cardiac arrest, Hypoxic-ischaemic encephalopathy	79.00	Female	COVID-19 immunisation; Torticollis(C); COVID-19 immunisation; COVID-19 immunisation; Depression(C)		4.1(b)	000037A
4.1(b)	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	4.1(b)	000081A
4.1(b)	GERMANY	Myocardial infarction	66.00	Female	COMIRNATY; COMIRNATY		4.1(b)	0001401
4.1(b)	GERMANY	Bone cancer	88.00	Female	COMIRNATY; COMIRNATY		4.1(b)	092F21A
4.1(b)	UNITED KINGDOM	Cerebrovascular accident, Grip strength decreased, Muscular weakness, Status epilepticus	83.00	Male	Vitamin B12 deficiency(H); Hypertension(C)	AMLODIPINE	4.1(b)	
4.1(b)	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		4.1(b)	000037A
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 11.29d Elderly: Fatal case narratives after Booster

Case ID	Narrative (Complete)
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 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) [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 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) [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 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.

Case ID	Narrative (Complete)
	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) [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 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 initially received via Zuellig Pharma (Reference number: 4.1(b) [redacted]) 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

Case ID	Narrative (Complete)
	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) [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 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.

Case ID	Narrative (Complete)
	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. 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

Case ID	Narrative (Complete)
	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. 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 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

Case ID	Narrative (Complete)
	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) [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 (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) [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 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). 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.

Case ID	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) [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 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. 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) [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 (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) [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.

Case ID	Narrative (Complete)
	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 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).

Case ID	Narrative (Complete)
	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 (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 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)	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)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) 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.

Case ID	Narrative (Complete)
	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 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 European Medicines Agency (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 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.

Case ID	Narrative (Complete)
	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). 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)	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 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.

Case ID	Narrative (Complete)
	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 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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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 (4.1(b) [redacted] 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) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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. 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

Case ID	Narrative (Complete)
	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 (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.

Case ID	Narrative (Complete)
	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 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 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. 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 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.

Case ID	Narrative (Complete)
	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) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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.

Case ID	Narrative (Complete)
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 (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 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 (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

Case ID	Narrative (Complete)
	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 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 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 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.

Case ID	Narrative (Complete)
	WWID was reported as 4.1(b) 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)	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) 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)	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.

Case ID	Narrative (Complete)
	Concomitant product use was not provided by the reporter. Treatment information was not provided. The Worldwide UID was reported as 4.1(b) [redacted] 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 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) [redacted]	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) [redacted]	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) [redacted] 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.

Case ID	Narrative (Complete)
	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) [redacted]	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. 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.

Case ID	Narrative (Complete)
	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)	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) 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)	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).

Case ID	Narrative (Complete)
	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. 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 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.

Case ID	Narrative (Complete)
	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 is 4.1(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: 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

Case ID	Narrative (Complete)
	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) [redacted] 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) [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 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

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	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) . Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow Up received is non significant.
4.1(b)	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) . 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)	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

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	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.). 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) [redacted]	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. 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.

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	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 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

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	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. 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)	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) 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)	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

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	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) [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] 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.

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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. 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.

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	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.
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) 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) [redacted] 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) [redacted]	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

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	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) [redacted]	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) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) 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 (4.1(b) [redacted]). 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

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	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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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) [redacted]). 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. 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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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 (4.1(b) [redacted]. 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

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	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) [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 (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) [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 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.. 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..

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	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) [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 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. 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.

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	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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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 (4.1(b) [redacted]). 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 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

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	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 (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 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 (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 (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 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 (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

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	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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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 (4.1(b) [redacted]). 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-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) [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 pharmacist, was received via the PMDA (4.1(b) [redacted]). 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) [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 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. 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.

Case ID	Narrative (Complete)
	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 (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 (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 (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 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.

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	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) (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)	This case was received via United Kingdom MHRA (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 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. 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)	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 physician, was received via the PMDA (4.1(b)). 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

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	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 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 Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] on 25-Feb-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 an anatomist, was received via the PMDA (4.1(b) [redacted]). 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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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) [redacted] and reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a physician, was received via the PMDA (4.1(b) [redacted]). 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

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	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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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) [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 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),

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	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. 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

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	(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. 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 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. 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.

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	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

Case ID	Narrative (Complete)
	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. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow-up information 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 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) [redacted] Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up received with no new information.
4.1(b) [redacted]	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) [redacted] 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

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	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) [redacted]	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. 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 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. 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.

Case ID	Narrative (Complete)
	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 [redacted] 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.
[redacted]	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 [redacted] 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
[redacted]	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.

Case ID	Narrative (Complete)
	For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. 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)	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.

Case ID	Narrative (Complete)
	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 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 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 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),

Case ID	Narrative (Complete)
	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. 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.

Case ID	Narrative (Complete)
4.1(b) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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 (4.1(b) [redacted]). 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. 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) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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

Case ID	Narrative (Complete)
	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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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 (4.1(b) [redacted]). 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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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 (4.1(b) [redacted]). 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

Case ID	Narrative (Complete)
	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) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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. 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) [redacted]	This case was initially received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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,

Case ID	Narrative (Complete)
	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 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) [redacted]	This case was received via European Medicines Agency (Reference number 4.1(b) [redacted]) 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). 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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) 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 (4.1(b) [redacted]). 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) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted]) 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

Case ID	Narrative (Complete)
	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 (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 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 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. 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.

Case ID	Narrative (Complete)
	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. Most recent FOLLOW-UP information incorporated above includes: On 25-Apr-2022: Follow up contains non significant information.

Case ID	Narrative (Complete)
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.

Case ID	Narrative (Complete)
	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 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) [redacted] 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) [redacted]	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) [redacted] 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) [redacted]	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.

Case ID	Narrative (Complete)
	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) [redacted] 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 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) [redacted]	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 4.1(b) [redacted], 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) [redacted] 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.

Case ID	Narrative (Complete)
4.1(b)	This case was initially received via European Medicines Agency (Reference number: 4.1(b)) 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) was found to be a duplicate for Report number-4.1(b) 4.1(b) upon receipt of follow up. All information kept in 4.1(b) (this report) and report 4.1(b) 4.1(b) 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 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 (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 (4.1(b)). Fracture of the left caput humeri and suspected hemodyscrasia was assessed as serious by the MAH. On an

Case ID	Narrative (Complete)
	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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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 (4.1(b) [redacted]). 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) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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

Case ID	Narrative (Complete)
	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 (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 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 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.

Case ID	Narrative (Complete)
	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 (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 Takeda Pharmaceuticals (Reference number: 4.1(b) on 28-Mar-2022 and was forwarded to Moderna on 29-Mar-2022. This case, initially reported to the Pharmaceuticals and Medical Devices Agency (PMDA) by a (physician), was received via the PMDA (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 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 (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 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 (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,

Case ID	Narrative (Complete)
	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) [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 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.

Case ID	Narrative (Complete)
	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)	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. 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.

Case ID	Narrative (Complete)
	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) [redacted] 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) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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.

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 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 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. 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 (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.

Case ID	Narrative (Complete)
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: On 07-Apr-2022: Translation document received on 10-Apr-2022 contains translated event verbatim with 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 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.

Case ID	Narrative (Complete)
	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) [redacted]	This case was initially received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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 (4.1(b) [redacted]). 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) [redacted]	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b) [redacted]) 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.

Case ID	Narrative (Complete)
	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. 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 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

Case ID	Narrative (Complete)
	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 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 (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 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

Case ID	Narrative (Complete)
	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.
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.

Case ID	Narrative (Complete)
	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.
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.

Case ID	Narrative (Complete)
	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 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 (4.1(b)). The vaccine recipient was hospitalized in schizophrenia. 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 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.

Case ID	Narrative (Complete)
	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) [redacted]	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) [redacted]	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 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) [redacted] 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

Case ID	Narrative (Complete)
	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 (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 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) 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)	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.

Case ID	Narrative (Complete)
	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. 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.

Case ID	Narrative (Complete)
4.1(b)	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. 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.

Case ID	Narrative (Complete)
	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) [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 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. 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 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.

Case ID	Narrative (Complete)
	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. 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) [redacted]	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) [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 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.

Case ID	Narrative (Complete)
	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. 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.

Case ID	Narrative (Complete)
	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 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)	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. 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 on4.1(b)-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

Case ID	Narrative (Complete)
	(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 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 (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 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.

Case ID	Narrative (Complete)
	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). 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

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	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)	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) . 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)	This case was received via United Kingdom MHRA (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 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. 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

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	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. 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 (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

Case ID	Narrative (Complete)
	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) [redacted]	This case was received via Takeda Pharmaceuticals (Reference number: 4.1(b) [redacted] 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 (4.1(b) [redacted]). 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) [redacted]	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

Case ID	Narrative (Complete)
	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 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.

Case ID	Narrative (Complete)
	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. 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) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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.

Case ID	Narrative (Complete)
	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: 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.

Case ID	Narrative (Complete)
	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. 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 4.1(b) 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.
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.

Case ID	Narrative (Complete)
	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) [redacted] 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) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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) [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. 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.

Case ID	Narrative (Complete)
	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 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

Case ID	Narrative (Complete)
	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) [redacted]	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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. 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) [redacted]	This case was initially received via United Kingdom MHRA (Reference number: 4.1(b) [redacted]) 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

Case ID	Narrative (Complete)
	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 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 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.

Case ID	Narrative (Complete)
	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 11.29e Elderly: Literature Search Methodology

((((("Aged, 80 and over"[MeSH Terms]) OR ("Elderly"[Text Word])) OR ("Elderly"[MeSH Terms])) 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 11.30a Children: Cumulative event counts in the < 18 years age group

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
Blood and lymphatic system disorders	*Subtotal*	*Subtotal*	*72*	*48*	*16*	*15*	*77*	*50*	*17*	*15*	*151*	*159*
	Anaemias haemolytic immune	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Coombs positive haemolytic anaemia	0	0	1	0	0	0	1	0	1	1
	Anaemias NEC	*Subtotal*	*2*	*0*	*2*	*1*	*3*	*0*	*1*	*1*	*5*	*5*
		Anaemia	2	0	1	1	3	0	0	1	4	4
		Microcytic anaemia	0	0	1	0	0	0	1	0	1	1
	Haemolyses NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Haemolysis	0	0	1	0	0	0	1	0	1	1
	Leukocytoses NEC	*Subtotal*	*0*	*0*	*2*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Hyperleukocytosis	0	0	1	0	0	0	1	0	1	1
		Lymphocytosis	0	0	1	0	1	0	0	0	1	1
	Lymphatic system disorders NEC	*Subtotal*	*70*	*48*	*7*	*6*	*73*	*50*	*5*	*6*	*131*	*134*
		Lymph node pain	0	1	0	0	0	1	0	0	1	1
		Lymphadenitis	2	3	0	1	2	4	0	0	6	6
		Lymphadenopathy	68	45	7	6	71	45	5	6	126	127
	Marrow depression and hypoplastic anaemias	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Pancytopenia	0	0	0	1	0	0	0	1	1	1
	Thrombocytopenias	*Subtotal*	*0*	*0*	*7*	*7*	*0*	*0*	*7*	*7*	*14*	*14*
		Immune thrombocytopenia	0	0	1	3	0	0	1	3	4	4
		Thrombocytopenia	0	0	4	4	0	0	4	4	8	8
		Thrombosis with thrombocytopenia	0	0	2	0	0	0	2	0	2	2
	Thrombocytoses	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Thrombocytosis	0	0	1	0	0	0	1	0	1	1
Cardiac disorders	*Subtotal*	*Subtotal*	*26*	*24*	*148*	*58*	*39*	*27*	*160*	*59*	*256*	*285*
	Cardiac disorders NEC	*Subtotal*	*2*	*1*	*1*	*0*	*2*	*1*	*1*	*0*	*4*	*4*
		Cardiac disorder	1	1	1	0	1	1	1	0	3	3
		Cardiovascular disorder	1	0	0	0	1	0	0	0	1	1
	Cardiac signs and symptoms NEC	*Subtotal*	*13*	*7*	*16*	*4*	*17*	*7*	*12*	*5*	*40*	*41*
		Cardiac discomfort	0	0	0	1	0	0	0	1	1	1
		Palpitations	13	7	16	4	17	7	12	4	40	40
	Ischaemic coronary artery disorders	*Subtotal*	*0*	*0*	*1*	*2*	*0*	*0*	*1*	*2*	*3*	*3*
		Angina pectoris	0	0	1	1	0	0	1	1	2	2
		Myocardial infarction	0	0	0	1	0	0	0	1	1	1
	Myocardial disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Cardiomegaly	0	1	0	0	0	1	0	0	1	1
	Noninfectious myocarditis	*Subtotal*	*1*	*1*	*98*	*36*	*1*	*1*	*100*	*36*	*136*	*138*
		Myocarditis	1	1	73	23	1	1	74	23	98	99
		Myopericarditis	0	0	25	13	0	0	26	13	38	39
	Noninfectious pericarditis	*Subtotal*	*2*	*0*	*21*	*8*	*2*	*0*	*21*	*8*	*31*	*31*
		Pericarditis	2	0	21	8	2	0	21	8	31	31
	Rate and rhythm disorders NEC	*Subtotal*	*10*	*14*	*18*	*9*	*14*	*15*	*16*	*8*	*51*	*53*
		Arrhythmia	2	1	4	0	2	1	4	0	7	7
		Bradycardia	0	0	2	1	0	0	2	1	3	3
		Bradycardia neonatal	0	0	1	0	0	0	1	0	1	1
		Cardiac flutter	0	0	1	0	0	0	1	0	1	1
		Extrasystoles	1	1	0	0	1	1	0	0	2	2
		Neonatal bradyarrhythmia	0	0	0	1	0	0	0	1	1	1
		Tachycardia	8	12	10	7	10	13	8	6	37	37
		Tachycardia paroxysmal	1	0	0	0	1	0	0	0	1	1
	Supraventricular arrhythmias	*Subtotal*	*2*	*0*	*4*	*1*	*3*	*1*	*4*	*0*	*7*	*8*
		Atrial fibrillation	1	0	1	0	1	0	1	0	2	2
		Atrial tachycardia	0	0	1	0	0	0	1	0	1	1
		Sinus arrhythmia	0	0	0	1	0	1	0	0	1	1
		Sinus bradycardia	1	0	0	0	1	0	0	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Sinus tachycardia	0	0	1	0	0	0	1	0	1	1
		Supraventricular tachycardia	0	0	2	0	1	0	1	0	2	2
	Tricuspid valvular disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Tricuspid valve incompetence	0	0	1	0	0	0	1	0	1	1
	Ventricular arrhythmias and cardiac arrest	*Subtotal*	*0*	*1*	*4*	*0*	*0*	*1*	*4*	*0*	*5*	*5*
		Cardiac arrest	0	0	3	0	0	0	3	0	3	3
		Ventricular extrasystoles	0	1	0	0	0	1	0	0	1	1
		Ventricular tachycardia	0	0	1	0	0	0	1	0	1	1
Congenital, familial and genetic disorders	*Subtotal*	*Subtotal*	*0*	*0*	*8*	*3*	*1*	*0*	*7*	*6*	*11*	*14*
	Cardiac septal defects congenital	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*2*	*2*
		Atrial septal defect	0	0	0	1	0	0	0	1	1	1
		Ventricular septal defect	0	0	1	0	0	0	1	0	1	1
	Cardiac valve disorders congenital	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Bicuspid aortic valve	0	0	0	1	0	0	0	1	1	1
	Congenital disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Aplasia	0	0	0	1	0	0	0	1	1	1
	Great vessel disorders congenital	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Transposition of the great vessels	0	0	1	0	0	0	1	0	1	1
	Haemoglobinopathies congenital	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Haemoglobinopathy	0	0	1	0	1	0	0	0	1	1
	Laryngeal and tracheal disorders congenital	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*2*	*2*
		Laryngomalacia	0	0	1	0	0	0	1	0	1	1
		Tracheo-oesophageal fistula	0	0	0	1	0	0	0	1	1	1
	Male reproductive tract disorders congenital	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Hypospadias	0	0	0	1	0	0	0	1	1	1
	Ocular disorders congenital NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Coloboma	0	0	1	0	0	0	1	0	1	1
	Persistent foetal circulation disorders	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*2*	*2*
		Patent ductus arteriosus	0	0	1	0	0	0	1	0	1	1
		Persistent foetal circulation	0	0	0	1	0	0	0	1	1	1
	Renal and urinary tract disorders congenital NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Congenital hydronephrosis	0	0	1	0	0	0	1	0	1	1
	Skin and subcutaneous tissue disorders congenital NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Congenital skin disorder	0	0	1	0	0	0	1	0	1	1
Ear and labyrinth disorders	*Subtotal*	*Subtotal*	*18*	*19*	*14*	*6*	*20*	*21*	*16*	*9*	*57*	*66*
	Ear disorders NEC	*Subtotal*	*6*	*0*	*2*	*2*	*7*	*0*	*1*	*2*	*10*	*10*
		Ear discomfort	0	0	0	1	0	0	0	1	1	1
		Ear pain	5	0	2	1	6	0	1	1	8	8
		Ear swelling	1	0	0	0	1	0	0	0	1	1
	Hearing losses	*Subtotal*	*1*	*1*	*7*	*2*	*1*	*2*	*7*	*1*	*11*	*11*
		Deafness	0	0	1	1	0	0	1	1	2	2
		Deafness transitory	0	0	1	0	0	0	1	0	1	1
		Hypoacusis	1	1	5	1	1	2	5	0	8	8
	Hyperacusia	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Hyperacusis	2	0	0	0	2	0	0	0	2	2
	Inner ear disorders NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Meniere's disease	0	0	1	0	0	0	1	0	1	1
	Inner ear signs and symptoms	*Subtotal*	*10*	*19*	*6*	*5*	*10*	*19*	*7*	*6*	*40*	*42*
		Tinnitus	2	3	2	4	2	3	2	4	11	11
		Vertigo	8	16	5	2	8	16	5	2	31	31
Endocrine disorders	*Subtotal*	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
	Acute and chronic thyroiditis	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Silent thyroiditis	1	0	0	0	1	0	0	0	1	1
Eye disorders	*Subtotal*	*Subtotal*	*31*	*12*	*22*	*3*	*49*	*13*	*26*	*3*	*68*	*91*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
	Conjunctival infections, irritations and inflammations	*Subtotal*	*1*	*0*	*2*	*0*	*3*	*0*	*1*	*0*	*3*	*4*
		Conjunctival hyperaemia	0	0	2	0	2	0	1	0	2	3
		Conjunctival oedema	1	0	0	0	1	0	0	0	1	1
	Eyelid movement disorders	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Blepharospasm	0	0	2	0	0	0	2	0	2	2
	Iris and uveal tract infections, irritations and inflammations	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Uveitis	0	0	1	0	0	0	1	0	1	1
	Lacrimation disorders	*Subtotal*	*2*	*1*	*0*	*0*	*2*	*1*	*0*	*0*	*3*	*3*
		Dry eye	0	1	0	0	0	1	0	0	1	1
		Lacrimation increased	2	0	0	0	2	0	0	0	2	2
	Lid, lash and lacrimal infections, irritations and inflammations	*Subtotal*	*2*	*4*	*1*	*0*	*2*	*4*	*1*	*0*	*7*	*7*
		Erythema of eyelid	1	1	0	0	1	1	0	0	2	2
		Eyelid oedema	0	2	1	0	0	2	1	0	3	3
		Swelling of eyelid	1	1	0	0	1	1	0	0	2	2
	Ocular disorders NEC	*Subtotal*	*8*	*1*	*3*	*1*	*9*	*1*	*2*	*1*	*13*	*13*
		Eye pain	3	1	2	0	4	1	1	0	6	6
		Eye swelling	3	0	1	0	3	0	1	0	4	4
		Periorbital swelling	2	0	0	1	2	0	0	1	3	3
	Ocular infections, inflammations and associated manifestations	*Subtotal*	*6*	*1*	*2*	*0*	*7*	*1*	*1*	*0*	*9*	*9*
		Eye discharge	1	0	0	0	1	0	0	0	1	1
		Eye irritation	1	0	2	0	2	0	1	0	3	3
		Ocular hyperaemia	4	1	0	0	4	1	0	0	5	5
	Ocular nerve and muscle disorders	*Subtotal*	*0*	*0*	*2*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Eye movement disorder	0	0	1	0	1	0	0	0	1	1
		Strabismus	0	0	1	0	0	0	1	0	1	1
	Ocular sensation disorders	*Subtotal*	*5*	*1*	*0*	*0*	*5*	*1*	*0*	*0*	*6*	*6*
		Asthenopia	1	0	0	0	1	0	0	0	1	1
		Photophobia	4	1	0	0	4	1	0	0	5	5
	Optic disc abnormalities NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Papilloedema	0	0	1	0	0	0	1	0	1	1
	Pupil disorders	*Subtotal*	*1*	*1*	*1*	*0*	*2*	*1*	*0*	*0*	*3*	*3*
		Mydriasis	1	1	1	0	2	1	0	0	3	3
	Visual disorders NEC	*Subtotal*	*7*	*4*	*11*	*2*	*9*	*4*	*13*	*2*	*24*	*28*
		Diplopia	1	0	5	1	1	0	5	1	7	7
		Vision blurred	7	4	9	1	8	4	8	1	21	21
	Visual field disorders	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Visual field defect	1	0	0	0	1	0	0	0	1	1
	Visual impairment and blindness (excl colour blindness)	*Subtotal*	*4*	*0*	*6*	*0*	*8*	*0*	*3*	*0*	*10*	*11*
		Blindness	0	0	1	0	0	0	1	0	1	1
		Visual impairment	4	0	5	0	8	0	2	0	9	10
Gastrointestinal disorders	*Subtotal*	*Subtotal*	*236*	*159*	*74*	*51*	*358*	*203*	*74*	*62*	*520*	*697*
	Abdominal findings abnormal	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Gastrointestinal sounds abnormal	0	0	1	0	1	0	0	0	1	1
	Colitis (excl infective)	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*2*	*2*
		Colitis ulcerative	0	0	1	0	0	0	1	0	1	1
		Enterocolitis haemorrhagic	0	0	0	1	0	0	0	1	1	1
	Dental disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Teething	0	1	0	0	0	1	0	0	1	1
	Diarrhoea (excl infective)	*Subtotal*	*36*	*21*	*8*	*2*	*39*	*21*	*5*	*2*	*67*	*67*
		Diarrhoea	35	21	8	2	38	21	5	2	66	66
		Diarrhoea neonatal	1	0	0	0	1	0	0	0	1	1
	Dyspeptic signs and symptoms	*Subtotal*	*2*	*0*	*1*	*0*	*3*	*0*	*0*	*0*	*3*	*3*
		Dyspepsia	2	0	1	0	3	0	0	0	3	3
	Faecal abnormalities NEC	*Subtotal*	*2*	*1*	*2*	*0*	*3*	*1*	*2*	*0*	*5*	*6*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
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		Abnormal faeces	0	1	0	0	0	1	0	0	1	1
		Faeces discoloured	1	0	1	0	1	0	1	0	2	2
		Mucous stools	1	0	2	0	2	0	1	0	3	3
	Flatulence, bloating and distension	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Flatulence	0	0	1	0	0	0	1	0	1	1
	Gastric ulcers and perforation	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Gastric ulcer	0	0	1	0	0	0	1	0	1	1
	Gastritis (excl infective)	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Gastritis	0	0	1	0	0	0	1	0	1	1
	Gastrointestinal and abdominal pains (excl oral and throat)	*Subtotal*	*31*	*33*	*13*	*9*	*34*	*33*	*10*	*9*	*86*	*86*
		Abdominal pain	20	25	9	8	21	25	8	8	62	62
		Abdominal pain lower	0	3	0	0	0	3	0	0	3	3
		Abdominal pain upper	11	5	4	1	13	5	2	1	21	21
	Gastrointestinal atonic and hypomotility disorders NEC	*Subtotal*	*3*	*3*	*1*	*0*	*4*	*3*	*0*	*0*	*7*	*7*
		Constipation	2	1	1	0	3	1	0	0	4	4
		Gastrooesophageal reflux disease	1	2	0	0	1	2	0	0	3	3
	Gastrointestinal disorders NEC	*Subtotal*	*2*	*8*	*0*	*0*	*2*	*8*	*0*	*0*	*10*	*10*
		Functional gastrointestinal disorder	0	1	0	0	0	1	0	0	1	1
		Gastrointestinal disorder	2	7	0	0	2	7	0	0	9	9
	Gastrointestinal dyskinetic disorders	*Subtotal*	*1*	*0*	*1*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Bowel movement irregularity	0	0	1	0	1	0	0	0	1	1
		Dyschezia	1	0	0	0	1	0	0	0	1	1
	Gastrointestinal inflammatory disorders NEC	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Enteritis	0	0	1	0	1	0	0	0	1	1
	Gastrointestinal mucosal dystrophies and secretion disorders	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Hyperchlorhydria	1	0	0	0	1	0	0	0	1	1
	Gastrointestinal signs and symptoms NEC	*Subtotal*	*7*	*2*	*1*	*1*	*8*	*2*	*0*	*1*	*11*	*11*
		Abdominal discomfort	4	2	0	1	4	2	0	1	7	7
		Dysphagia	2	0	1	0	3	0	0	0	3	3
		Odynophagia	1	0	0	0	1	0	0	0	1	1
	Gastrointestinal spastic and hypermotility disorders	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Frequent bowel movements	1	0	0	0	1	0	0	0	1	1
	Intestinal haemorrhages	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Intestinal haematoma	0	0	1	0	0	0	1	0	1	1
	Nausea and vomiting symptoms	*Subtotal*	*176*	*105*	*51*	*39*	*230*	*121*	*40*	*42*	*371*	*433*
		Infantile spitting up	0	2	0	0	0	2	0	0	2	2
		Infantile vomiting	2	1	1	0	3	1	0	0	4	4
		Nausea	115	56	30	21	127	58	19	20	222	224
		Retching	0	2	0	0	0	2	0	0	2	2
		Vomiting	92	56	28	24	100	58	21	22	200	201
	Non-site specific gastrointestinal haemorrhages	*Subtotal*	*1*	*0*	*5*	*2*	*1*	*0*	*8*	*2*	*8*	*11*
		Gastrointestinal haemorrhage	0	0	2	0	0	0	2	0	2	2
		Haematemesis	0	0	1	2	0	0	1	2	3	3
		Haematochezia	1	0	3	0	1	0	4	0	4	5
		Melaena	0	0	1	0	0	0	1	0	1	1
	Oral dryness and saliva altered	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Salivary hypersecretion	0	0	1	0	1	0	0	0	1	1
	Oral soft tissue disorders NEC	*Subtotal*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*2*	*2*
		Cheilitis	0	2	0	0	0	2	0	0	2	2
	Oral soft tissue signs and symptoms	*Subtotal*	*7*	*4*	*3*	*1*	*10*	*4*	*2*	*2*	*15*	*18*
		Hypoaesthesia oral	0	2	2	1	1	2	1	1	5	5
		Lip discolouration	1	0	1	0	1	0	1	0	2	2
		Lip erythema	0	1	0	0	0	1	0	0	1	1
		Lip pain	1	0	0	0	1	0	0	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
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		Lip pruritus	1	0	0	0	1	0	0	0	1	1
		Oral mucosal blistering	1	0	0	0	1	0	0	0	1	1
		Oral mucosal eruption	0	1	0	0	0	1	0	0	1	1
		Oral mucosal erythema	1	0	0	0	1	0	0	0	1	1
		Oral pain	1	0	0	1	1	0	0	1	2	2
		Paraesthesia oral	3	0	0	0	3	0	0	0	3	3
	Oral soft tissue swelling and oedema	*Subtotal*	*8*	*2*	*1*	*3*	*9*	*4*	*1*	*2*	*14*	*16*
		Lip oedema	3	1	0	1	3	1	0	1	5	5
		Lip swelling	3	1	1	2	3	3	1	1	7	8
		Mouth swelling	1	0	0	0	1	0	0	0	1	1
		Palatal oedema	1	0	0	0	1	0	0	0	1	1
		Palatal swelling	1	0	0	0	1	0	0	0	1	1
	Stomatitis and ulceration	*Subtotal*	*3*	*1*	*0*	*0*	*4*	*1*	*0*	*0*	*4*	*5*
		Aphthous ulcer	2	0	0	0	2	0	0	0	2	2
		Mouth ulceration	1	1	0	0	1	1	0	0	2	2
		Stomatitis	1	0	0	0	1	0	0	0	1	1
	Tongue disorders	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Tongue disorder	1	0	0	0	1	0	0	0	1	1
	Tongue signs and symptoms	*Subtotal*	*2*	*2*	*1*	*1*	*2*	*2*	*1*	*1*	*6*	*6*
		Swollen tongue	1	1	0	0	1	1	0	0	2	2
		Tongue discolouration	1	1	0	0	1	1	0	0	2	2
		Tongue eruption	0	0	1	0	0	0	1	0	1	1
		Tongue pruritus	0	0	0	1	0	0	0	1	1	1
	Umbilical hernias	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Umbilical hernia	1	0	0	0	1	0	0	0	1	1
General disorders and administration site conditions	*Subtotal*	*Subtotal*	*1,480*	*872*	*219*	*140*	*2,331*	*1,582*	*282*	*206*	*2,711*	*4,401*
	Administration site reactions NEC	*Subtotal*	*4*	*6*	*0*	*1*	*4*	*6*	*0*	*1*	*11*	*11*
		Administration site erythema	2	0	0	0	2	0	0	0	2	2
		Administration site induration	0	1	0	0	0	1	0	0	1	1
		Administration site inflammation	1	0	0	0	1	0	0	0	1	1
		Administration site joint erythema	0	1	0	0	0	1	0	0	1	1
		Administration site lymphadenopathy	1	1	0	0	1	1	0	0	2	2
		Administration site oedema	0	1	0	0	0	1	0	0	1	1
		Administration site pain	0	1	0	1	0	1	0	1	2	2
		Administration site pruritus	0	1	0	0	0	1	0	0	1	1
	Adverse effect absent	*Subtotal*	*490*	*33*	*0*	*0*	*490*	*33*	*0*	*0*	*523*	*523*
		No adverse event	490	33	0	0	490	33	0	0	523	523
	Application and instillation site reactions	*Subtotal*	*5*	*2*	*0*	*0*	*5*	*2*	*0*	*0*	*7*	*7*
		Application site erythema	1	1	0	0	1	1	0	0	2	2
		Application site pain	3	0	0	0	3	0	0	0	3	3
		Application site reaction	1	1	0	0	1	1	0	0	2	2
	Asthenic conditions	*Subtotal*	*253*	*171*	*67*	*34*	*324*	*195*	*57*	*36*	*525*	*612*
		Asthenia	52	81	18	12	57	81	14	13	163	165
		Fatigue	158	68	36	14	171	71	27	13	276	282
		Malaise	89	42	22	11	96	43	16	10	164	165
	Body temperature altered	*Subtotal*	*0*	*0*	*6*	*0*	*0*	*0*	*6*	*0*	*6*	*6*
		Hyperthermia	0	0	5	0	0	0	5	0	5	5
		Hypothermia	0	0	1	0	0	0	1	0	1	1
	Death and sudden death	*Subtotal*	*0*	*0*	*5*	*5*	*0*	*0*	*5*	*5*	*10*	*10*
		Death	0	0	3	4	0	0	3	4	7	7
		Death neonatal	0	0	2	0	0	0	2	0	2	2
		Premature baby death	0	0	0	1	0	0	0	1	1	1
	Febrile disorders	*Subtotal*	*434*	*432*	*107*	*74*	*465*	*442*	*89*	*69*	*1,047*	*1,065*
		Fever neonatal	0	0	1	0	0	0	1	0	1	1

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			Non Serious		Serious		Non Serious		Serious			
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		Hyperpyrexia	5	0	9	8	5	0	9	8	22	22
		Pyrexia	429	432	97	66	460	442	79	61	1,024	1,042
	Feelings and sensations NEC	*Subtotal*	*104*	*84*	*21*	*11*	*122*	*87*	*13*	*12*	*220*	*234*
		Chills	74	74	12	10	80	74	7	10	170	171
		Feeling abnormal	24	3	4	0	26	3	3	0	31	32
		Feeling cold	5	4	3	0	7	4	1	0	12	12
		Feeling hot	4	5	3	1	6	5	1	1	13	13
		Feeling jittery	1	0	0	0	1	0	0	0	1	1
		Hunger	0	0	0	1	0	0	0	1	1	1
		Sensation of foreign body	0	0	1	0	0	0	1	0	1	1
		Sense of oppression	1	0	0	0	1	0	0	0	1	1
		Thirst	1	1	0	0	1	1	0	0	2	2
	Gait disturbances	*Subtotal*	*4*	*1*	*3*	*0*	*4*	*1*	*3*	*0*	*8*	*8*
		Gait disturbance	4	0	3	0	4	0	3	0	7	7
		Gait inability	0	1	0	0	0	1	0	0	1	1
	General signs and symptoms NEC	*Subtotal*	*120*	*191*	*21*	*11*	*131*	*245*	*14*	*10*	*343*	*400*
		Adhesion	2	0	0	0	2	0	0	0	2	2
		Concomitant disease aggravated	1	0	0	0	1	0	0	0	1	1
		Condition aggravated	1	1	7	1	3	1	5	1	10	10
		Crying	10	4	0	0	10	4	0	0	14	14
		Developmental delay	2	0	0	0	2	0	0	0	2	2
		Exercise tolerance decreased	0	0	1	1	0	0	1	1	2	2
		General physical health deterioration	1	1	1	0	1	1	1	0	3	3
		Ill-defined disorder	0	0	1	0	0	0	1	0	1	1
		Illness	9	1	1	0	10	1	0	0	11	11
		Induration	0	27	0	0	0	27	0	0	27	27
		Influenza like illness	21	33	7	2	25	33	3	2	63	63
		Local reaction	1	94	1	0	2	95	0	0	96	97
		Multiple organ dysfunction syndrome	0	0	1	0	0	0	1	0	1	1
		Nonspecific reaction	1	0	0	0	1	0	0	0	1	1
		Performance status decreased	1	0	1	0	1	0	1	0	2	2
		Peripheral swelling	15	6	2	2	17	7	1	1	25	26
		Physical deconditioning	1	0	0	0	1	0	0	0	1	1
		Swelling	7	71	0	5	7	71	0	5	83	83
		Swelling face	3	3	0	1	3	5	0	0	7	8
		Unevaluable event	45	0	0	0	45	0	0	0	45	45
	Inflammations	*Subtotal*	*0*	*4*	*2*	*0*	*0*	*4*	*2*	*0*	*6*	*6*
		Inflammation	0	4	2	0	0	4	2	0	6	6
	Infusion site reactions	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Infusion site rash	1	0	0	0	1	0	0	0	1	1
	Injection site reactions	*Subtotal*	*87*	*59*	*9*	*7*	*125*	*75*	*7*	*6*	*162*	*213*
		Injected limb mobility decreased	1	0	0	2	1	0	0	2	3	3
		Injection site cyst	2	0	0	0	2	0	0	0	2	2
		Injection site erythema	19	11	1	1	19	13	1	0	32	33
		Injection site haematoma	1	1	0	0	1	1	0	0	2	2
		Injection site hypoaesthesia	4	0	0	0	4	0	0	0	4	4
		Injection site induration	2	1	0	0	2	1	0	0	3	3
		Injection site inflammation	5	0	0	0	5	0	0	0	5	5
		Injection site mass	1	0	0	0	1	0	0	0	1	1
		Injection site oedema	5	0	1	0	5	0	1	0	6	6
		Injection site pain	49	40	6	2	52	41	3	1	97	97
		Injection site paraesthesia	0	0	0	1	0	0	0	1	1	1
		Injection site pruritus	7	0	0	0	7	0	0	0	7	7
		Injection site rash	2	0	1	0	2	0	1	0	3	3

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
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		Injection site reaction	8	6	0	2	8	6	0	2	16	16
		Injection site swelling	8	6	1	1	9	7	1	0	16	17
		Injection site urticaria	1	1	0	0	1	1	0	0	2	2
		Injection site vesicles	1	1	0	0	1	1	0	0	2	2
		Injection site warmth	5	3	0	1	5	4	0	0	9	9
	Mass conditions NEC	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Mass	1	0	0	0	1	0	0	0	1	1
		Nodule	1	0	0	0	1	0	0	0	1	1
	Oedema NEC	*Subtotal*	*11*	*3*	*4*	*2*	*11*	*3*	*5*	*2*	*20*	*21*
		Face oedema	2	0	1	0	2	0	1	0	3	3
		Localised oedema	3	0	1	1	3	0	1	1	5	5
		Oedema	3	1	0	0	3	1	0	0	4	4
		Oedema peripheral	3	2	3	1	3	2	3	1	9	9
	Pain and discomfort NEC	*Subtotal*	*109*	*299*	*64*	*40*	*135*	*309*	*59*	*40*	*512*	*543*
		Axillary pain	14	5	1	0	14	5	1	0	20	20
		Chest discomfort	16	8	9	5	19	8	6	5	38	38
		Chest pain	40	43	56	23	50	44	47	22	162	163
		Discomfort	5	1	0	0	5	1	0	0	6	6
		Facial pain	0	1	0	0	0	1	0	0	1	1
		Pain	39	247	7	14	42	249	5	13	307	309
		Tenderness	5	1	0	0	5	1	0	0	6	6
	Therapeutic and nontherapeutic responses	*Subtotal*	*9*	*12*	*2*	*12*	*12*	*12*	*0*	*12*	*35*	*36*
		Adverse drug reaction	0	0	0	1	0	0	0	1	1	1
		Adverse event	3	0	0	1	4	0	0	1	4	5
		Adverse reaction	1	0	0	0	1	0	0	0	1	1
		Idiosyncratic drug reaction	0	0	1	0	1	0	0	0	1	1
		Immediate post-injection reaction	2	0	1	0	3	0	0	0	3	3
		No reaction on previous exposure to drug	2	1	0	0	2	1	0	0	3	3
		Therapeutic response unexpected	1	0	0	0	1	0	0	0	1	1
		Therapy partial responder	0	11	0	0	0	11	0	0	11	11
		Vaccination failure	0	0	0	10	0	0	0	10	10	10
	Trophic disorders	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Metaplasia	0	0	0	1	0	0	0	1	1	1
	Ulcers NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Ulcer	0	1	0	0	0	1	0	0	1	1
	Vaccination site reactions	*Subtotal*	*317*	*134*	*21*	*9*	*500*	*167*	*22*	*12*	*481*	*701*
		Extensive swelling of vaccinated limb	2	4	0	0	2	4	0	0	6	6
		Vaccination site anaesthesia	0	1	0	0	0	1	0	0	1	1
		Vaccination site bruising	1	0	0	0	1	0	0	0	1	1
		Vaccination site discolouration	2	0	0	0	2	0	0	0	2	2
		Vaccination site discomfort	2	6	0	0	3	6	0	0	8	9
		Vaccination site erythema	69	18	2	1	70	19	1	1	90	91
		Vaccination site hypoaesthesia	2	0	1	0	2	0	1	0	3	3
		Vaccination site induration	4	1	0	1	4	1	0	1	6	6
		Vaccination site inflammation	11	3	0	1	11	3	0	1	15	15
		Vaccination site joint erythema	2	0	0	0	2	0	0	0	2	2
		Vaccination site lymphadenopathy	7	8	0	1	7	8	0	1	16	16
		Vaccination site macule	3	1	0	1	3	1	0	1	5	5
		Vaccination site mass	9	0	0	0	9	0	0	0	9	9
		Vaccination site movement impairment	4	0	1	0	4	0	1	0	5	5
		Vaccination site oedema	31	4	2	0	31	5	2	0	37	38
		Vaccination site pain	194	70	13	6	206	72	8	5	283	291
		Vaccination site paraesthesia	0	1	0	0	0	1	0	0	1	1
		Vaccination site plaque	3	1	0	0	3	1	0	0	4	4

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Vaccination site pruritus	22	4	2	0	22	4	2	0	28	28
		Vaccination site rash	30	4	1	0	30	4	1	0	35	35
		Vaccination site reaction	20	18	4	1	22	18	2	1	43	43
		Vaccination site swelling	32	15	3	0	34	15	3	0	50	52
		Vaccination site urticaria	3	2	0	0	3	2	0	0	5	5
		Vaccination site warmth	29	2	1	1	29	2	1	1	33	33
Hepatobiliary disorders	*Subtotal*	*Subtotal*	*3*	*2*	*7*	*0*	*4*	*2*	*6*	*0*	*12*	*12*
	Cholestasis and jaundice	*Subtotal*	*2*	*1*	*1*	*0*	*2*	*1*	*1*	*0*	*4*	*4*
		Hyperbilirubinaemia	0	0	1	0	0	0	1	0	1	1
		Jaundice	2	1	0	0	2	1	0	0	3	3
	Hepatic and hepatobiliary disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Liver disorder	0	1	0	0	0	1	0	0	1	1
	Hepatic enzymes and function abnormalities	*Subtotal*	*0*	*0*	*2*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Hepatic function abnormal	0	0	1	0	0	0	1	0	1	1
		Hypertransaminasaemia	0	0	1	0	1	0	0	0	1	1
	Hepatic failure and associated disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Acute hepatic failure	0	0	1	0	0	0	1	0	1	1
	Hepatobiliary signs and symptoms	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Hepatomegaly	1	0	0	0	1	0	0	0	1	1
	Hepatocellular damage and hepatitis NEC	*Subtotal*	*0*	*0*	*3*	*0*	*0*	*0*	*3*	*0*	*3*	*3*
		Hepatic cytolysis	0	0	2	0	0	0	2	0	2	2
		Hepatitis acute	0	0	1	0	0	0	1	0	1	1
Immune system disorders	*Subtotal*	*Subtotal*	*26*	*253*	*24*	*28*	*27*	*272*	*23*	*29*	*331*	*351*
	Allergic conditions NEC	*Subtotal*	*5*	*30*	*2*	*3*	*5*	*30*	*2*	*3*	*40*	*40*
		Hypersensitivity	5	30	1	3	5	30	1	3	39	39
		Type I hypersensitivity	0	0	1	0	0	0	1	0	1	1
	Allergies to foods, food additives, drugs and other chemicals	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Food allergy	0	0	0	1	0	0	0	1	1	1
	Anaphylactic and anaphylactoid responses	*Subtotal*	*1*	*1*	*13*	*3*	*1*	*1*	*13*	*3*	*18*	*18*
		Anaphylactic reaction	1	1	9	3	1	1	9	3	14	14
		Anaphylactic shock	0	0	4	0	0	0	4	0	4	4
	Autoimmune disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Autoimmune disorder	0	0	0	1	0	0	0	1	1	1
	Immune and associated conditions NEC	*Subtotal*	*20*	*239*	*9*	*22*	*21*	*241*	*8*	*21*	*290*	*291*
		Haemophagocytic lymphohistiocytosis	0	0	1	0	0	0	1	0	1	1
		Immunisation reaction	20	239	4	20	21	241	3	19	283	284
		Multisystem inflammatory syndrome in children	0	0	3	2	0	0	3	2	5	5
		Vaccine associated enhanced disease	0	0	1	0	0	0	1	0	1	1
Infections and infestations	*Subtotal*	*Subtotal*	*42*	*51*	*29*	*20*	*48*	*53*	*26*	*21*	*142*	*148*
	Abdominal and gastrointestinal infections	*Subtotal*	*0*	*1*	*5*	*1*	*0*	*1*	*5*	*2*	*7*	*8*
		Abdominal abscess	0	0	0	1	0	0	0	1	1	1
		Appendicitis	0	0	2	0	0	0	2	0	2	2
		Appendicitis perforated	0	0	0	1	0	0	0	1	1	1
		Dysentery	0	1	3	0	0	1	3	0	4	4
	Bacterial infections NEC	*Subtotal*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*2*	*2*
		Arthritis bacterial	0	0	0	1	0	0	0	1	1	1
		Cellulitis	0	1	0	0	0	1	0	0	1	1
	Borrelial infections	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Erythema migrans	1	0	0	0	1	0	0	0	1	1
	Candida infections	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Candida infection	1	0	0	0	1	0	0	0	1	1
	Cardiac infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Myocarditis infectious	0	0	1	0	0	0	1	0	1	1
	Central nervous system and spinal infections	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Myelitis	0	0	0	1	0	0	0	1	1	1
	Chlamydial infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Chlamydial infection	0	0	1	0	0	0	1	0	1	1
	Coronavirus infections	*Subtotal*	*6*	*4*	*2*	*13*	*7*	*4*	*1*	*13*	*25*	*25*
		Asymptomatic COVID-19	0	1	0	0	0	1	0	0	1	1
		COVID-19	5	3	2	12	6	3	1	12	22	22
		COVID-19 pneumonia	0	0	0	1	0	0	0	1	1	1
		Suspected COVID-19	1	0	0	0	1	0	0	0	1	1
	Cytomegaloviral infections	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Cytomegalovirus infection	0	0	1	0	1	0	0	0	1	1
	Dental and oral soft tissue infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Sialoadenitis	0	0	1	0	0	0	1	0	1	1
	Ear infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Ear infection	0	0	1	0	0	0	1	0	1	1
	Epstein-Barr viral infections	*Subtotal*	*1*	*2*	*1*	*0*	*1*	*2*	*1*	*0*	*4*	*4*
		Epstein-Barr virus infection	0	2	0	0	0	2	0	0	2	2
		Hepatitis infectious mononucleosis	0	0	1	0	0	0	1	0	1	1
		Infectious mononucleosis	1	0	0	0	1	0	0	0	1	1
	Female reproductive tract infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Vulvitis	0	0	1	0	0	0	1	0	1	1
	Flaviviral infections	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Dengue fever	0	1	0	0	0	1	0	0	1	1
	Herpes viral infections	*Subtotal*	*9*	*11*	*3*	*0*	*9*	*11*	*3*	*0*	*23*	*23*
		Genital herpes	1	1	0	0	1	1	0	0	2	2
		Herpes simplex	1	0	0	0	1	0	0	0	1	1
		Herpes zoster	5	7	1	0	5	7	1	0	13	13
		Herpes zoster oticus	0	0	1	0	0	0	1	0	1	1
		Herpes zoster reactivation	1	0	0	0	1	0	0	0	1	1
		Oral herpes	1	3	1	0	1	3	1	0	5	5
	Infections NEC	*Subtotal*	*2*	*2*	*1*	*1*	*2*	*3*	*1*	*0*	*6*	*6*
		Abscess	0	2	0	0	0	2	0	0	2	2
		Abscess limb	1	0	0	0	1	0	0	0	1	1
		Infection	1	0	0	0	1	0	0	0	1	1
		Localised infection	0	0	1	0	0	0	1	0	1	1
		Respiratory tract infection	0	0	0	1	0	1	0	0	1	1
	Influenza viral infections	*Subtotal*	*3*	*6*	*3*	*1*	*3*	*6*	*3*	*1*	*13*	*13*
		Influenza	3	6	3	1	3	6	3	1	13	13
	Lower respiratory tract and lung infections	*Subtotal*	*0*	*0*	*1*	*1*	*1*	*0*	*1*	*1*	*2*	*3*
		Bronchitis	0	0	1	0	1	0	0	0	1	1
		Pneumonia	0	0	1	1	0	0	1	1	2	2
	Male reproductive tract infections	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Orchitis	0	1	0	0	0	1	0	0	1	1
	Neisseria infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Gonorrhoea	0	0	1	0	0	0	1	0	1	1
	Skin structures and soft tissue infections	*Subtotal*	*1*	*1*	*1*	*0*	*1*	*1*	*1*	*0*	*3*	*3*
		Dermo-hypodermitis	0	0	1	0	0	0	1	0	1	1
		Pustule	0	1	0	0	0	1	0	0	1	1
		Skin infection	1	0	0	0	1	0	0	0	1	1
	Tuberculous infections	*Subtotal*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*2*	*2*
		Disseminated Bacillus Calmette-Guerin infection	0	1	0	0	0	1	0	0	1	1
		Erythema induratum	0	0	1	0	0	0	1	0	1	1
	Upper respiratory tract infections	*Subtotal*	*17*	*20*	*5*	*2*	*20*	*20*	*2*	*2*	*44*	*44*
		Nasopharyngitis	10	16	3	1	11	16	2	1	30	30
		Rhinitis	6	4	0	1	6	4	0	1	11	11

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Sinusitis	1	0	2	0	3	0	0	0	3	3
	Vascular infections	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Lymphangitis	0	1	0	0	0	1	0	0	1	1
	Viral infections NEC	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Viral infection	1	0	0	0	1	0	0	0	1	1
		Viral rash	0	0	1	0	0	0	1	0	1	1
Injury, poisoning and procedural complications	*Subtotal*	*Subtotal*	*4,494*	*222*	*96*	*20*	*4,841*	*268*	*37*	*15*	*4,832*	*5,161*
	Abdominal and gastrointestinal injuries NEC	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Lip injury	0	0	1	0	1	0	0	0	1	1
	Bone and joint injuries NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Joint injury	0	0	1	0	0	0	1	0	1	1
	Cerebral injuries NEC	*Subtotal*	*0*	*0*	*3*	*0*	*0*	*0*	*3*	*0*	*3*	*3*
		Brain herniation	0	0	1	0	0	0	1	0	1	1
		Concussion	0	0	2	0	0	0	2	0	2	2
	Conditions caused by cold	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Chillblains	0	1	0	0	0	1	0	0	1	1
	Exposures associated with pregnancy, delivery and lactation	*Subtotal*	*158*	*19*	*34*	*9*	*177*	*22*	*21*	*6*	*220*	*226*
		Exposure during pregnancy	5	1	1	0	6	1	0	0	7	7
		Exposure via breast milk	136	15	24	3	149	16	15	2	178	182
		Foetal exposure during pregnancy	1	2	4	4	3	3	2	3	11	11
		Maternal exposure during breast feeding	11	1	3	1	11	1	3	1	16	16
		Maternal exposure during pregnancy	7	0	1	1	8	1	0	0	9	9
		Paternal exposure before pregnancy	0	0	1	0	0	0	1	0	1	1
	Intentional product use issues	*Subtotal*	*6*	*0*	*0*	*0*	*6*	*0*	*0*	*0*	*6*	*6*
		Intentional dose omission	2	0	0	0	2	0	0	0	2	2
		Intentional product use issue	4	0	0	0	4	0	0	0	4	4
	Limb fractures and dislocations	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Tibia fracture	0	0	0	1	0	0	0	1	1	1
	Medication errors, product use errors and issues NEC	*Subtotal*	*20*	*3*	*0*	*2*	*21*	*3*	*0*	*2*	*25*	*26*
		Circumstance or information capable of leading to medication error	1	0	0	0	1	0	0	0	1	1
		Medication error	7	2	0	2	7	2	0	2	11	11
		Product use issue	3	0	0	0	3	0	0	0	3	3
		Vaccination error	8	1	0	0	8	1	0	0	9	9
		Wrong patient	1	0	0	0	1	0	0	0	1	1
		Wrong technique in product usage process	1	0	0	0	1	0	0	0	1	1
	Muscle, tendon and ligament injuries	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Muscle rupture	0	0	0	1	0	0	0	1	1	1
	Non-site specific injuries NEC	*Subtotal*	*4*	*3*	*11*	*2*	*12*	*3*	*3*	*2*	*20*	*20*
		Animal bite	0	0	0	1	0	0	0	1	1	1
		Fall	2	0	11	1	10	0	3	1	14	14
		Injury	2	2	0	0	2	2	0	0	4	4
		Wound	0	1	0	0	0	1	0	0	1	1
	Off label uses	*Subtotal*	*96*	*17*	*5*	*1*	*100*	*19*	*2*	*0*	*119*	*121*
		Off label use	96	17	5	1	100	19	2	0	119	121
	Overdoses NEC	*Subtotal*	*1*	*7*	*1*	*0*	*2*	*7*	*0*	*0*	*9*	*9*
		Overdose	1	7	1	0	2	7	0	0	9	9
	Product administration errors and issues	*Subtotal*	*4,301*	*181*	*47*	*3*	*4,490*	*207*	*4*	*1*	*4,532*	*4,702*
		Accidental overdose	2	0	1	0	3	0	0	0	3	3
		Accidental underdose	4	2	2	0	6	2	0	0	8	8
		Expired product administered	26	6	0	0	26	6	0	0	32	32
		Extra dose administered	1	0	0	0	1	0	0	0	1	1
		Inappropriate schedule of product administration	76	14	0	0	76	14	0	0	90	90
		Incomplete course of vaccination	4	0	0	0	4	0	0	0	4	4

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Incorrect dose administered	7	0	0	0	7	0	0	0	7	7
		Incorrect product administration duration	1	0	0	0	1	0	0	0	1	1
		Incorrect product formulation administered	18	1	0	0	18	1	0	0	19	19
		Incorrect route of product administration	2	0	0	0	2	0	0	0	2	2
		Poor quality product administered	1	8	0	0	1	8	0	0	9	9
		Product administered at inappropriate site	4	0	0	0	4	0	0	0	4	4
		Product administered by wrong person	1	0	0	0	1	0	0	0	1	1
		Product administered to patient of inappropriate age	4,232	170	44	3	4,277	172	4	1	4,449	4,454
		Product administration error	10	3	0	0	10	3	0	0	13	13
		Product dose omission issue	35	0	0	0	35	0	0	0	35	35
		Wrong patient received product	2	0	0	0	2	0	0	0	2	2
		Wrong product administered	16	1	0	0	16	1	0	0	17	17
	Product dispensing errors and issues	*Subtotal*	*3*	*0*	*0*	*0*	*3*	*0*	*0*	*0*	*3*	*3*
		Drug dispensed to wrong patient	2	0	0	0	2	0	0	0	2	2
		Product dispensing issue	1	0	0	0	1	0	0	0	1	1
	Product preparation errors and issues	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Product preparation issue	2	0	0	0	2	0	0	0	2	2
	Product prescribing errors and issues	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Product prescribing error	0	0	0	1	0	0	0	1	1	1
	Product selection errors and issues	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Product selection error	2	0	0	0	2	0	0	0	2	2
	Product storage errors and issues in the product use system	*Subtotal*	*13*	*2*	*0*	*0*	*13*	*2*	*0*	*0*	*15*	*15*
		Product storage error	13	2	0	0	13	2	0	0	15	15
	Site specific injuries NEC	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Face injury	0	0	1	0	0	0	1	0	1	1
		Limb injury	0	0	1	0	0	0	1	0	1	1
	Skin injuries NEC	*Subtotal*	*4*	*0*	*3*	*0*	*7*	*0*	*1*	*0*	*7*	*8*
		Contusion	4	0	2	0	5	0	1	0	6	6
		Skin abrasion	0	0	1	0	1	0	0	0	1	1
		Skin laceration	0	0	1	0	1	0	0	0	1	1
	Underdoses NEC	*Subtotal*	*4*	*1*	*0*	*0*	*4*	*1*	*0*	*0*	*5*	*5*
		Intentional underdose	1	0	0	0	1	0	0	0	1	1
		Underdose	3	1	0	0	3	1	0	0	4	4
	Vaccination related complications	*Subtotal*	*1*	*3*	*0*	*1*	*1*	*3*	*0*	*1*	*5*	*5*
		Reaction to previous exposure to any vaccine	1	0	0	0	1	0	0	0	1	1
		Vaccination complication	0	3	0	1	0	3	0	1	4	4
Investigations	*Subtotal*	*Subtotal*	*36*	*42*	*31*	*11*	*43*	*52*	*47*	*10*	*120*	*152*
	Autoimmunity analyses	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*2*	*0*	*1*	*2*
		Antinuclear antibody	0	0	1	0	0	0	1	0	1	1
		Rheumatoid factor	0	0	1	0	0	0	1	0	1	1
	Blood counts NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Full blood count	0	0	1	0	0	0	1	0	1	1
	Blood gas and acid base analyses	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Oxygen saturation decreased	0	0	0	1	0	0	0	1	1	1
	Carbohydrate tolerance analyses (incl diabetes)	*Subtotal*	*2*	*0*	*1*	*0*	*3*	*0*	*0*	*0*	*3*	*3*
		Blood glucose abnormal	0	0	1	0	1	0	0	0	1	1
		Blood glucose decreased	1	0	0	0	1	0	0	0	1	1
		Blood glucose increased	1	0	0	0	1	0	0	0	1	1
	Cardiac auscultatory investigations	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Cardiac murmur	1	0	0	0	1	0	0	0	1	1
	Cardiac function diagnostic procedures	*Subtotal*	*1*	*0*	*2*	*0*	*1*	*0*	*2*	*0*	*3*	*3*
		Cardiovascular function test abnormal	1	0	0	0	1	0	0	0	1	1
		Echocardiogram	0	0	1	0	0	0	1	0	1	1
		Venous pressure jugular	0	0	1	0	0	0	1	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
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	Cell marker analyses	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		HLA-B*27 positive	1	0	0	0	1	0	0	0	1	1
	Central nervous system imaging procedures	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*2*	*0*	*1*	*2*
		Magnetic resonance imaging head	0	0	1	0	0	0	1	0	1	1
		Magnetic resonance imaging spinal	0	0	1	0	0	0	1	0	1	1
	Chemistry analyses NEC	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Inflammatory marker increased	1	0	1	0	1	0	1	0	2	2
	Coagulation and bleeding analyses	*Subtotal*	*0*	*1*	*1*	*1*	*0*	*2*	*1*	*1*	*3*	*4*
		Blood fibrinogen increased	0	1	0	0	0	1	0	0	1	1
		Fibrin D dimer increased	0	1	0	1	0	1	0	1	2	2
		Protein C increased	0	0	1	0	0	0	1	0	1	1
	ECG investigations	*Subtotal*	*2*	*0*	*5*	*0*	*2*	*0*	*6*	*0*	*7*	*8*
		Electrocardiogram	1	0	1	0	1	0	1	0	2	2
		Electrocardiogram abnormal	1	0	0	0	1	0	0	0	1	1
		Electrocardiogram change	0	0	1	0	0	0	1	0	1	1
		Electrocardiogram QT prolonged	0	0	1	0	0	0	1	0	1	1
		Electrocardiogram ST segment abnormal	0	0	1	0	0	0	1	0	1	1
		Electrocardiogram ST segment elevation	0	0	1	0	0	0	1	0	1	1
		Electrocardiogram T wave inversion	0	0	1	0	0	0	1	0	1	1
	Foetal and neonatal diagnostic procedures	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Foetal heart rate abnormal	0	0	1	0	0	0	1	0	1	1
	Haematological analyses NEC	*Subtotal*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*2*	*2*
		Red blood cell sedimentation rate	0	0	1	0	0	0	1	0	1	1
		Red blood cell sedimentation rate increased	0	1	0	0	0	1	0	0	1	1
	Heart rate and pulse investigations	*Subtotal*	*6*	*5*	*6*	*4*	*8*	*5*	*5*	*4*	*21*	*22*
		Heart rate abnormal	1	0	0	0	1	0	0	0	1	1
		Heart rate increased	5	4	5	3	6	4	4	3	17	17
		Heart rate irregular	1	1	1	1	1	1	1	1	4	4
	Hepatobiliary function diagnostic procedures	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*2*	*0*	*1*	*2*
		Alanine aminotransferase increased	0	0	1	0	0	0	1	0	1	1
		Aspartate aminotransferase increased	0	0	1	0	0	0	1	0	1	1
	Imaging procedures NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Ultrasound scan	0	0	1	0	0	0	1	0	1	1
	Immunology analyses NEC	*Subtotal*	*0*	*4*	*0*	*0*	*0*	*4*	*0*	*0*	*4*	*4*
		Antibody test abnormal	0	3	0	0	0	3	0	0	3	3
		Antibody test negative	0	1	0	0	0	1	0	0	1	1
	Investigations NEC	*Subtotal*	*2*	*1*	*3*	*0*	*2*	*1*	*3*	*0*	*6*	*6*
		Blood test	1	0	1	0	1	0	1	0	2	2
		Blood test abnormal	1	0	0	0	1	0	0	0	1	1
		Laboratory test	0	0	2	0	0	0	2	0	2	2
		Polymerase chain reaction	0	1	0	0	0	1	0	0	1	1
	Metabolism tests NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		N-terminal prohormone brain natriuretic peptide increased	0	0	1	0	0	0	1	0	1	1
	Microbiology and serology tests NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Blood culture	0	0	1	0	0	0	1	0	1	1
	Physical examination procedures and organ system status	*Subtotal*	*3*	*4*	*4*	*1*	*3*	*4*	*4*	*1*	*12*	*12*
		Body temperature abnormal	0	1	0	0	0	1	0	0	1	1
		Body temperature decreased	1	0	1	0	1	0	1	0	2	2
		Body temperature increased	2	2	1	0	2	2	1	0	5	5
		Grip strength decreased	0	0	1	0	0	0	1	0	1	1
		Menstruation normal	0	1	0	0	0	1	0	0	1	1
		Respiratory rate increased	0	0	1	0	0	0	1	0	1	1
		Weight decreased	0	0	0	1	0	0	0	1	1	1
	Pituitary analyses anterior	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*2*	*0*	*0*	*1*	*2*

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		Blood thyroid stimulating hormone decreased	0	1	0	0	0	1	0	0	1	1
		Blood thyroid stimulating hormone increased	0	1	0	0	0	1	0	0	1	1
	Platelet analyses	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Platelet count increased	1	0	0	0	1	0	0	0	1	1
	Protein analyses NEC	*Subtotal*	*1*	*0*	*2*	*0*	*1*	*0*	*2*	*0*	*3*	*3*
		C-reactive protein	0	0	1	0	0	0	1	0	1	1
		C-reactive protein increased	1	0	1	0	1	0	1	0	2	2
	Red blood cell analyses	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Haemoglobin decreased	1	0	0	0	1	0	0	0	1	1
	Respiratory tract and thoracic imaging procedures	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Chest X-ray	0	0	1	0	0	0	1	0	1	1
	Skeletal and cardiac muscle analyses	*Subtotal*	*1*	*0*	*7*	*2*	*1*	*0*	*8*	*2*	*10*	*11*
		Blood creatine phosphokinase increased	0	0	1	0	0	0	1	0	1	1
		Troponin I increased	0	0	3	0	0	0	3	0	3	3
		Troponin increased	0	0	3	2	0	0	4	2	5	6
		Troponin T	1	0	0	0	1	0	0	0	1	1
	Thyroid analyses	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Thyroid hormones increased	0	1	0	0	0	1	0	0	1	1
	Tissue enzyme analyses NEC	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*1*	*1*	*0*	*2*	*2*
		Blood lactate dehydrogenase increased	0	0	1	1	0	1	1	0	2	2
	Vascular tests NEC (incl blood pressure)	*Subtotal*	*13*	*11*	*1*	*0*	*14*	*11*	*0*	*0*	*25*	*25*
		Blood pressure decreased	3	1	1	0	4	1	0	0	5	5
		Blood pressure increased	10	10	0	0	10	10	0	0	20	20
	Virus identification and serology	*Subtotal*	*2*	*17*	*1*	*1*	*2*	*20*	*1*	*1*	*21*	*24*
		SARS-CoV-2 antibody test	0	1	0	0	0	1	0	0	1	1
		SARS-CoV-2 antibody test negative	0	14	0	0	0	14	0	0	14	14
		SARS-CoV-2 test	0	1	0	0	0	1	0	0	1	1
		SARS-CoV-2 test negative	1	2	0	0	1	2	0	0	3	3
		SARS-CoV-2 test positive	1	2	1	1	1	2	1	1	5	5
	White blood cell analyses	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		White blood cell count decreased	1	0	0	0	1	0	0	0	1	1
Metabolism and nutrition disorders	*Subtotal*	*Subtotal*	*35*	*15*	*13*	*13*	*41*	*15*	*8*	*14*	*76*	*78*
	Appetite disorders	*Subtotal*	*25*	*12*	*2*	*8*	*26*	*12*	*1*	*8*	*47*	*47*
		Decreased appetite	24	12	2	8	25	12	1	8	46	46
		Increased appetite	1	0	0	0	1	0	0	0	1	1
	Diabetes mellitus (incl subtypes)	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Type 1 diabetes mellitus	0	0	0	1	0	0	0	1	1	1
	Diabetic complications NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Diabetic ketoacidosis	0	0	0	1	0	0	0	1	1	1
	General nutritional disorders NEC	*Subtotal*	*7*	*3*	*7*	*2*	*10*	*3*	*4*	*2*	*19*	*19*
		Abnormal loss of weight	1	0	0	0	1	0	0	0	1	1
		Cachexia	0	0	0	1	0	0	0	1	1	1
		Feeding disorder	2	1	1	0	3	1	0	0	4	4
		Food aversion	0	0	1	0	0	0	1	0	1	1
		Neonatal insufficient breast milk syndrome	0	0	2	0	0	0	2	0	2	2
		Poor feeding infant	3	2	2	1	4	2	1	1	8	8
		Underweight	1	0	0	0	1	0	0	0	1	1
		Weight gain poor	0	0	1	0	1	0	0	0	1	1
	Hyperglycaemic conditions NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Hyperglycaemia	0	0	1	0	0	0	1	0	1	1
	Hypoglycaemic conditions NEC	*Subtotal*	*3*	*0*	*2*	*1*	*3*	*0*	*2*	*1*	*6*	*6*
		Hypoglycaemia	3	0	1	1	3	0	1	1	5	5
		Hypoglycaemia neonatal	0	0	1	0	0	0	1	0	1	1
	Total fluid volume decreased	*Subtotal*	*1*	*0*	*1*	*1*	*2*	*0*	*0*	*1*	*3*	*3*

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		Dehydration	1	0	1	1	2	0	0	1	3	3
Musculoskeletal and connective tissue disorders	*Subtotal*	*Subtotal*	*352*	*248*	*65*	*27*	*444*	*389*	*59*	*33*	*692*	*925*
	Arthropathies NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Arthritis	0	1	0	0	0	1	0	0	1	1
	Bone related signs and symptoms	*Subtotal*	*3*	*3*	*3*	*1*	*5*	*3*	*1*	*1*	*10*	*10*
		Bone pain	2	2	2	1	3	2	1	1	7	7
		Pain in jaw	0	1	1	0	1	1	0	0	2	2
		Spinal pain	1	0	0	0	1	0	0	0	1	1
	Joint related disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Rotator cuff syndrome	0	1	0	0	0	1	0	0	1	1
	Joint related signs and symptoms	*Subtotal*	*60*	*134*	*16*	*9*	*68*	*134*	*13*	*9*	*219*	*224*
		Arthralgia	59	132	16	8	65	132	13	8	215	218
		Joint stiffness	0	1	0	1	0	1	0	1	2	2
		Joint swelling	3	1	0	0	3	1	0	0	4	4
	Lupus erythematosus (incl subtypes)	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Systemic lupus erythematosus	0	0	1	0	0	0	1	0	1	1
	Muscle pains	*Subtotal*	*113*	*158*	*17*	*13*	*117*	*160*	*13*	*12*	*301*	*302*
		Myalgia	113	158	17	13	117	160	13	12	301	302
	Muscle related signs and symptoms NEC	*Subtotal*	*9*	*4*	*2*	*1*	*10*	*4*	*2*	*1*	*16*	*17*
		Muscle spasms	8	4	1	1	8	4	1	1	14	14
		Muscle tightness	2	0	0	0	2	0	0	0	2	2
		Muscle twitching	0	0	1	0	0	0	1	0	1	1
	Muscle tone abnormalities	*Subtotal*	*2*	*0*	*1*	*1*	*2*	*0*	*1*	*1*	*4*	*4*
		Muscle rigidity	1	0	1	1	1	0	1	1	3	3
		Torticollis	1	0	0	0	1	0	0	0	1	1
	Muscle weakness conditions	*Subtotal*	*12*	*2*	*8*	*4*	*15*	*2*	*6*	*4*	*26*	*27*
		Muscular weakness	12	2	8	4	15	2	6	4	26	27
	Musculoskeletal and connective tissue conditions NEC	*Subtotal*	*11*	*3*	*3*	*0*	*12*	*3*	*2*	*0*	*17*	*17*
		Growth retardation	1	0	0	0	1	0	0	0	1	1
		Mobility decreased	6	0	1	0	6	0	1	0	7	7
		Musculoskeletal stiffness	4	3	2	0	5	3	1	0	9	9
	Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	*Subtotal*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*2*	*2*
		Facial asymmetry	0	1	1	0	0	1	1	0	2	2
	Musculoskeletal and connective tissue pain and discomfort	*Subtotal*	*196*	*72*	*29*	*6*	*212*	*80*	*18*	*5*	*303*	*315*
		Back pain	8	7	2	2	9	8	1	1	19	19
		Limb discomfort	4	13	1	0	5	13	0	0	18	18
		Musculoskeletal chest pain	1	0	0	1	2	0	0	1	2	3
		Musculoskeletal pain	1	3	0	0	1	3	0	0	4	4
		Neck pain	2	7	2	0	2	7	2	0	11	11
		Pain in extremity	183	49	24	3	193	49	15	3	259	260
	Soft tissue disorders NEC	*Subtotal*	*3*	*0*	*0*	*0*	*3*	*0*	*0*	*0*	*3*	*3*
		Axillary mass	1	0	0	0	1	0	0	0	1	1
		Groin pain	1	0	0	0	1	0	0	0	1	1
		Soft tissue mass	1	0	0	0	1	0	0	0	1	1
	Tendon disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Enthesopathy	0	0	1	0	0	0	1	0	1	1
Nervous system disorders	*Subtotal*	*Subtotal*	*472*	*410*	*203*	*130*	*602*	*478*	*260*	*185*	*1,215*	*1,525*
	Abnormal reflexes	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Hyporeflexia	0	0	1	0	0	0	1	0	1	1
	Abnormal sleep-related events	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Sleep paralysis	1	0	0	0	1	0	0	0	1	1
	Absence seizures	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*2*	*2*
		Petit mal epilepsy	0	0	1	1	0	0	1	1	2	2
	Acute polyneuropathies	*Subtotal*	*0*	*0*	*1*	*3*	*0*	*0*	*1*	*3*	*4*	*4*

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		Guillain-Barre syndrome	0	0	1	3	0	0	1	3	4	4
	Autonomic nervous system disorders	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Autonomic nervous system imbalance	0	0	1	0	1	0	0	0	1	1
	Central nervous system haemorrhages and cerebrovascular accidents	*Subtotal*	*0*	*0*	*4*	*1*	*0*	*0*	*4*	*2*	*5*	*6*
		Cerebral haemorrhage	0	0	2	0	0	0	2	0	2	2
		Intraventricular haemorrhage	0	0	0	1	0	0	0	1	1	1
		Intraventricular haemorrhage neonatal	0	0	1	0	0	0	1	0	1	1
		Reversible ischaemic neurological deficit	0	0	1	0	0	0	1	0	1	1
		Subarachnoid haemorrhage	0	0	0	1	0	0	0	1	1	1
	Cerebrovascular venous and sinus thrombosis	*Subtotal*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*	*2*
		Cerebral venous thrombosis	0	0	0	1	0	0	0	1	1	1
		Transverse sinus thrombosis	0	0	0	1	0	0	0	1	1	1
	Chronic polyneuropathies	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Chronic inflammatory demyelinating polyradiculoneuropathy	0	0	0	1	0	0	0	1	1	1
	Coma states	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Coma	0	0	1	0	0	0	1	0	1	1
	Coordination and balance disturbances	*Subtotal*	*4*	*3*	*4*	*3*	*4*	*3*	*5*	*3*	*14*	*15*
		Balance disorder	2	2	3	0	2	2	3	0	7	7
		Cerebellar syndrome	0	0	0	1	0	0	0	1	1	1
		Coordination abnormal	1	0	0	0	1	0	0	0	1	1
		Dysstasia	1	1	0	1	1	1	0	1	3	3
		Nystagmus	0	0	2	1	0	0	2	1	3	3
	Cranial nerve disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Paresis cranial nerve	0	0	0	1	0	0	0	1	1	1
	Disturbances in consciousness NEC	*Subtotal*	*38*	*43*	*77*	*34*	*44*	*43*	*74*	*36*	*192*	*197*
		Altered state of consciousness	0	0	2	0	0	0	2	0	2	2
		Depressed level of consciousness	0	0	4	2	0	0	4	2	6	6
		Lethargy	5	1	1	2	6	1	0	2	9	9
		Loss of consciousness	5	5	21	16	5	5	21	16	47	47
		Somnolence	12	8	5	0	13	8	4	0	25	25
		Somnolence neonatal	1	0	0	0	1	0	0	0	1	1
		Syncope	15	29	47	16	19	29	43	16	107	107
	Dyskinesias and movement disorders NEC	*Subtotal*	*5*	*1*	*2*	*2*	*5*	*1*	*2*	*2*	*10*	*10*
		Dyskinesia	2	0	0	0	2	0	0	0	2	2
		Foetal movement disorder	1	0	1	0	1	0	1	0	2	2
		Motor dysfunction	1	0	1	2	1	0	1	2	4	4
		Movement disorder	0	1	0	0	0	1	0	0	1	1
		Psychomotor hyperactivity	1	0	0	0	1	0	0	0	1	1
	Dystonias	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Dystonia	0	1	0	0	0	1	0	0	1	1
	Encephalitis NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Immune-mediated encephalitis	0	0	1	0	0	0	1	0	1	1
	Encephalopathies NEC	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Encephalopathy	0	0	2	0	0	0	2	0	2	2
	Facial cranial nerve disorders	*Subtotal*	*2*	*1*	*9*	*7*	*2*	*2*	*9*	*6*	*19*	*19*
		Bell's palsy	0	0	3	2	0	0	3	2	5	5
		Facial paralysis	1	1	6	3	1	1	6	3	11	11
		Facial paresis	1	0	0	2	1	1	0	1	3	3
	Generalised tonic-clonic seizures	*Subtotal*	*0*	*0*	*2*	*1*	*0*	*0*	*2*	*2*	*3*	*4*
		Generalised tonic-clonic seizure	0	0	2	1	0	0	2	2	3	4
	Headaches NEC	*Subtotal*	*291*	*309*	*65*	*56*	*306*	*310*	*52*	*56*	*721*	*724*
		Headache	291	309	65	55	306	310	52	55	720	723
		Tension headache	0	0	0	1	0	0	0	1	1	1
	Increased intracranial pressure disorders	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
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		Idiopathic intracranial hypertension	0	0	0	1	0	0	0	1	1	1
	Memory loss (excl dementia)	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Memory impairment	1	0	1	0	1	0	1	0	2	2
	Mental impairment (excl dementia and memory loss)	*Subtotal*	*3*	*1*	*5*	*2*	*3*	*1*	*5*	*2*	*11*	*11*
		Cognitive disorder	0	0	1	0	0	0	1	0	1	1
		Disturbance in attention	3	1	4	2	3	1	4	2	10	10
	Migraine headaches	*Subtotal*	*5*	*5*	*1*	*6*	*5*	*5*	*2*	*6*	*17*	*18*
		Hemiplegic migraine	0	0	1	1	0	0	1	1	2	2
		Migraine	5	4	1	2	5	4	1	2	12	12
		Migraine with aura	0	1	0	2	0	1	0	2	3	3
		Status migrainosus	0	0	0	1	0	0	0	1	1	1
	Muscle tone abnormal	*Subtotal*	*1*	*4*	*2*	*2*	*1*	*4*	*2*	*2*	*9*	*9*
		Hypertonia	0	0	1	2	0	0	1	2	3	3
		Hypotonia	1	4	1	0	1	4	1	0	6	6
	Narcolepsy and hypersomnia	*Subtotal*	*1*	*1*	*2*	*1*	*1*	*1*	*2*	*1*	*5*	*5*
		Hypersomnia	1	1	2	1	1	1	2	1	5	5
	Nervous system disorders NEC	*Subtotal*	*1*	*0*	*3*	*0*	*1*	*0*	*3*	*0*	*4*	*4*
		Nervous system disorder	0	0	3	0	0	0	3	0	3	3
		Psychomotor skills impaired	1	0	0	0	1	0	0	0	1	1
	Neurological signs and symptoms NEC	*Subtotal*	*128*	*62*	*47*	*18*	*150*	*66*	*30*	*17*	*255*	*263*
		Clonus	0	0	0	1	0	0	0	1	1	1
		Dizziness	96	53	29	13	106	55	21	11	191	193
		Dizziness postural	1	1	0	0	1	1	0	0	2	2
		Fontanelle bulging	0	0	0	1	0	0	0	1	1	1
		Head discomfort	0	1	0	0	0	1	0	0	1	1
		Infant irritability	0	0	1	0	0	0	1	0	1	1
		Presyncope	34	9	16	4	43	9	7	4	63	63
		Unresponsive to stimuli	0	0	1	0	0	0	1	0	1	1
	Neuromuscular disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Hypotonic-hyporesponsive episode	0	0	0	1	0	0	0	1	1	1
	Neuromuscular junction dysfunction	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Myasthenia gravis crisis	1	0	0	0	1	0	0	0	1	1
	Olfactory nerve disorders	*Subtotal*	*6*	*1*	*2*	*0*	*6*	*1*	*2*	*0*	*9*	*9*
		Anosmia	5	0	1	0	5	0	1	0	6	6
		Parosmia	1	1	1	0	1	1	1	0	3	3
	Optic nerve disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Optic neuritis	0	0	0	1	0	0	0	1	1	1
	Paraesthesias and dysaesthesias	*Subtotal*	*38*	*14*	*20*	*8*	*48*	*16*	*20*	*8*	*80*	*92*
		Burning sensation	1	1	1	2	1	1	1	2	5	5
		Dysaesthesia	1	0	1	0	1	0	1	0	2	2
		Formication	0	0	1	0	0	0	1	0	1	1
		Hemihypoaesthesia	0	0	0	1	0	0	0	1	1	1
		Hyperaesthesia	2	1	1	0	2	1	1	0	4	4
		Hypoaesthesia	24	6	10	2	26	6	9	2	42	43
		Paraesthesia	17	7	8	4	18	8	7	3	36	36
	Paralysis and paresis (excl cranial nerve)	*Subtotal*	*0*	*0*	*2*	*3*	*0*	*0*	*2*	*3*	*5*	*5*
		Hemiparesis	0	0	1	1	0	0	1	1	2	2
		Monoplegia	0	0	1	0	0	0	1	0	1	1
		Paralysis	0	0	0	1	0	0	0	1	1	1
		Paraparesis	0	0	0	1	0	0	0	1	1	1
	Partial simple seizures NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Simple partial seizures	0	0	1	0	0	0	1	0	1	1
	Peripheral neuropathies NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Neuropathy peripheral	0	0	1	0	0	0	1	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
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	Seizures and seizure disorders NEC	*Subtotal*	*2*	*7*	*25*	*17*	*2*	*7*	*25*	*17*	*51*	*51*
		Change in seizure presentation	0	0	1	0	0	0	1	0	1	1
		Clonic convulsion	0	0	2	0	0	0	2	0	2	2
		Epilepsy	0	1	3	2	0	1	3	2	6	6
		Febrile convulsion	0	1	1	2	0	1	1	2	4	4
		Partial seizures	0	0	0	1	0	0	0	1	1	1
		Seizure	2	5	17	11	2	5	17	11	35	35
		Status epilepticus	0	0	0	1	0	0	0	1	1	1
		Tonic convulsion	0	0	1	0	0	0	1	0	1	1
	Sensory abnormalities NEC	*Subtotal*	*7*	*7*	*3*	*3*	*8*	*8*	*2*	*3*	*20*	*21*
		Ageusia	4	1	2	0	5	1	1	0	7	7
		Dysgeusia	0	1	0	0	0	1	0	0	1	1
		Electric shock sensation	1	0	0	0	1	0	0	0	1	1
		Hypogeusia	1	0	0	0	1	0	0	0	1	1
		Intercostal neuralgia	0	0	0	1	0	0	0	1	1	1
		Neuralgia	0	3	0	0	0	3	0	0	3	3
		Restless legs syndrome	0	0	0	1	0	0	0	1	1	1
		Sensory disturbance	0	1	0	1	0	2	0	1	2	3
		Taste disorder	1	1	1	0	1	1	1	0	3	3
	Sleep disturbances NEC	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Sleep deficit	0	0	1	0	0	0	1	0	1	1
		Sudden onset of sleep	1	0	0	0	1	0	0	0	1	1
	Speech and language abnormalities	*Subtotal*	*4*	*0*	*1*	*1*	*4*	*0*	*1*	*1*	*6*	*6*
		Dysarthria	2	0	0	0	2	0	0	0	2	2
		Language disorder	1	0	0	1	1	0	0	1	2	2
		Slow speech	0	0	1	0	0	0	1	0	1	1
		Speech disorder	1	0	0	0	1	0	0	0	1	1
	Structural brain disorders NEC	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Brain injury	0	0	1	0	0	0	1	0	1	1
		Cerebral ventricular rupture	0	0	1	0	0	0	1	0	1	1
	Tremor (excl congenital)	*Subtotal*	*5*	*9*	*4*	*7*	*7*	*9*	*3*	*7*	*25*	*26*
		Intention tremor	0	0	1	0	0	0	1	0	1	1
		Resting tremor	0	0	1	0	0	0	1	0	1	1
		Tremor	5	9	3	7	7	9	1	7	24	24
Pregnancy, puerperium and perinatal conditions	*Subtotal*	*Subtotal*	*3*	*1*	*14*	*0*	*4*	*1*	*18*	*0*	*18*	*23*
	Abortions spontaneous	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Abortion spontaneous	0	0	1	0	0	0	1	0	1	1
	Amniotic fluid and cavity disorders of pregnancy NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Meconium in amniotic fluid	0	0	1	0	0	0	1	0	1	1
	Foetal complications NEC	*Subtotal*	*0*	*0*	*5*	*0*	*0*	*0*	*5*	*0*	*5*	*5*
		Foetal cardiac disorder	0	0	1	0	0	0	1	0	1	1
		Foetal hypokinesia	0	0	4	0	0	0	4	0	4	4
	Foetal growth complications	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Foetal macrosomia	0	0	1	0	0	0	1	0	1	1
	Foetal position and presentation abnormalities	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Shoulder dystocia	0	0	1	0	0	0	1	0	1	1
	Gestational age and weight conditions	*Subtotal*	*1*	*1*	*5*	*0*	*1*	*1*	*6*	*0*	*7*	*8*
		Low birth weight baby	1	0	3	0	1	0	3	0	4	4
		Premature baby	0	1	3	0	0	1	3	0	4	4
	Labour onset and length abnormalities	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Premature delivery	1	0	0	0	1	0	0	0	1	1
	Neonatal hepatobiliary disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Jaundice neonatal	0	0	1	0	0	0	1	0	1	1
	Stillbirth and foetal death	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*

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			Non Serious		Serious		Non Serious		Serious			
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		Foetal death	0	0	1	0	0	0	1	0	1	1
		Stillbirth	0	0	1	0	0	0	1	0	1	1
	Umbilical cord complications	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Umbilical cord short	1	0	0	0	1	0	0	0	1	1
		Umbilical granuloma	1	0	0	0	1	0	0	0	1	1
Product issues	*Subtotal*	*Subtotal*	*6*	*8*	*0*	*0*	*7*	*8*	*0*	*0*	*14*	*15*
	Device issues NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Device connection issue	1	0	0	0	1	0	0	0	1	1
	Device physical property and chemical issues	*Subtotal*	*1*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*1*	*2*
		Needle issue	1	0	0	0	1	0	0	0	1	1
		Syringe issue	1	0	0	0	1	0	0	0	1	1
	Product distribution and storage issues	*Subtotal*	*3*	*8*	*0*	*0*	*3*	*8*	*0*	*0*	*11*	*11*
		Inappropriate release of product for distribution	1	0	0	0	1	0	0	0	1	1
		Product temperature excursion issue	2	8	0	0	2	8	0	0	10	10
	Product quality issues NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Product substitution issue	1	0	0	0	1	0	0	0	1	1
Psychiatric disorders	*Subtotal*	*Subtotal*	*42*	*37*	*20*	*12*	*51*	*43*	*25*	*15*	*111*	*134*
	Abnormal behaviour NEC	*Subtotal*	*2*	*0*	*3*	*1*	*3*	*0*	*2*	*1*	*6*	*6*
		Abnormal behaviour	1	0	1	0	2	0	0	0	2	2
		Behaviour disorder	1	0	0	0	1	0	0	0	1	1
		Staring	0	0	2	1	0	0	2	1	3	3
	Affect alterations NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Affect lability	0	0	1	0	0	0	1	0	1	1
	Anxiety disorders NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Separation anxiety disorder	0	0	1	0	0	0	1	0	1	1
	Anxiety symptoms	*Subtotal*	*7*	*19*	*2*	*2*	*8*	*19*	*2*	*2*	*30*	*31*
		Agitation	1	1	0	2	1	1	0	2	4	4
		Anxiety	4	15	1	0	4	15	1	0	20	20
		Immunisation stress-related response	0	2	0	0	0	2	0	0	2	2
		Nervousness	3	1	0	0	3	1	0	0	4	4
		Stress	0	0	1	0	0	0	1	0	1	1
	Behaviour and socialisation disturbances	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Paranoia	0	0	1	0	0	0	1	0	1	1
	Confusion and disorientation	*Subtotal*	*5*	*3*	*2*	*4*	*5*	*3*	*2*	*4*	*14*	*14*
		Confusional state	5	3	2	4	5	3	2	4	14	14
	Deliria	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Delirium	0	0	1	0	0	0	1	0	1	1
	Delusional disorders	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Alice in wonderland syndrome	0	0	1	0	1	0	0	0	1	1
	Delusional symptoms	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Delusion	0	0	1	0	0	0	1	0	1	1
	Depressive disorders	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Depression	0	0	0	1	0	0	0	1	1	1
	Disturbances in initiating and maintaining sleep	*Subtotal*	*9*	*8*	*0*	*0*	*9*	*9*	*0*	*0*	*17*	*18*
		Initial insomnia	1	1	0	0	1	1	0	0	2	2
		Insomnia	7	8	0	0	7	8	0	0	15	15
		Middle insomnia	1	0	0	0	1	0	0	0	1	1
	Dyssomnias	*Subtotal*	*2*	*0*	*2*	*0*	*2*	*0*	*2*	*0*	*4*	*4*
		Poor quality sleep	2	0	2	0	2	0	2	0	4	4
	Emotional and mood disturbances NEC	*Subtotal*	*9*	*3*	*1*	*1*	*10*	*3*	*1*	*1*	*14*	*15*
		Dysphoria	2	0	0	0	3	0	0	0	2	3
		Emotional distress	1	0	0	0	1	0	0	0	1	1
		Irritability	4	3	1	1	4	3	1	1	9	9
		Mood altered	2	0	0	0	2	0	0	0	2	2

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			Non Serious		Serious		Non Serious		Serious			
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	Fear symptoms and phobic disorders (incl social phobia)	*Subtotal*	*0*	*2*	*0*	*2*	*0*	*2*	*0*	*3*	*4*	*5*
		Aerophobia	0	0	0	1	0	0	0	1	1	1
		Fear	0	1	0	0	0	1	0	0	1	1
		Hydrophobia	0	0	0	1	0	0	0	1	1	1
		Phonophobia	0	1	0	1	0	1	0	1	2	2
	Fluctuating mood symptoms	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Mood swings	1	0	0	0	1	0	0	0	1	1
	Hallucinations (excl sleep-related)	*Subtotal*	*1*	*1*	*2*	*0*	*1*	*2*	*2*	*0*	*4*	*5*
		Hallucination	0	0	2	0	0	0	2	0	2	2
		Hallucination, auditory	0	1	0	0	0	1	0	0	1	1
		Hallucination, visual	1	1	0	0	1	1	0	0	2	2
	Increased physical activity levels	*Subtotal*	*2*	*2*	*0*	*1*	*2*	*2*	*0*	*1*	*5*	*5*
		Restlessness	2	2	0	1	2	2	0	1	5	5
	Mood disorders NEC	*Subtotal*	*1*	*1*	*1*	*0*	*2*	*1*	*0*	*0*	*3*	*3*
		Apathy	0	1	0	0	0	1	0	0	1	1
		Listless	1	0	1	0	2	0	0	0	2	2
	Panic attacks and disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Panic reaction	0	0	1	0	0	0	1	0	1	1
	Parasomnias	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Sleep terror	1	0	0	0	1	0	0	0	1	1
		Somnambulism	0	0	1	0	0	0	1	0	1	1
	Perception disturbances NEC	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Jamais vu	0	0	1	0	1	0	0	0	1	1
	Psychiatric elimination disorders	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Enuresis	0	1	0	0	0	1	0	0	1	1
	Psychiatric symptoms NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Psychiatric symptom	0	0	1	0	0	0	1	0	1	1
	Psychotic disorder NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Psychotic disorder	0	0	1	0	0	0	1	0	1	1
	Sleep disorders NEC	*Subtotal*	*4*	*0*	*2*	*0*	*4*	*0*	*2*	*0*	*6*	*6*
		Sleep disorder	4	0	2	0	4	0	2	0	6	6
	Somatic symptom disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Conversion disorder	0	0	1	0	0	0	1	0	1	1
	Suicidal and self-injurious behaviour	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Suicide attempt	0	0	0	1	0	0	0	1	1	1
	Thinking disturbances	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Thinking abnormal	1	0	1	0	1	0	1	0	2	2
	Tic disorders	*Subtotal*	*0*	*1*	*1*	*1*	*0*	*1*	*1*	*1*	*3*	*3*
		Tic	0	1	1	1	0	1	1	1	3	3
Renal and urinary disorders	*Subtotal*	*Subtotal*	*6*	*3*	*9*	*6*	*7*	*4*	*14*	*8*	*24*	*33*
	Bladder and urethral symptoms	*Subtotal*	*3*	*2*	*4*	*1*	*4*	*2*	*4*	*1*	*10*	*11*
		Dysuria	2	2	1	0	2	2	1	0	5	5
		Incontinence	0	0	1	0	0	0	1	0	1	1
		Micturition urgency	0	0	0	1	0	0	0	1	1	1
		Pollakiuria	0	0	1	0	0	0	1	0	1	1
		Urinary incontinence	0	0	2	0	1	0	1	0	2	2
		Urinary retention	1	0	0	0	1	0	0	0	1	1
	Glomerulonephritis and nephrotic syndrome	*Subtotal*	*0*	*1*	*1*	*4*	*0*	*1*	*2*	*4*	*6*	*7*
		Glomerulonephritis	0	0	0	2	0	0	0	2	2	2
		IgA nephropathy	0	0	1	1	0	0	1	1	2	2
		Nephrotic syndrome	0	1	0	1	0	1	0	1	2	2
		Post infection glomerulonephritis	0	0	1	0	0	0	1	0	1	1
	Renal failure and impairment	*Subtotal*	*1*	*0*	*1*	*1*	*1*	*0*	*1*	*1*	*3*	*3*
		Acute kidney injury	0	0	1	1	0	0	1	1	2	2

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
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		Renal impairment	1	0	0	0	1	0	0	0	1	1
	Renal structural abnormalities and trauma	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Pyelocaliectasis	0	0	1	0	0	0	1	0	1	1
	Urinary abnormalities	*Subtotal*	*2*	*0*	*4*	*2*	*2*	*1*	*5*	*2*	*8*	*10*
		Chromaturia	1	0	0	0	1	0	0	0	1	1
		Haematuria	1	0	3	2	1	1	3	1	6	6
		Myoglobinuria	0	0	1	0	0	0	1	0	1	1
		Proteinuria	0	0	1	1	0	0	1	1	2	2
	Urinary tract signs and symptoms NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Renal pain	0	0	1	0	0	0	1	0	1	1
Reproductive system and breast disorders	*Subtotal*	*Subtotal*	*59*	*61*	*6*	*6*	*94*	*100*	*5*	*11*	*132*	*210*
	Breast disorders NEC	*Subtotal*	*2*	*2*	*0*	*0*	*2*	*2*	*0*	*0*	*4*	*4*
		Breast enlargement	0	1	0	0	0	1	0	0	1	1
		Breast mass	1	0	0	0	1	0	0	0	1	1
		Gynaecomastia	1	1	0	0	1	1	0	0	2	2
	Breast infections and inflammations	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Breast inflammation	1	0	0	0	1	0	0	0	1	1
	Breast signs and symptoms	*Subtotal*	*4*	*2*	*0*	*0*	*4*	*2*	*0*	*0*	*6*	*6*
		Breast engorgement	0	1	0	0	0	1	0	0	1	1
		Breast pain	1	0	0	0	1	0	0	0	1	1
		Breast swelling	1	0	0	0	1	0	0	0	1	1
		Breast tenderness	1	0	0	0	1	0	0	0	1	1
		Nipple exudate bloody	0	1	0	0	0	1	0	0	1	1
		Nipple pain	1	0	0	0	1	0	0	0	1	1
	Menstruation and uterine bleeding NEC	*Subtotal*	*29*	*32*	*3*	*4*	*41*	*45*	*2*	*7*	*68*	*95*
		Dysmenorrhoea	4	9	0	0	4	9	0	0	13	13
		Intermenstrual bleeding	6	4	1	1	8	5	0	0	12	13
		Menstrual discomfort	0	2	0	0	0	2	0	0	2	2
		Menstrual disorder	18	10	1	3	20	12	1	5	32	38
		Menstruation irregular	9	17	1	2	9	17	1	2	29	29
	Menstruation with decreased bleeding	*Subtotal*	*17*	*24*	*0*	*2*	*17*	*25*	*0*	*2*	*43*	*44*
		Amenorrhoea	9	14	0	2	9	14	0	2	25	25
		Hypomenorrhoea	0	4	0	0	0	4	0	0	4	4
		Menstruation delayed	3	5	0	0	3	5	0	0	8	8
		Oligomenorrhoea	5	2	0	0	5	2	0	0	7	7
	Menstruation with increased bleeding	*Subtotal*	*18*	*18*	*1*	*2*	*22*	*22*	*0*	*2*	*39*	*46*
		Heavy menstrual bleeding	14	14	1	2	15	16	0	2	31	33
		Menometrorrhagia	0	1	0	0	0	1	0	0	1	1
		Polymenorrhoea	7	5	0	0	7	5	0	0	12	12
	Ovarian and fallopian tube cysts and neoplasms	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Ovarian cyst	1	0	0	0	1	0	0	0	1	1
	Penile disorders NEC (excl erection and ejaculation)	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Penile pain	1	0	0	0	1	0	0	0	1	1
	Reproductive tract disorders NEC (excl neoplasms)	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Genital ulceration	1	0	1	0	1	0	1	0	2	2
	Reproductive tract signs and symptoms NEC	*Subtotal*	*0*	*3*	*0*	*0*	*0*	*4*	*0*	*0*	*3*	*4*
		Genital erythema	0	1	0	0	0	1	0	0	1	1
		Genital swelling	0	1	0	0	0	1	0	0	1	1
		Pelvic pain	0	2	0	0	0	2	0	0	2	2
	Scrotal disorders NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Varicocele	0	0	1	0	0	0	1	0	1	1
	Testicular and epididymal disorders NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Testicular pain	0	0	1	0	0	0	1	0	1	1
	Uterine disorders NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*

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			Non Serious		Serious		Non Serious		Serious			
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		Uterine haemorrhage	1	0	0	0	1	0	0	0	1	1
	Vulvovaginal disorders NEC	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Vaginal haemorrhage	2	0	0	0	2	0	0	0	2	2
	Vulvovaginal signs and symptoms	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Vaginal discharge	1	0	0	0	1	0	0	0	1	1
Respiratory, thoracic and mediastinal disorders	*Subtotal*	*Subtotal*	*97*	*71*	*64*	*33*	*141*	*83*	*71*	*39*	*265*	*334*
	Breathing abnormalities	*Subtotal*	*37*	*35*	*40*	*17*	*44*	*36*	*34*	*18*	*129*	*132*
		Dyspnoea	31	34	36	15	38	34	29	16	116	117
		Hyperventilation	6	0	1	0	6	0	1	0	7	7
		Respiration abnormal	0	0	0	1	0	0	0	1	1	1
		Respiratory depression	0	0	2	0	0	0	2	0	2	2
		Respiratory distress	0	0	2	0	0	0	2	0	2	2
		Respiratory fatigue	0	2	0	0	0	2	0	0	2	2
		Tachypnoea	0	0	0	1	0	0	0	1	1	1
	Bronchospasm and obstruction	*Subtotal*	*5*	*3*	*6*	*6*	*7*	*3*	*4*	*6*	*20*	*20*
		Asthma	1	0	2	3	2	0	1	3	6	6
		Asthmatic crisis	0	0	1	1	0	0	1	1	2	2
		Bronchospasm	1	2	0	1	1	2	0	1	4	4
		Obstructive airways disorder	0	0	1	0	1	0	0	0	1	1
		Wheezing	3	1	2	1	3	1	2	1	7	7
	Coughing and associated symptoms	*Subtotal*	*19*	*17*	*8*	*4*	*21*	*18*	*8*	*4*	*48*	*51*
		Cough	19	17	7	4	21	18	6	3	47	48
		Haemoptysis	0	0	1	1	0	0	1	1	2	2
		Productive cough	0	0	1	0	0	0	1	0	1	1
	Laryngeal spasm, oedema and obstruction	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Laryngeal oedema	0	1	0	0	0	1	0	0	1	1
	Lower respiratory tract signs and symptoms	*Subtotal*	*1*	*0*	*1*	*1*	*1*	*0*	*1*	*1*	*3*	*3*
		Hiccups	0	0	0	1	0	0	0	1	1	1
		Pulmonary pain	1	0	1	0	1	0	1	0	2	2
	Nasal congestion and inflammations	*Subtotal*	*4*	*2*	*2*	*0*	*5*	*2*	*1*	*0*	*8*	*8*
		Nasal congestion	4	2	2	0	5	2	1	0	8	8
	Nasal disorders NEC	*Subtotal*	*13*	*5*	*2*	*3*	*14*	*5*	*1*	*3*	*23*	*23*
		Epistaxis	12	5	2	3	13	5	1	3	22	22
		Nasal oedema	1	0	0	0	1	0	0	0	1	1
	Neonatal hypoxic conditions	*Subtotal*	*0*	*0*	*3*	*0*	*0*	*0*	*4*	*0*	*3*	*4*
		Infantile apnoea	0	0	1	0	0	0	1	0	1	1
		Neonatal hypoxia	0	0	1	0	0	0	1	0	1	1
		Neonatal respiratory distress syndrome	0	0	2	0	0	0	2	0	2	2
	Newborn respiratory disorders NEC	*Subtotal*	*1*	*0*	*2*	*1*	*1*	*0*	*3*	*1*	*4*	*5*
		Neonatal aspiration	0	0	2	0	0	0	2	0	2	2
		Neonatal dyspnoea	0	0	0	1	0	0	0	1	1	1
		Respiratory disorder neonatal	0	0	1	0	0	0	1	0	1	1
		Transient tachypnoea of the newborn	1	0	0	0	1	0	0	0	1	1
	Pharyngeal disorders (excl infections and neoplasms)	*Subtotal*	*2*	*1*	*1*	*0*	*2*	*1*	*1*	*0*	*4*	*4*
		Pharyngeal oedema	0	1	0	0	0	1	0	0	1	1
		Pharyngeal swelling	1	0	1	0	1	0	1	0	2	2
		Tonsillar hypertrophy	1	0	0	0	1	0	0	0	1	1
	Pneumothorax and pleural effusions NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Pneumothorax	0	0	1	0	0	0	1	0	1	1
	Pulmonary oedemas	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Pulmonary congestion	0	0	1	0	0	0	1	0	1	1
	Pulmonary thrombotic and embolic conditions	*Subtotal*	*0*	*1*	*1*	*2*	*0*	*1*	*1*	*2*	*4*	*4*
		Pulmonary embolism	0	1	1	2	0	1	1	2	4	4
	Respiratory signs and symptoms NEC	*Subtotal*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*2*	*2*

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			Non Serious		Serious		Non Serious		Serious			
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		Painful respiration	0	1	1	0	0	1	1	0	2	2
	Respiratory tract disorders NEC	*Subtotal*	*1*	*0*	*3*	*0*	*2*	*0*	*2*	*0*	*4*	*4*
		Lung disorder	0	0	1	0	1	0	0	0	1	1
		Respiratory disorder	0	0	1	0	0	0	1	0	1	1
		Respiratory tract congestion	1	0	0	0	1	0	0	0	1	1
		Respiratory tract oedema	0	0	1	0	0	0	1	0	1	1
	Upper respiratory tract signs and symptoms	*Subtotal*	*33*	*14*	*10*	*3*	*44*	*15*	*8*	*4*	*60*	*71*
		Dysphonia	2	1	0	0	2	1	0	0	3	3
		Increased viscosity of upper respiratory secretion	0	1	0	0	0	1	0	0	1	1
		Nasal discomfort	0	1	0	0	0	1	0	0	1	1
		Oropharyngeal discomfort	1	0	1	0	1	0	1	0	2	2
		Oropharyngeal pain	22	10	7	2	25	10	5	2	41	42
		Rhinorrhoea	10	1	1	0	11	1	0	0	12	12
		Sneezing	2	0	2	0	3	0	1	0	4	4
		Throat irritation	2	1	0	1	2	1	0	2	4	5
		Throat tightness	0	0	1	0	0	0	1	0	1	1
Skin and subcutaneous tissue disorders	*Subtotal*	*Subtotal*	*188*	*180*	*50*	*32*	*241*	*220*	*49*	*36*	*450*	*546*
	Alopecias	*Subtotal*	*2*	*3*	*0*	*0*	*2*	*4*	*0*	*0*	*5*	*6*
		Alopecia	1	2	0	0	1	2	0	0	3	3
		Alopecia areata	1	2	0	0	1	2	0	0	3	3
	Angioedemas	*Subtotal*	*1*	*0*	*7*	*3*	*1*	*0*	*7*	*3*	*11*	*11*
		Angioedema	0	0	7	2	0	0	7	2	9	9
		Circumoral swelling	1	0	0	1	1	0	0	1	2	2
	Apocrine and eccrine gland disorders	*Subtotal*	*12*	*6*	*6*	*2*	*14*	*6*	*4*	*2*	*26*	*26*
		Cold sweat	3	4	3	0	5	4	1	0	10	10
		Hyperhidrosis	9	2	2	0	9	2	2	0	13	13
		Night sweats	0	0	1	2	0	0	1	2	3	3
	Bullous conditions	*Subtotal*	*4*	*4*	*9*	*1*	*4*	*4*	*9*	*1*	*18*	*18*
		Blister	3	1	0	0	3	1	0	0	4	4
		Dermatitis bullous	0	0	1	0	0	0	1	0	1	1
		Erythema multiforme	1	3	7	1	1	3	7	1	12	12
		SJS-TEN overlap	0	0	1	0	0	0	1	0	1	1
	Dermal and epidermal conditions NEC	*Subtotal*	*18*	*3*	*1*	*1*	*19*	*3*	*1*	*1*	*23*	*24*
		Pain of skin	5	0	0	0	5	0	0	0	5	5
		Papule	1	0	0	0	1	0	0	0	1	1
		Skin burning sensation	2	1	1	0	2	1	1	0	4	4
		Skin discolouration	1	0	0	0	1	0	0	0	1	1
		Skin disorder	1	1	0	0	1	1	0	0	2	2
		Skin reaction	6	1	0	1	6	1	0	1	8	8
		Skin warm	3	0	0	0	3	0	0	0	3	3
	Dermatitis and eczema	*Subtotal*	*6*	*8*	*1*	*1*	*6*	*8*	*1*	*1*	*16*	*16*
		Dermatitis	2	1	0	0	2	1	0	0	3	3
		Dermatitis allergic	2	1	1	1	2	1	1	1	5	5
		Dermatitis atopic	1	1	0	0	1	1	0	0	2	2
		Eczema	1	0	0	0	1	0	0	0	1	1
		Neurodermatitis	0	1	0	0	0	1	0	0	1	1
		Perioral dermatitis	0	1	0	0	0	1	0	0	1	1
		Prurigo	0	2	0	0	0	2	0	0	2	2
		Skin irritation	0	1	0	0	0	1	0	0	1	1
	Dermatitis ascribed to specific agent	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Drug eruption	0	0	1	0	0	0	1	0	1	1
	Erythemas	*Subtotal*	*30*	*64*	*5*	*4*	*32*	*65*	*5*	*3*	*103*	*105*
		Erythema	30	64	5	4	32	65	5	3	103	105
	Exfoliative conditions	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*

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		Skin exfoliation	1	0	0	0	1	0	0	0	1	1
	Granulomatous and deep cutaneous inflammatory conditions	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Granuloma annulare	0	0	1	0	0	0	1	0	1	1
	Panniculitides	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Erythema nodosum	0	0	1	0	0	0	1	0	1	1
	Papulosquamous conditions	*Subtotal*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*0*	*2*	*2*
		Lichen sclerosus	0	1	0	0	0	1	0	0	1	1
		Pityriasis rosea	1	0	0	0	1	0	0	0	1	1
	Photosensitivity and photodermatosis conditions	*Subtotal*	*2*	*0*	*0*	*1*	*2*	*0*	*0*	*1*	*3*	*3*
		Photosensitivity reaction	2	0	0	1	2	0	0	1	3	3
	Pruritus NEC	*Subtotal*	*25*	*27*	*3*	*4*	*26*	*28*	*2*	*3*	*59*	*59*
		Pruritus	25	27	3	4	26	28	2	3	59	59
	Psoriatic conditions	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Psoriasis	0	1	0	0	0	1	0	0	1	1
	Purpura and related conditions	*Subtotal*	*0*	*1*	*2*	*3*	*0*	*1*	*2*	*3*	*6*	*6*
		Ecchymosis	0	1	0	0	0	1	0	0	1	1
		Henoch-Schonlein purpura	0	0	2	1	0	0	2	1	3	3
		Petechiae	0	0	0	2	0	0	0	2	2	2
	Rashes, eruptions and exanthems NEC	*Subtotal*	*87*	*71*	*9*	*12*	*94*	*76*	*7*	*10*	*179*	*187*
		Nodular rash	0	0	1	0	0	0	1	0	1	1
		Rash	68	57	7	10	74	60	5	9	142	148
		Rash erythematous	5	0	0	0	5	0	0	0	5	5
		Rash macular	0	3	1	0	0	3	1	0	4	4
		Rash maculo-papular	5	4	0	1	5	5	0	0	10	10
		Rash papular	3	2	0	0	3	2	0	0	5	5
		Rash pruritic	6	4	0	1	6	4	0	1	11	11
		Rash scarlatiniform	1	0	0	0	1	0	0	0	1	1
		Rash vesicular	0	2	0	0	0	2	0	0	2	2
	Skin and subcutaneous tissue ulcerations	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Skin ulcer	0	0	1	0	0	0	1	0	1	1
	Skin cysts and polyps	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Dermal cyst	0	1	0	0	0	1	0	0	1	1
	Skin vasculitides	*Subtotal*	*0*	*0*	*2*	*1*	*0*	*0*	*2*	*1*	*3*	*3*
		Cutaneous vasculitis	0	0	1	1	0	0	1	1	2	2
		Hypersensitivity vasculitis	0	0	1	0	0	0	1	0	1	1
	Skin vasomotor conditions	*Subtotal*	*3*	*0*	*1*	*0*	*3*	*0*	*1*	*0*	*4*	*4*
		Livedo reticularis	3	0	1	0	3	0	1	0	4	4
	Urticarias	*Subtotal*	*32*	*21*	*6*	*7*	*36*	*22*	*4*	*7*	*66*	*69*
		Mechanical urticaria	1	0	0	0	1	0	0	0	1	1
		Solar urticaria	1	0	0	0	1	0	0	0	1	1
		Urticaria	31	21	6	7	34	22	4	7	65	67
Social circumstances	*Subtotal*	*Subtotal*	*5*	*2*	*3*	*0*	*5*	*3*	*3*	*0*	*10*	*11*
	Disability issues	*Subtotal*	*5*	*1*	*2*	*0*	*5*	*1*	*2*	*0*	*8*	*8*
		Bedridden	1	0	0	0	1	0	0	0	1	1
		Impaired work ability	4	0	1	0	4	0	1	0	5	5
		Loss of personal independence in daily activities	0	1	1	0	0	1	1	0	2	2
	Employment issues	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Sick leave	0	1	0	0	0	1	0	0	1	1
	Social issues NEC	*Subtotal*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*2*	*2*
		Impaired quality of life	0	1	0	0	0	1	0	0	1	1
		Patient uncooperative	0	0	1	0	0	0	1	0	1	1
Surgical and medical procedures	*Subtotal*	*Subtotal*	*64*	*31*	*9*	*5*	*67*	*32*	*6*	*4*	*109*	*109*
	Cardiac therapeutic procedures NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Cardioversion	0	0	1	0	0	0	1	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
	Immunisations	*Subtotal*	*9*	*5*	*6*	*3*	*10*	*5*	*5*	*3*	*23*	*23*
		COVID-19 immunisation	9	5	6	3	10	5	5	3	23	23
	Therapeutic procedures NEC	*Subtotal*	*55*	*26*	*2*	*2*	*57*	*27*	*0*	*1*	*85*	*85*
		Interchange of vaccine products	55	26	2	2	57	27	0	1	85	85
Vascular disorders	*Subtotal*	*Subtotal*	*31*	*23*	*18*	*9*	*39*	*24*	*14*	*9*	*81*	*86*
	Blood pressure disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Blood pressure fluctuation	0	0	0	1	0	0	0	1	1	1
	Circulatory collapse and shock	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Circulatory collapse	0	0	1	0	0	0	1	0	1	1
		Peripheral circulatory failure	0	0	1	0	0	0	1	0	1	1
	Haemorrhages NEC	*Subtotal*	*1*	*4*	*1*	*1*	*1*	*4*	*1*	*1*	*7*	*7*
		Haematoma	1	3	1	1	1	3	1	1	6	6
		Haemorrhage	0	1	0	0	0	1	0	0	1	1
	Non-site specific embolism and thrombosis	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Thrombosis	0	0	2	0	0	0	2	0	2	2
	Non-site specific vascular disorders NEC	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Capillary fragility	1	0	0	0	1	0	0	0	1	1
		Hyperaemia	1	0	0	0	1	0	0	0	1	1
	Peripheral embolism and thrombosis	*Subtotal*	*1*	*0*	*3*	*1*	*2*	*0*	*2*	*1*	*5*	*5*
		Pelvic venous thrombosis	0	0	0	1	0	0	0	1	1	1
		Superficial vein thrombosis	1	0	2	0	2	0	1	0	3	3
		Venous thrombosis limb	0	0	1	0	0	0	1	0	1	1
	Peripheral vascular disorders NEC	*Subtotal*	*10*	*7*	*1*	*1*	*10*	*7*	*1*	*1*	*19*	*19*
		Cyanosis	1	1	1	1	1	1	1	1	4	4
		Flushing	6	1	0	0	6	1	0	0	7	7
		Hot flush	3	3	0	0	3	3	0	0	6	6
		Peripheral vascular disorder	0	2	0	0	0	2	0	0	2	2
	Peripheral vasoconstriction, necrosis and vascular insufficiency	*Subtotal*	*1*	*4*	*1*	*1*	*1*	*4*	*1*	*1*	*7*	*7*
		Peripheral coldness	1	2	1	0	1	2	1	0	4	4
		Raynaud's phenomenon	0	2	0	1	0	2	0	1	3	3
	Phlebitis NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Phlebitis superficial	0	0	0	1	0	0	0	1	1	1
	Site specific vascular disorders NEC	*Subtotal*	*10*	*5*	*8*	*2*	*16*	*5*	*4*	*2*	*25*	*27*
		Pallor	10	5	8	2	16	5	4	2	25	27
	Vascular hypertensive disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Hypertension	0	1	0	0	0	1	0	0	1	1
	Vascular hypotensive disorders	*Subtotal*	*6*	*3*	*1*	*1*	*6*	*3*	*1*	*1*	*11*	*11*
		Hypotension	6	3	1	1	6	3	1	1	11	11
	Vasculitides NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Vasculitis	1	0	0	0	1	0	0	0	1	1
Grand total			5,652	1,451	508	295	9,582	3,943	1,253	789	7,906	15,567

Appendix 11.30b Children: Summary of Serious cases in children 2-11 years of age

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
4.1(b) [redacted]	Facial paresis, Paraparesis, Product administered to patient of inappropriate age	11	Female	This spontaneous case was reported by a consumer and describes the occurrence of PARAPARESIS (Partial paralysis in legs and face) in an 11-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) 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 dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced PARAPARESIS (Partial paralysis in legs and face) (seriousness criterion medically significant), FACIAL PARESIS (Partial paralysis in legs and face) and PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (11 year old girl who got your vaccine). At the time of the report, PARAPARESIS (Partial paralysis in legs and face) and FACIAL PARESIS (Partial paralysis in legs and face) outcome was unknown and PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE (11 year old girl who got your vaccine) had resolved. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. No concomitant medication was provided. No Treatment medication was provided. It was reported that the 11 year old girl who got vaccine that now has partial paralysis in her legs and face. Company comment: This case of product administered to patient of inappropriate age concerns a 11-year-old female patient with no reported medical history who experienced serious unexpected event of paraparesis, that occurred after the dose of the mRNA-1273 . The rechallenge was not applicable due to unspecified number of doses administered. 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] 4.1(D) [redacted]
[redacted]	Exposure via breast milk, Lethargy	2	Female	This case was received via 4.1(b) [redacted] (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 consumer and describes the occurrence of LETHARGY (Lethargy) and EXPOSURE VIA BREAST MILK (Exposure via breast milk) in a 2-year-old female child exposed to mRNA-1273 (Moderna CoviD-19 Vaccine) , while the mother received the product for an unknown indication. Patient has not had symptoms associated with COVID-19 Not had a COVID-19 test. On 11-Nov-2021, the mother received first dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 09-Jan-2022, received second dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. Last menstrual period and estimated date of delivery were not provided. On 12-Nov-2021, the child was diagnosed with LETHARGY (Lethargy) (seriousness criterion medically significant). On an unknown date, the child was diagnosed with EXPOSURE VIA BREAST MILK (Exposure via breast milk) (seriousness criterion medically significant). The delivery occurred on an unknown date, which was reported as Unknown. For neonate 1, The outcome was reported as Unknown. At the time of the report, LETHARGY (Lethargy) had not resolved and EXPOSURE VIA BREAST MILK (Exposure via breast milk) outcome was unknown.	4.1(b) [redacted]

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
				No concomitant medication reported No treatment medication reported Patient's mother had her first dose of Moderna vaccination on 11-Nov-2021. She breast fed her daughter who is 29 months old. She has been very lethargic today, not her usual bubbly self at all (10-Jan-2022). This occured the day after my first dose of Moderna vaccination too which I had on 11-Nov-2021, she was lethargic on 12-Nov-21. After her first vaccination it resolved within 24hrs, but she felt it needed reporting. She had expected to receive the Pfizer vaccine as that has had more research in connection with breast feeding. However her local walk in centre was no longer offering Pfizer. So she had little choice in the matter. Patient has not tested positive for COVID-19 since having the vaccine. Patient is not enrolled in clinical trial. Adverse reaction did not occur as a result of an exposure during pregnancy. Most recent FOLLOW-UP information incorporated above includes: On 12-Jan-2022: Significant follow up received: Events, Medical history, Dose 1 details, Route of administration, Action taken updated.	
4.1(b) [redacted]	Chills	4	Male	This regulatory authority case was reported by a consumer and describes the occurrence of CHILLS (Chills) in a 49-month-old male patient who received mRNA-1273 (COVID-19 Vaccine Moderna) (batch no. 068F21A) for an unknown indication. No Medical History information was reported. On 02-Dec-2021, the patient received dose of mRNA-1273 (COVID-19 Vaccine Moderna) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced CHILLS (Chills) (seriousness criterion death). It is unknown if an autopsy was performed. No concomitant medications were reported. The onset date and time of the reaction for event Chills is 26132:22:00 and the end date and time of the reaction has been given as 26132:22:25 and the duration of the event is given as 25 minutes. The patient has experienced chest pain, Chills, Malaise 18 days after 2nd dose of Moderna vaccine. Patient has type 2 diabetes mellitus along with cardiomegaly which has been detected on 2016. He also experienced edema in both legs. A wound is also present in his left leg as observed by his family members. He was admitted to 4.1(b) [redacted] Hospital on December 21, 2021. No treatment medications were reported. Company Comment: This regulatory case concerns a reported 49-month-old (calculated age from provided birthdate is 49 years old), male patient with left leg wound and pre-existing type II diabetes mellitus and cardiomegaly, who experienced the unexpected, fatal event of Chills. The patient experienced the reported event of Chills along with chest pain and malaise 18 days after the second dose of mRNA-1273 vaccine. He was reportedly admitted in a provincial hospital the next day however, the clinical course and medical interventions conducted were not provided in the case. The date of demise was not mentioned. It is unknown if autopsy was performed. The left leg wound in the setting of pre-existing diabetes could be a confounder for the development of the chills. The chronic, pre-existing conditions of cardiomegaly and type II diabetes mellitus remain as 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.	4.1(b) [redacted]
4.1(b) [redacted]	Medication error, Product prescribing error	7	Female	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] on 14-Mar-2022 and was forwarded to Moderna on 14-Mar-2022.	4.1(b) [redacted]

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
				This regulatory authority case was reported by a physician and describes the occurrence of MEDICATION ERROR (Incorrect vaccine administration for age group and dose) and PRODUCT PRESCRIBING ERROR (Drug prescribing error) in a 7-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3006276) for COVID-19 vaccination. No Medical History information was reported. On 19-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Subcutaneous) .5 milliliter. On 19-Jan-2022, the patient experienced MEDICATION ERROR (Incorrect vaccine administration for age group and dose) (seriousness criterion life threatening) and PRODUCT PRESCRIBING ERROR (Drug prescribing error) (seriousness criterion life threatening). At the time of the report, MEDICATION ERROR (Incorrect vaccine administration for age group and dose) and PRODUCT PRESCRIBING ERROR (Drug prescribing error) had resolved. mRNA-1273 (Spikevax) (Subcutaneous) was withdrawn on an unknown date. For mRNA-1273 (Spikevax) (Subcutaneous), the reporter did not provide any causality assessments. No concomitant product was provided. No treatment information was provided. Company comment-This regulatory authority case concerns a pediatric 7-year-old female patient with no relevant medical history reported, who experienced unexpected serious (Life threatening) events of Medication error(Reported as Incorrect vaccine administration for age group and dose) and Product prescribing error on the same day after a dose of mRNA-1273 vaccine administration. No additional details provided on clinical events and treatment details. The benefit-risk relationship of the mRNA-1273 vaccine is not affected by this report. Event seriousness assessed as per Regulatory Authority reporting, however there was no information in the source document supporting that the events resulted in a life threatening situation.	
4.1(b) [redacted]	Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth, Muscle rupture, Myalgia, Rash, Vaccination site pain	4	Female	This case was received via European Medicines Agency (Reference number: 4.1(b) [redacted] 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 MUSCLE RUPTURE (muscle pain, small muscle fiber tear on the thigh) in a 47-month-old female patient who received mRNA-1273 (Spikevax) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. It was reported that the patient had Latex allergy. Information on risk factors or pre-existing conditions reported as Lupus CLE. On 05-Feb-2022, the patient received second dose of mRNA-1273 (Spikevax) (Intramuscular) .5 milliliter. On 06-Feb-2022, the patient experienced INJECTION SITE ERYTHEMA (Severe swelling at the puncture site, palm-sized, after under erythema. pain, pressure-sensitive and overheated.), MUSCLE RUPTURE (muscle pain, small muscle fiber tear on the thigh) (seriousness criterion medically significant), INJECTION SITE PAIN (Severe swelling at the puncture site, palm-sized, after under erythema. pain, pressure-sensitive and overheated.), INJECTION SITE SWELLING (Severe swelling at the puncture site, palm-sized, after under erythema. pain, pressure-sensitive and overheated.), VACCINATION SITE PAIN (Severe swelling at the puncture site, palm-sized, after under erythema. pain, pressure-sensitive and overheated.), RASH (Severe swelling at the puncture site, palm-sized, after under erythema. pain, pressure-sensitive and overheated.), MYALGIA (muscle pain, small muscle fiber tear on the thigh) and INJECTION SITE WARMTH (Severe swelling at the puncture site, palm-sized, after under erythema. pain, pressure-sensitive and overheated.). At the time of the report, INJECTION SITE ERYTHEMA (Severe swelling at the puncture site, palm-sized, after under erythema. pain, pressure-sensitive and overheated.), MUSCLE RUPTURE (muscle pain, small muscle fiber tear on the thigh), INJECTION SITE PAIN (Severe swelling at the puncture site, palm-sized,	4.1(b) [redacted]

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
				after under erythema. pain, pressure-sensitive and overheated.), INJECTION SITE SWELLING (Severe swelling at the puncture site, palm-sized, after under erythema. pain, pressure-sensitive and overheated.), VACCINATION SITE PAIN (Severe swelling at the puncture site, palm-sized, after under erythema. pain, pressure-sensitive and overheated.), RASH (Severe swelling at the puncture site, palm-sized, after under erythema. pain, pressure-sensitive and overheated.), MYALGIA (muscle pain, small muscle fiber tear on the thigh) and INJECTION SITE WARMTH (Severe swelling at the puncture site, palm-sized, after under erythema. pain, pressure-sensitive and overheated.) was resolving. No concomitant drug was reported. It was reported that patient was taking antihistamines against allergic skin reaction on the arm and observed improvement 2 days after the start of use, redness persists and also reported that muscles could hardly be tense, keeping objects more difficult, lifting arm too and For muscle pain, Ibuprofen 400 was taken, muscle fiber rupture was treated with hepathromb, but still visible. Company comment: This regulatory case concerns a 47-month-old female patient with relevant medical history of Lupus CLE, who experienced the unexpected serious (medically significant) event Muscle rupture, one day after a dose of mRNA-1273. It was reported that the patient developed muscle pain, small muscle fiber tear on the thigh. For muscle pain, Ibuprofen 400 was taken, muscle fiber rupture was treated with hepathromb. At the time of reporting, the event was resolving. Medical history of Lupus CLE 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. Most recent FOLLOW-UP information incorporated above includes: On 17-Mar-2022: Upon query received from business partner, non-significant correction was performed on 31-Mar-2022. The age of the patient was updated from 47-year-old to 47-month-old in the company comment.	
4.1(b) [redacted]	Phlebitis superficial	6	Female	This regulatory authority case was reported by a consumer and describes the occurrence of PHLEBITIS SUPERFICIAL (on both sides.) in a 6-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 045621A) for COVID-19 vaccination. No Medical History information was reported. On 20-Jan-2022, the patient received dose of mRNA-1273 (Spikevax) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PHLEBITIS SUPERFICIAL (on both sides.) (seriousness criterion medically significant). At the time of the report, PHLEBITIS SUPERFICIAL (on both sides.) was resolving. The action taken with mRNA-1273 (Spikevax) (Intramuscular) was unknown. Initial. 4.1(b) [redacted] Concomitant medications were not reported. Treatment medications were not reported. COMPANY COMMENT: This is a regulatory authority case concerning a 6-year-old, female patient with no reported medical history, who experienced the unexpected serious (medically significant) event of Phlebitis superficial. The event occurred on an unknown date after the unspecified dose of mRNA-1273 COVID 19 Vaccine which was administered on January 20, 2022. The event was reported as resolving. No further medical information available. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.	4.1(b) [redacted]

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
4.1(b)	Chest pain, Tension headache	10	Female	This case was received via 4.1(b) (Reference number: 4.1(b)) on 08-May-2022 and was forwarded to Moderna on 08-May-2022. This regulatory authority case was reported by a consumer and describes the occurrence of CHEST PAIN (Chest pain) and TENSION HEADACHE (Tension headache) in a 10-year-old female patient who received mRNA-1273 (Moderna CoviD-19 Vaccine) for COVID-19 vaccination. It was reported that patient has no allergies and full healthy. On 26-Apr-2022, the patient received dose of mRNA-1273 (Moderna CoviD-19 Vaccine) (unknown route) 1 dosage form. On 04-May-2022, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion medically significant) and TENSION HEADACHE (Tension headache) (seriousness criterion medically significant). On 06-May-2022, TENSION HEADACHE (Tension headache) was resolving. At the time of the report, CHEST PAIN (Chest pain) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, SARS-CoV-2 test: negative (Negative) Test Result: Negative. The action taken with mRNA-1273 (Moderna CoviD-19 Vaccine) (Unknown) was unknown. No concomitant medication information provided. The patient experienced severe headache latest for 2 days about a week after vaccine and shortly followed by a continuous cough for 4 days and extreme sore throat, chest pain and slight difficult breathing owing to phlegm on chest. No temperature was reported. Reported adverse reaction did not occur as a result of an exposure during pregnancy.The reaction was not occurred as a result of a mistake made in the administration of the vaccine. No treatment medication information provided. Company Comment: This regulatory authority case concerns a 10 year old female patient with no medical history reported, who experienced Serious (Medically significant) unexpected events of chest pain and tension headache which occurred 8 days post vaccination with an unknown dose number of mRNA-1273 vaccine . The patient experienced severe headache which lasted for 2 days about a week after vaccine and shortly followed by a continuous cough for 4 days and extreme sore throat, chest pain and slight difficult breathing owing to phlegm on chest. No temperature was reported. This patient was reported to have a . Negative Covid-19 RAT tests throughout.The details surrounding the events like treatment information , results of other laboratories/diagnostic procedures or any medical consultation done were not reported. Outcome of the event chest pain was reported as not resolved while for the event tension headache it was reported as resolving. The benefit -risk relationship of mRNA -1273 (Moderna Covid 19 Vaccine) is not affected by this report. Events' seriousness assessed as per regulatory report. Most recent FOLLOW-UP information incorporated above includes: On 08-May-2022: Upon Internal Review on 20-Jun-2022, Non Significant correction was performed to update Reference type as E2B Authority number from E2B company number and liner in the paper icon was added as "it was reported that patient has no allergies and full healthy".	4.1(b)
4.1(b)	Pruritus, Pyrexia	9	Female	This regulatory authority case was reported by an other health care professional and describes the occurrence of PYREXIA (Fever) and PRURITUS (Skin itching) in a 9-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 10-May-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 16-May-2022, the patient experienced PYREXIA (Fever) (seriousness	4.1(b)

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
				criterion medically significant) and PRURITUS (Skin itching) (seriousness criterion medically significant). At the time of the report, PYREXIA (Fever) and PRURITUS (Skin itching) was resolving. 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 age of the patient was reported as 9.5. No concomitant medications were reported. After first dose of Moderna, patient had discomfort symptoms (fever above 39 degrees occurred on May 10, tongue ulceration occurred on May 11, and general rash occurred on May 14). As it was worried that they were discomforts caused by vaccination, the patient went to Hospital on May 10 for consultations and treatments. The doctor told the patient that the patient had to go to the emergency department for treatment because of fever. Treatment medications included anti-inflammatory and anti-fever drugs, then the patient returned to home for rest. Now the patient had taken the drugs for two days, but the symptoms still existed. Upon follow-up on 16-May-2022, the father of the patient said that the symptoms existed and the angular stomatitis was serious. The doctor had prescribed oral ointment and oral spray painkillers. It was suggested that the father of the patient could increase the immunity of the patient, supplement vitamin B and C and drink appropriate water, and for the angular stomatitis, ice could be put into mouth to relieve the pain. The father of the patient asked about the application process for relief for harm, and explanations were made, and the patient would be further followed up. The worldwide UID was reported as 4.1(b) [redacted] Company comment: This is a Regulatory Authority case concerning a 9 years female child patient with no medical history reported, who experienced the unexpected serious (medically significant) events of pyrexia, pruritus, which occurred 6 days after first dose of mRNA1273 vaccine. It is reported that after vaccination patient had fever, tongue ulceration and general rash, patient went to hospital for consultation and treatment, doctor told to go to emergency and advised treatment medications included anti-inflammatory and anti-fever drugs, then the patient returned to home for rest. Now the patient has taken the drugs for two days, but the symptoms still exist. Upon follow-up on 16-May-2022, the father of the patient said that the symptoms existed and the angular stomatitis was serious,doctor had prescribed oral ointment and oral spray painkillers. Advise had given to increase the immunity of the patient, supplement vitamin B and C and drink appropriate water, and for the angular stomatitis, ice could be put into mouth to relieve the pain. The father of the patient asked about the application process for relief for harm, and explanations were made. . 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]	Muscular weakness	7	Male	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 23-May-2022 and was forwarded to Moderna on 25-May-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of MUSCULAR WEAKNESS (Limb weakness) in a 7-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Attention deficit hyperactivity disorder (History of ADHD (attention deficit hyperactivity disorder, complex type), receiving long-term treatment and rehabilitation in the Department of Neurology in a children's Hospital, using Tetalin for treatment.). On 07-May-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 11-May-2022, the patient experienced MUSCULAR WEAKNESS (Limb	4.1(b) [redacted]

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
				weakness) (seriousness criterion hospitalization). At the time of the report, MUSCULAR WEAKNESS (Limb weakness) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Echocardiogram: no myocarditis was found no myocarditis was found. There was no abnormality.. On an unknown date, Heart rate: fast At present, only the heartbeat is fast.. On an unknown date, Troponin I: 166.5 (High) The hs-Troponin-I was very high: 166.5 ng/L.. 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 product use was provided by the reporter. On 5/9, he complained that was unable to walk because of foot pain (limping when walking). He was observed for 2 days and then referred to Hospital. The mother of the pt felt that the symptoms were for by the vaccine. On 5/11/2022, the pt was admitted to the hospital. He had dry cough on 5/8. On 9-May, the pt had chest tightness, pain of both lower limbs and inconvenience in walking. The pt was hospitalized for observations, and no myocarditis was found in ECG. Antitussive drugs and antihistamines were received. On 15/12, the hospital was consulted. During report, the related symptoms of pain and weakness was relieved, and the pt could get out of bed and ambulate. MD said that he was hospitalized for observation due to slightly high myocardial enzyme. During report, only the heartbeat was fast. The mother said that he could get out of bed (but the feet were weak) and he had pain. On 5/13/22: The other symptoms were relieved, and the myocardial index was decreased, the feet was still a little weak, which was reported to the doctor and would be observed. Discharged on 5/14, the phenomenon of myocarditis had become stable. For pharyngitis, cough and expectorant drugs were taken home, the symptoms were relieved. He would return hospital on Wednesday. WWID number of the case was 4.1(b) [redacted] COMPANY COMMENT: This is an spontaneous case concerning a 7-years-old male patient with medical history of concurrent medical conditions included Attention deficit hyperactivity disorder who experienced the unexpected (seriousness criterion hospitalization) event of MUSCULAR WEAKNESS 5 days after 1st dose of mRNA-1273 vaccine. On an unknown date, echocardiogram was found no myocarditis, heart rate fast and Troponin-I was very high (166.5 ng/L).The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Event´s seriousness assessed as reporting. Most recent FOLLOW-UP information incorporated above includes: On 23-May-2022: Upon internal Review on 01-Jun-2022, non-significant correction was made to update company comment.	
4.1(b) [redacted]	Nausea, Vomiting	11	Female	This regulatory authority case was reported by an other health care professional and describes the occurrence of NAUSEA (Nausea) and VOMITING (Vomiting) in an 11-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 006K21A_1110210-CDC) for COVID-19 vaccination. No Medical History information was reported. On 11-May-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .5 milliliter. On 11-May-2022, the patient experienced NAUSEA (Nausea) (seriousness criterion medically significant) and VOMITING (Vomiting) (seriousness criterion medically significant). At the time of the report, NAUSEA (Nausea) and VOMITING (Vomiting) had resolved.	4.1(b) [redacted]

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
				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. Patient age reported as 11.6 years. Concomitant product use was not provided by the reporter. About 5 minutes later the patient had frequent nausea and vomiting and went to the emergency department for consultations and treatments due to the discomforts. On 13-May-2022, the father of the patient said that the patient complained of chest tightness at that time, and there was no other symptom. The patient went to school that day and health education was carried out to the father of the patient to pay more attention to the changes of child's symptoms. The father of the patient said that he knew it and acknowledged the care from the district management. No treatment information was provided. WWID was reported as 4.1(b) [redacted] Company comment. This regulatory case concerns a 11 – year – old, female patient with no medical history reported, who experienced the unexpected, serious medically significant events of nausea and vomiting, the same day after the administration of the first dose of mRNA-1273 vaccine. The report stated that the patient had frequent nausea and vomiting and went to the emergency department for consultation and treatment. Two days later, the reporter mentioned the patient had chest tightness. No further details were provided for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	
4.1(b) [redacted]	Nausea, Vomiting	9	Male	This regulatory authority case was reported by an other health care professional and describes the occurrence of NAUSEA (Nausea) and VOMITING (Vomiting) in a 9-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 13-May-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-May-2022, the patient experienced NAUSEA (Nausea) (seriousness criterion medically significant) and VOMITING (Vomiting) (seriousness criterion medically significant). The patient was treated with METOCLOPRAMIDE HYDROCHLORIDE (PRIMPERAN) (intramuscular) at a dose of 0.7 Amp ST; DIPHENHYDRAMINE (intramuscular) at a dose of 0.7 Amp ST; DOMPERIDONE (NIDOLIUM) at a dose of 1 dosage form three times a day; DIPHENHYDRAMINE HYDROCHLORIDE (VENA [DIPHENHYDRAMINE HYDROCHLORIDE]) at a dose of 1 Tab, tid; LACTOMIN (BIOFERMIN [LACTOMIN]) at a dose of S1 Tab, tid or a total of 3 days and PARACETAMOL (DEPYRETIN) at a dose of 0.5 tab, prn. At the time of the report, NAUSEA (Nausea) and VOMITING (Vomiting) was resolving. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 18-May-2022, Blood pressure measurement: 111/81 Test Result: 111/81 mmHg. On 18-May-2022, Body temperature: 35 Test Result: 35°C. On 18-May-2022, Coma scale: e4v5m6 Test Result: E4V5M6. On 18-May-2022, Heart rate: 86 Test Result: 86 BPM. On 18-May-2022, Respiratory rate: 20 Test Result: 20 times/min. 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. Worldwide UID was reported as 4.1(b) [redacted]	4.1(b) [redacted]

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
				No concomitant medication information provided May 13, 2022: The first dose of Moderna vaccine was administered. May 18, 2022: The patient came to our hospital for emergency consultations and treatments, and the chief complaint was that the patient vomited for 4 times from the evening. The doctor examined and the patient was vomited tonight and after dinner the patient had no fever, received COVID Moderna vaccine first dose on May 13 with no chest pain, no RLQ pain, nor peritoneal sign, no cough, having physical conditions prone to vomiting. After consultations and diagnosis the patient was allowed to be discharged from the hospital under stable conditions. Since it was impossible to rule out the correlation between the nausea and vomiting and the adverse reactions of the COVID-19 vaccine. Company Comment: This regulatory authority case concerns a 9-year-old male patient with no medical history reported who experienced the unexpected, serious (medically significant) events of Nausea and Vomiting which occurred five days after receiving the first dose of mRNA-1273 vaccine. There were no other accompanying signs and symptoms. Patient consulted the emergency room after developing four episodes of vomiting. His vital signs were stable except for a low body temperature. Diagnosis was not provided but he was treated with intramuscular injections of metoclopramide and diphenhydramine. His condition improved hence discharged with home medications of domperidone, diphenhydramine, lactomin and paracetamol. 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]	Palpitations	10	Male	This regulatory authority case was reported by an other health care professional and describes the occurrence of PALPITATIONS (Palpitation) in a 10-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 13-May-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-May-2022, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced PALPITATIONS (Palpitation) (seriousness criterion medically significant). The patient was treated with TAITA NO.1 (iv drip) at a dose of 500 ml IVD ST; DICLOFENAC POTASSIUM (CATAFLAM [DICLOFENAC POTASSIUM]) (oral) at a dose of 1 dosage form four times per day; DEXTROMETHORPHAN HYDROBROMIDE, LYSOZYME HYDROCHLORIDE, POTASSIUM CRESOLSULFONATE (MEDICON A) (oral) at a dose of 1 dosage form three times a day and PARACETAMOL (DEPYRETIN) (oral) at a dose of 1 dosage form as required. At the time of the report, PALPITATIONS (Palpitation) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On an unknown date, Blood creatine phosphokinase: 66 u/l (normal) 66 u/l. On an unknown date, Blood creatine phosphokinase MB: 0.4 ng/ml (normal) 0.4 ng/ml. On an unknown date, Blood creatinine: 0.57 mg/dl (normal) 0.57 mg/dl. On an unknown date, Blood pressure measurement: 117/59 mm hg (Low) 117/59 mm Hg. On an unknown date, Body temperature: 38.2 degree c (High) 38.2 degree C. On an unknown date, C-reactive protein: 1.97 mg/dl (normal) 1.97 mg/dl. On an unknown date, Coma scale: e4v5m6 (normal) E4V5M6. On an unknown date, Heart rate: 150 bpm (High) 150 BPM. On an unknown date, Oxygen saturation: 97 percent (normal) 97 percent. On an unknown date, SARS-CoV-2 test: positive (Positive) Positive. On an unknown date, Troponin I: < 0.0023 ng/ml (normal) < 0.0023 ng/ml. On an unknown date, White blood cell count: 13.94x 1000/ul 13.94x 1000/ul. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown.	4.1(b) [redacted]

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
				For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Company comment: This is a regulatory case concerning a 10-year-old male patient with no reported medical history, who experienced the serious (medically significant) unexpected event palpitations, the next following day after the first dose of mRNA-1273. Patient sought for medical attention due to fever and palpitations. Vital signs examination showed HR 150 bpm and T°38.2°C. Lab test was performed: WBC, CK-MB, CPK, Tropo-I, CRP and creatinine with normal results. COVID-19 PCR test was reported with a positive result. Symptomatic medication was given and patient was discharged. Concomitant event pyrexia remains a confounder for event palpitations. The benefit-risk relationship of mRNA-1273 is not affected by this report. The worldwide UID was reported as 4.1(b) [redacted] The patient age was reported as 10.5 Concomitant medication list was not provided. On 14-May-2022, patient came to hospital for emergency consultations and treatments. Vital signs: RR: 20 times/min.The doctor examined the patients chief complaint that the first dose of moderna vaccine was administers on 13-May-2022, and palpitations/ fever occurred.BT:38.2 C at triage, no chest pain, no cough, but may be happens later, no GI s/s. After consultations and diagnosis, according the doctors advice, the patient was given (injection) Taita no1 500 ml IVD ST, and (oral drug) cataflam 0.75 tab plus sugar 0.33 g po st. After consultation and diagnosis, the patient was in stable conditions and was allowed to be discharged from hospital. Since the correlation between palpitation and covid 19 vaccine adverse reactions could not be ruled out, the doctor reported the vaccine adverse reactions. Discharge drugs (oral drugs): Cataflam 1 tab QID, medicon A 1 cap tid, and depyretin 1 tab prn (total 10 capsules) for total 3 days.	
4.1(b) [redacted]	Asthma, Chills, Palpitations, Pyrexia	10	Female	This regulatory authority case was reported by an other health care professional and describes the occurrence of CHILLS (Chill), PYREXIA (Fever), PALPITATIONS (Palpitation, and respiratory asthma) and ASTHMA (Palpitation, and respiratory asthma) in a 10-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 13-May-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-May-2022, the patient experienced CHILLS (Chill) (seriousness criterion hospitalization), PYREXIA (Fever) (seriousness criterion hospitalization), PALPITATIONS (Palpitation, and respiratory asthma) (seriousness criterion hospitalization) and ASTHMA (Palpitation, and respiratory asthma) (seriousness criterion hospitalization). The patient was hospitalized from 14-May-2022 to 16-May-2022 due to ASTHMA, CHILLS, PALPITATIONS and PYREXIA. The patient was treated with DIPHENHYDRAMINE at a dose of 15 milligram; ACETAMINOPHEN (oral) for Fever, at a dose of 1 dosage form as required; ACETAMINOPHEN for Fever, at a dose of 500mg/cap, 3/4 cap PRN; ACETAMINOPHEN for Fever, at a dose of 500mg/cap 3/4 cap PRNQ6H; DOXYCYCLINE at a dose of .5 dosage form every twelve hours; DOXYCYCLINE at a dose of .5 dosage form every twelve hours; DICLOFENAC for Fever, at a dose of 25mg/cap 3/4 cap PRNQ8H; DICLOFENAC for Fever, at a dose of 25mg/cap 3/4 cap PRN; ACETYLCYSTEINE at a dose of .5 dosage form three times a day and CHLORPHENAMINE MALEATE, GUAIFENESIN, METHYLEPHEDRINE HYDROCHLORIDE-DL (SECORINE) at a dose of 5 milliliter three times a day. At the time of the report, CHILLS (Chill), PYREXIA (Fever), PALPITATIONS (Palpitation, and respiratory asthma) and ASTHMA (Palpitation, and respiratory asthma) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 16-May-2022, COVID-19 screening: positive (Positive) Positive. On 17-May-2022, SARS-CoV-2 test: positive (Positive) Positive. On an unknown date, Body temperature: 36.7 c 36.7 C, over 38 c (High) over 38 C and over 38.5 c (High) over 38.5 C.	4.1(b) [redacted]

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
				On an unknown date, Chest X-ray: pulmonary stria hyperplasia pulmonary stria hyperplasia. On an unknown date, Coma scale: e4m6v5 E4M6V5. On an unknown date, Electrocardiogram: sinus tachycardia sinus tachycardia. On an unknown date, Heart rate: 121 121 BPM. On an unknown date, Mycoplasma test: positive (Positive) Positive. On an unknown date, Oxygen saturation: 96 96 %. On an unknown date, Respiratory rate: 20 times/min 20 times/min. 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 patient's age was reported as 10.1. No concomitant medication was reported. On 14-May-2022: The patient had respiratory asthma, palpitation and shivering in the evening, so the patient went to hospital for emergency consultations and treatments. In the emergency department, the patient was given the injection of Tai-ta NO.2 500 ml and Diphenhydramine and Acetaminophen, and then the patient was admitted. During the period of hospitalization, the patient was given Tai-ta NO.2 and Doxycycline. During the period of hospitalization, the patient had fever repeatedly, and when the body temperature was over 38 C, the patient was given Acetaminophen, and when the body temperature was over 38.5 C, the patient was given Diclofenac. On 16-May-2022: The patient was discharged from the hospital with drugs Doxycycline well as other drugs Acetylcysteine, Secorine potion, Acetaminophen, and Diclofenac for a total of three days and returned home. On 16-May-2022, the rapid screening test for the patient was positive, and on 17-May-2022, the PCR test was positive. The patient was diagnosed COVID-19. The patient was isolated at home with the father with COVID-19 diagnosed and confirmed (May 15) and the mother with COVID-19 diagnosed and confirmed (May 17). At present, the patient had a good spirit and vitality, and the patient had no fever and could eat. Health education was given for the precautions and the patient would be further followed up and cared. On 20-May-2022: The mother of the patient stated that the current conditions were good and there was no discomfort reaction. Th World UID: 4.1(b) [redacted] Company Comment: This regulatory authority case concerns a 10 years old female patient with no relevant medical history reported, who experienced the unexpected serious (seriousness criterion hospitalization) events chills, pyrexia, palpitation, asthma, which occurred one day after first dose of mRNA-1273 vaccine. It is reported that On 14-May-2022 patient had respiratory asthma, palpitation and shivering in the evening, so the patient went to hospital for emergency consultations and treatments. In the emergency department Coma scale:E4M6V5, Electrocardiogram: sinus tachycardia, Oxygen saturation: 96 96 %,, Respiratory rate: 20 times/min, the patient was given the injection of Tai-ta NO.2 500 ml and Diphenhydramine and Acetaminophen, and then the patient was admitted. During the period of hospitalization, the patient was given Tai-ta NO.2 and Doxycycline. During the period of hospitalization, the patient had fever repeatedly, and when the body temperature was over 38 C, the patient was given Acetaminophen, and when the body temperature was over 38.5 C, the patient was given Diclofenac,after2 days patient discharged from the hospital with drugs Doxycycline well as other drugs Acetylcysteine, Secorine potion, Acetaminophen, and Diclofenac for a total of three days and returned home. Rapid screening test for the patient was positive, next day the PCR test was positive. patient was diagnosed with COVID-19. patient was isolated at home with the father with COVID-19 diagnosed and confirmed (May 15) and the mother with COVID-19 diagnosed and confirmed (May 17). At present, the patient had a good spirit and vitality. Health education was given for the precautions and the patient would be further followed up and cared. On 20-May-2022: The mother of the patient stated that the current conditions were good and there was no discomfort reaction. 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	

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
4.1(b) [redacted]	Nausea, Vomiting	9	Male	This regulatory authority case was reported by an other health care professional and describes the occurrence of NAUSEA (Nausea) and VOMITING (Vomiting) in a 9-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 prophylaxis. Family history included COVID-19 (the younger sister of the patient was diagnosed.). On 20-May-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-May-2022, the patient experienced NAUSEA (Nausea) (seriousness criterion medically significant) and VOMITING (Vomiting) (seriousness criterion medically significant). The patient was treated with TAITA NO.1 at a dose of 500 milliliter IVD ST; METOCLOPRAMIDE HYDROCHLORIDE (PRIMPERAN) at a dose of 0.5 Amp and DIPHENHYDRAMINE HYDROCHLORIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE at a dose of 0.9 Amp. At the time of the report, NAUSEA (Nausea) and VOMITING (Vomiting) had resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 21-May-2022, SARS-CoV-2 test: positive (Positive) Positive. On an unknown date, Amylase: 74 74 U/L. On an unknown date, Blood creatine phosphokinase: 276 276U/L. On an unknown date, Blood creatinine: 0.6 0.6 mg/dL. On an unknown date, Blood pressure measurement: 114 / 69 114 / 69 mmHg. On an unknown date, Body temperature: 35.8 35.8°C. On an unknown date, C-reactive protein: 2.36 2.36 mg/L. On an unknown date, Coma scale: e4v5m6 E4V5M6. On an unknown date, Heart rate: 93 93 BPM. On an unknown date, Lipase: 20.4 20.4U/L. On an unknown date, Oxygen saturation: 98 98%. On an unknown date, Respiratory rate: 20 20 times/min. On an unknown date, Troponin I: <0.0023 <0.0023 ng/mL. On an unknown date, Urinary system X-ray: there was too much stool there was too much stool. On an unknown date, White blood cell count: 18.25 18.25 x1000/uL. 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 WWUID included 4.1(b) [redacted] No concomitant medication was reported. On 20-May-2022 it was reported that first dose of Moderna vaccine was inoculated. On 21-May-2022: The patient went to hospital for emergency consultation and treatments at 14:00 p.m. and complained that patient received Moderna vaccine on May 20 and later vomiting, abdominal pain, and hand cramps occurred. The patient had been in close contact with a COVID-19 patient (the younger sister of the patient was diagnosed to have COVID-19) and the history of career was a (student). Vital signs GCS E4V5M6; BP 114/69 mmHg, HR 93 BPM, RR 20 times/min, BT 35.8 degree C, SpO2 98 percent. After examination patients was vomiting and abdominal pain since 21-May-2022. Fever (-), spasm over the both hands were noted , his younger sister got covid-19 infection. After consultations and diagnosis, according to the doctor's advice, the patient was given (injection) TAITA No. 1 500 ml IVD ST, primperan 0.5 Amp plus diphenhydramine 0.9 Amp plus Aq dest 20ml ST IVP. According to the doctor's advice, KUB was carried out and showed there was too much stool, according to the doctor the patient was given drug 4.1(b) [redacted] 20m 1PceST ENEMA. Lab test includd WBC: 18.25 x1000/uL; CK 276U/L; Tropo-I <0.0023 ng/mL; CRP (Quantitative) 2.36 mg/L; AMY 74 U/L; Lipase 20.4U/L; Creatinine 0.6 mg/dL; COVID-19 PCR test positive. The patient was in stable condition and was allowed to leave the hospital. Since it was impossible to exclude the correlation between nausea and vomiting and the adverse reactions of COVID-19 vaccine, the doctor reported the adverse reactions of the vaccine. Discharge drugs (oral drugs): 4.1(b) [redacted] S 1 Tab TID, 4.1(b) [redacted]	4.1(b) [redacted]

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
				1 Tab TID, and 4.1(b) 1 Tab TID for a total of 3 days, as well as 4.1(b) 1 Tab PRN (a total of 6 tablets). At 22:00 pm the patient returned to hospital for emergency consultations and diagnosis by the doctor. Patient will follow up in the outpatient clinic. Company Comment: This is a regulatory case concerning a 9-year-old male patient with no reported medical history, who experienced the unexpected, serious (medically significant) events of Nausea and Vomiting, 1 day after receiving the first dose of mRNA-1273 vaccine. The patient reported to have vomiting, abdominal pain and hand cramps. Sought consult at a hospital, an imaging of the KUB showed too much stool and patient was given Enema. The patient also tested positive for COVID-19. The patient was in stable condition and was allowed to leave the hospital. The events had resolved at the time of the report. The benefit-risk relationship of mRNA-1273 is not affected by this report. Events retained as serious as per Regulatory Authority.	
4.1(b) [redacted]	Immune thrombocytopenia	7	Male	This regulatory authority case was reported by an other health care professional and describes the occurrence of IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenic purpura) in a 7-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 prophylaxis. No Medical History information was reported. On 12-May-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 24-May-2022, after starting mRNA-1273 (Moderna COVID-19 Vaccine), the patient experienced IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenic purpura) (seriousness criterion hospitalization). The patient was hospitalized on 26-May-2022 due to IMMUNE THROMBOCYTOPENIA. The patient was treated with IMMUNOGLOBULIN HUMAN NORMAL (HUMAN IMMUNOGLOBULIN) from 26-May-2022 to 27-May-2022 at a dose of 1 dosage form. At the time of the report, IMMUNE THROMBOCYTOPENIA (Immune thrombocytopenic purpura) had not resolved. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 22-May-2022, SARS-CoV-2 test: positive (Positive) confirmed to have COVID-19. On 26-May-2022, Fibrin D dimer: 976.1 976.1 ng/mL (FEU).. On 26-May-2022, Platelet count: less than 10 x10^3/ul. Less than 10 x10^3/ul. (low). 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. On 20 May 2022, both lower limbs developed ecchymosis (the mother of the patient said that she thought the patient was naughty and bumped into something, so she did not care it) and red spots occurred on the neck. On 21 May 2022, the patient had a fever and went to see a doctor in a clinic and then returned home. On 22 May 2022, as the grandpa living together was diagnosed to have COVID-19, the mother of the patient took the patient to Hospital for medical consultations and treatments. The PCR was positive and the patient was confirmed to have COVID-19. The patient was isolated at home. On 25 May 2022, the mother of the patient found that the patient had red foams in the mouth. On 26 May 2022, video consultations and diagnosis were carried out, and the doctor suggested the patient to go to see a doctor. In the evening on 26 May 2022, the patient went to the emergency department of the hospital for medical consultations and treatments.On 30 May 2022 After the patient received the vaccine, erythema occurred in the ears firstly, which was gradually spread to the tongue, hands, feet and genitals, and there was phenomenon of fever. WWUID included 4.1(b) [redacted] Company Comment:	4.1(b) [redacted]

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
				This regulatory case concerns a 7-year-old male patient, with no reported medical history, who experienced the unexpected serious (hospitalization) AESI of Immune thrombocytopenia that occurred 12 days after receiving the 1st dose of mRNA-1273 vaccine. As reported, after the patient received the vaccine, erythema occurred in the ears firstly, which was gradually spread to the tongue, hands, feet and genitals. Eight days post- vaccination, patient developed ecchymosis on both lower extremities and red spots on the neck. The next day, patient developed fever, sought medical consult (clinic), and was sent home. SARS-CoV-2 test was reported positive and patient was isolated at home. Thirteen days post vaccination, patient was noted to have red foams in the mouth, medical video consult was done and was advised to see a medical doctor. Fourteen days post-vaccination, patient was brought to emergency room, presented with ecchymosis on both lower extremities, purple lips, nasal bleeding, fever, rhinorrhea, productive cough, and reported 12 hours of no eating and urinating. Blood tests done with results of platelet: <10* x10^3/ul and D-dimer: 976.1 ng/mL (FEU). Patient was hospitalized, started on human immunoglobulin as treatment regimen (18g total 300cc: 5 cc/hr in the first hour, 10 cc/hr in the second hour, 20 cc/hr in the third hour; and 30 cc/hr finally). On the following day, fever subsided, no bleeding noted, ecchymosis did not progress, vital signs reported stable, and patient was able to eat. The outcome of event was reported as not resolved. 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) [redacted]	Pruritus, Rash	9	Female	This regulatory authority case was reported by an other health care professional and describes the occurrence of PRURITUS (Skin itching) and RASH (Skin rash (non-injection site)) in a 9-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 prophylaxis. No Medical History information was reported. On 20-May-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 27-May-2022, the patient experienced PRURITUS (Skin itching) (seriousness criterion medically significant) and RASH (Skin rash (non-injection site)) (seriousness criterion medically significant). At the time of the report, PRURITUS (Skin itching) and RASH (Skin rash (non-injection site)) was resolving. 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 details provided. On 01-June-2022 mother of the patient said that there had been no discomfort when the vaccination was received on 20-May-2022. On 27-May-2022, the patient said that the body of the patient was itchy and unwell, and that urticaria on the back and redness, swelling and pain of the left arm occurred. On 28-May-2022 patient went to see a doctor, and the doctor said that the symptoms w ere related to the vaccination. The patient went to the hospital for consultations and treatments on 30-May-2022. The patient would visit the hospital for follow-up on 02-Jun-2022. No treatment medication details provided. The Worldwide UID number was reported as 4.1(b) [redacted] Company comment: This regulatory authority case concerns a 9-year-old female patient, with no medical history reported, who experienced the serious (due to medically significant), unexpected event of PRURITUS and RASH, 7 days after the first dose of mRNA 1273 vaccine. As per source document, a week after vaccination she experienced urticaria on the back and redness, swelling and pain of the left arm, she made a consultation and the doctor said that the symptoms w ere related to the vaccination and she received a non-specified treatment. The benefit-risk relationship of mRNA 1273 vaccine is not affected by this report. The seriousness criteria of the events were assessed as per regulatory authority report.	4.1(b) [redacted]

Case ID	ALL PT'S	Patient Age (Years)	Patient Gender	Narrative (Complete)	WW Identifier
				Most recent FOLLOW-UP information incorporated above includes: On 06-Jun-2022: Amendment: Upon internal review on 14-Jun-2022, non-significant correction was performed. Safety received date was updated from 06-Jun-2022 to 08-Jun-2022.	
4.1(b) [redacted]	Dizziness	9	Female	This case was received via an unknown source (no reference has been entered for a health authority or license partner) on 06-Jun-2022 and was forwarded to Moderna on 08-Jun-2022. This regulatory authority case was reported by an other health care professional and describes the occurrence of DIZZINESS (Dizziness) in a 9-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 048M21A_1110519-CDC) for COVID-19 prophylaxis. No Medical History information was reported. On 06-May-2022, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) .25 milliliter. On 02-Jun-2022, the patient experienced DIZZINESS (Dizziness) (seriousness criterion hospitalization). The patient was hospitalized for 7 days due to DIZZINESS. At the time of the report, DIZZINESS (Dizziness) was resolving. 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. Worldwide unique ID was reported as 4.1(b) [redacted] Concomitant medications were not reported. It was reported that patient had first dose of Moderna vaccine and there were discomfort symptoms (dizziness and headache). The patient went to the general pediatric ward for treatments. The certificate of diagnosis stated Giddiness. The patient was hospitalized for one week. Treatment information was not reported. Company comment. This regulatory case concerns a 9 – year – old, female patient with no medical history reported, who experienced the unexpected, serious (due to hospitalization) event of dizziness. The event occurred 27 days after the first dose of mRNA-1273 vaccine (0,25 mL dosage). The report stated that the patient experienced discomfort symptoms, dizziness and headache and she was hospitalized for one week with diagnosis of Giddiness. No further details were provided for medical review. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.	4.1(b) [redacted]

Appendix 11.30c Children: Details on event counts during the reporting period in the 0-5 years age group

SOC	HLT	PT	# Cases				# Events				Cases Grand total	Events Grand total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
Blood and lymphatic system disorders	*Subtotal*	*Subtotal*	*1*	*2*	*1*	*1*	*1*	*3*	*2*	*1*	*5*	*7*
	Anaemias haemolytic immune	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Coombs positive haemolytic anaemia	0	0	1	0	0	0	1	0	1	1
	Haemolyses NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Haemolysis	0	0	1	0	0	0	1	0	1	1
	Lymphatic system disorders NEC	*Subtotal*	*1*	*2*	*0*	*1*	*1*	*3*	*0*	*1*	*4*	*5*
		Lymphadenitis	0	0	0	1	0	1	0	0	1	1
		Lymphadenopathy	1	2	0	1	1	2	0	1	4	4
Cardiac disorders	*Subtotal*	*Subtotal*	*3*	*3*	*4*	*1*	*3*	*3*	*5*	*1*	*11*	*12*
	Cardiac signs and symptoms NEC	*Subtotal*	*1*	*1*	*1*	*0*	*1*	*1*	*1*	*0*	*3*	*3*
		Palpitations	1	1	1	0	1	1	1	0	3	3
	Rate and rhythm disorders NEC	*Subtotal*	*1*	*2*	*2*	*1*	*1*	*2*	*2*	*1*	*6*	*6*
		Bradycardia neonatal	0	0	1	0	0	0	1	0	1	1
		Neonatal bradyarrhythmia	0	0	0	1	0	0	0	1	1	1
		Tachycardia	1	2	1	0	1	2	1	0	4	4
	Supraventricular arrhythmias	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Atrial fibrillation	1	0	1	0	1	0	1	0	2	2
	Tricuspid valvular disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Tricuspid valve incompetence	0	0	1	0	0	0	1	0	1	1
Congenital, familial and genetic disorders	*Subtotal*	*Subtotal*	*0*	*0*	*8*	*2*	*1*	*0*	*7*	*5*	*10*	*13*
	Cardiac septal defects congenital	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*2*	*2*
		Atrial septal defect	0	0	0	1	0	0	0	1	1	1
		Ventricular septal defect	0	0	1	0	0	0	1	0	1	1
	Cardiac valve disorders congenital	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Bicuspid aortic valve	0	0	0	1	0	0	0	1	1	1
	Great vessel disorders congenital	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Transposition of the great vessels	0	0	1	0	0	0	1	0	1	1
	Haemoglobinopathies congenital	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Haemoglobinopathy	0	0	1	0	1	0	0	0	1	1
	Laryngeal and tracheal disorders congenital	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*2*	*2*
		Laryngomalacia	0	0	1	0	0	0	1	0	1	1
		Tracheo-oesophageal fistula	0	0	0	1	0	0	0	1	1	1
	Male reproductive tract disorders congenital	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Hypospadias	0	0	0	1	0	0	0	1	1	1
	Ocular disorders congenital NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Coloboma	0	0	1	0	0	0	1	0	1	1
	Persistent foetal circulation disorders	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*2*	*2*
		Patent ductus arteriosus	0	0	1	0	0	0	1	0	1	1
		Persistent foetal circulation	0	0	0	1	0	0	0	1	1	1
	Renal and urinary tract disorders congenital NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Congenital hydronephrosis	0	0	1	0	0	0	1	0	1	1
	Skin and subcutaneous tissue disorders congenital NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Congenital skin disorder	0	0	1	0	0	0	1	0	1	1
Ear and labyrinth disorders	*Subtotal*	*Subtotal*	*1*	*1*	*2*	*1*	*1*	*2*	*5*	*2*	*5*	*10*
	Ear disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Ear pain	0	0	0	1	0	0	0	1	1	1
	Hearing losses	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*1*	*1*	*0*	*2*	*2*
		Hypoacusis	0	0	1	1	0	1	1	0	2	2
	Inner ear disorders NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Meniere's disease	0	0	1	0	0	0	1	0	1	1
	Inner ear signs and symptoms	*Subtotal*	*1*	*1*	*2*	*1*	*1*	*1*	*3*	*1*	*5*	*6*
		Tinnitus	1	1	2	1	1	1	2	1	5	5
		Vertigo	0	0	1	0	0	0	1	0	1	1
Eye disorders	*Subtotal*	*Subtotal*	*2*	*2*	*0*	*0*	*2*	*2*	*0*	*0*	*4*	*4*
	Lid, lash and lacrimal infections, irritations and inflammations	*Subtotal*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*2*	*2*
		Erythema of eyelid	0	1	0	0	0	1	0	0	1	1

SOC	HLT	PT	# Cases				# Events				Case Grand total	Events Grand total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Eyelid oedema	0	1	0	0	0	1	0	0	1	1
	Ocular disorders NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Eye pain	1	0	0	0	1	0	0	0	1	1
	Ocular infections, inflammations and associated manifestations	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Eye discharge	1	0	0	0	1	0	0	0	1	1
Gastrointestinal disorders	*Subtotal*	*Subtotal*	*39*	*21*	*14*	*4*	*63*	*27*	*22*	*6*	*78*	*118*
	Abdominal findings abnormal	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Gastrointestinal sounds abnormal	0	0	1	0	1	0	0	0	1	1
	Diarrhoea (excl infective)	*Subtotal*	*20*	*6*	*3*	*0*	*20*	*6*	*3*	*0*	*29*	*29*
		Diarrhoea	19	6	3	0	19	6	3	0	28	28
		Diarrhoea neonatal	1	0	0	0	1	0	0	0	1	1
	Faecal abnormalities NEC	*Subtotal*	*2*	*1*	*2*	*0*	*3*	*1*	*2*	*0*	*5*	*6*
		Abnormal faeces	0	1	0	0	0	1	0	0	1	1
		Faeces discoloured	1	0	1	0	1	0	1	0	2	2
		Mucous stools	1	0	2	0	2	0	1	0	3	3
	Flatulence, bloating and distension	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Flatulence	0	0	1	0	0	0	1	0	1	1
	Gastric ulcers and perforation	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Gastric ulcer	0	0	1	0	0	0	1	0	1	1
	Gastritis (excl infective)	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Gastritis	0	0	1	0	0	0	1	0	1	1
	Gastrointestinal and abdominal pains (excl oral and throat)	*Subtotal*	*4*	*4*	*2*	*1*	*4*	*4*	*2*	*1*	*11*	*11*
		Abdominal pain	3	3	2	1	3	3	2	1	9	9
		Abdominal pain lower	0	1	0	0	0	1	0	0	1	1
		Abdominal pain upper	1	0	0	0	1	0	0	0	1	1
	Gastrointestinal atonic and hypomotility disorders NEC	*Subtotal*	*3*	*2*	*1*	*0*	*4*	*2*	*0*	*0*	*6*	*6*
		Constipation	2	1	1	0	3	1	0	0	4	4
		Gastrooesophageal reflux disease	1	1	0	0	1	1	0	0	2	2
	Gastrointestinal disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Functional gastrointestinal disorder	0	1	0	0	0	1	0	0	1	1
	Gastrointestinal dyskinetic disorders	*Subtotal*	*1*	*0*	*1*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Bowel movement irregularity	0	0	1	0	1	0	0	0	1	1
		Dyschezia	1	0	0	0	1	0	0	0	1	1
	Gastrointestinal signs and symptoms NEC	*Subtotal*	*1*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*2*	*2*
		Abdominal discomfort	1	0	0	1	1	0	0	1	2	2
	Gastrointestinal spastic and hypermotility disorders	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Frequent bowel movements	1	0	0	0	1	0	0	0	1	1
	Nausea and vomiting symptoms	*Subtotal*	*19*	*10*	*5*	*2*	*22*	*11*	*5*	*2*	*36*	*40*
		Infantile spitting up	0	1	0	0	0	1	0	0	1	1
		Infantile vomiting	2	1	1	0	3	1	0	0	4	4
		Nausea	7	6	0	1	7	6	0	1	14	14
		Vomiting	12	3	4	1	12	3	5	1	20	21
	Non-site specific gastrointestinal haemorrhages	*Subtotal*	*0*	*0*	*4*	*1*	*0*	*0*	*7*	*1*	*5*	*8*
		Gastrointestinal haemorrhage	0	0	2	0	0	0	2	0	2	2
		Haematemesis	0	0	1	1	0	0	1	1	2	2
		Haematochezia	0	0	2	0	0	0	3	0	2	3
		Melaena	0	0	1	0	0	0	1	0	1	1
	Oral soft tissue signs and symptoms	*Subtotal*	*2*	*2*	*0*	*0*	*2*	*2*	*0*	*0*	*4*	*4*
		Hypoaesthesia oral	0	1	0	0	0	1	0	0	1	1
		Lip discolouration	1	0	0	0	1	0	0	0	1	1
		Oral mucosal eruption	0	1	0	0	0	1	0	0	1	1
		Paraesthesia oral	1	0	0	0	1	0	0	0	1	1
	Oral soft tissue swelling and oedema	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Lip swelling	0	0	0	1	0	0	0	1	1	1
	Tongue disorders	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Tongue disorder	1	0	0	0	1	0	0	0	1	1

SOC	HLT	PT	# Cases				# Events				Case Grand total	Events Grand total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
	Tongue signs and symptoms	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Tongue discolouration	1	0	0	0	1	0	0	0	1	1
	Umbilical hernias	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Umbilical hernia	1	0	0	0	1	0	0	0	1	1
General disorders and administration site conditions	*Subtotal*	*Subtotal*	*77*	*63*	*20*	*7*	*122*	*112*	*25*	*7*	*167*	*266*
	Adverse effect absent	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		No adverse event	1	0	0	0	1	0	0	0	1	1
	Application and instillation site reactions	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Application site reaction	0	1	0	0	0	1	0	0	1	1
	Asthenic conditions	*Subtotal*	*21*	*16*	*7*	*2*	*27*	*19*	*7*	*2*	*46*	*55*
		Asthenia	4	5	0	0	4	5	0	0	9	9
		Fatigue	11	10	7	1	14	11	6	1	29	32
		Malaise	9	3	1	1	9	3	1	1	14	14
	Death and sudden death	*Subtotal*	*0*	*0*	*2*	*2*	*0*	*0*	*2*	*2*	*4*	*4*
		Death	0	0	0	1	0	0	0	1	1	1
		Death neonatal	0	0	2	0	0	0	2	0	2	2
		Premature baby death	0	0	0	1	0	0	0	1	1	1
	Febrile disorders	*Subtotal*	*41*	*25*	*9*	*3*	*44*	*26*	*9*	*2*	*78*	*81*
		Fever neonatal	0	0	1	0	0	0	1	0	1	1
		Pyrexia	41	25	8	3	44	26	8	2	77	80
	Feelings and sensations NEC	*Subtotal*	*7*	*7*	*1*	*1*	*9*	*9*	*1*	*1*	*16*	*20*
		Chills	4	7	1	1	4	7	1	1	13	13
		Feeling abnormal	3	0	0	0	4	0	0	0	3	4
		Feeling cold	0	1	0	0	0	1	0	0	1	1
		Feeling hot	0	1	0	0	0	1	0	0	1	1
		Thirst	1	0	0	0	1	0	0	0	1	1
	Gait disturbances	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Gait inability	0	1	0	0	0	1	0	0	1	1
	General signs and symptoms NEC	*Subtotal*	*19*	*9*	*4*	*0*	*19*	*11*	*4*	*0*	*32*	*34*
		Condition aggravated	0	0	2	0	0	0	2	0	2	2
		Crying	10	3	0	0	10	3	0	0	13	13
		General physical health deterioration	0	0	1	0	0	0	1	0	1	1
		Illness	4	1	0	0	4	1	0	0	5	5
		Induration	0	1	0	0	0	1	0	0	1	1
		Influenza like illness	3	2	1	0	3	2	1	0	6	6
		Local reaction	0	3	0	0	0	3	0	0	3	3
		Peripheral swelling	2	0	0	0	2	0	0	0	2	2
		Swelling	0	1	0	0	0	1	0	0	1	1
	Inflammations	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Inflammation	0	1	0	0	0	1	0	0	1	1
	Injection site reactions	*Subtotal*	*4*	*14*	*1*	*1*	*5*	*22*	*1*	*0*	*20*	*28*
		Injection site erythema	1	2	0	1	1	3	0	0	4	4
		Injection site hypoaesthesia	1	0	0	0	1	0	0	0	1	1
		Injection site pain	0	12	0	1	0	13	0	0	13	13
		Injection site pruritus	1	0	0	0	1	0	0	0	1	1
		Injection site rash	1	0	0	0	1	0	0	0	1	1
		Injection site swelling	1	3	1	1	1	4	1	0	6	6
		Injection site warmth	0	1	0	1	0	2	0	0	2	2
	Pain and discomfort NEC	*Subtotal*	*7*	*3*	*1*	*1*	*7*	*4*	*1*	*0*	*12*	*12*
		Chest pain	0	2	0	0	0	2	0	0	2	2
		Discomfort	3	0	0	0	3	0	0	0	3	3
		Pain	4	1	1	1	4	2	1	0	7	7
	Therapeutic and nontherapeutic responses	*Subtotal*	*1*	*8*	*0*	*0*	*1*	*8*	*0*	*0*	*9*	*9*
		Immediate post-injection reaction	1	0	0	0	1	0	0	0	1	1
		Therapy partial responder	0	8	0	0	0	8	0	0	8	8
	Vaccination site reactions	*Subtotal*	*8*	*8*	*0*	*1*	*9*	*10*	*0*	*0*	*17*	*19*

SOC	HLT	PT	# Cases				# Events				Cases Grand total	Events Grand total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Vaccination site discomfort	1	1	0	0	2	1	0	0	2	3
		Vaccination site erythema	0	1	0	0	0	1	0	0	1	1
		Vaccination site oedema	0	1	0	0	0	1	0	0	1	1
		Vaccination site pain	5	3	0	1	5	4	0	0	9	9
		Vaccination site rash	1	0	0	0	1	0	0	0	1	1
		Vaccination site reaction	0	3	0	0	0	3	0	0	3	3
		Vaccination site warmth	1	0	0	0	1	0	0	0	1	1
Hepatobiliary disorders	*Subtotal*	*Subtotal*	*1*	*1*	*2*	*0*	*1*	*1*	*2*	*0*	*4*	*4*
	Cholestasis and jaundice	*Subtotal*	*1*	*1*	*1*	*0*	*1*	*1*	*1*	*0*	*3*	*3*
		Hyperbilirubinaemia	0	0	1	0	0	0	1	0	1	1
		Jaundice	1	1	0	0	1	1	0	0	2	2
	Hepatic failure and associated disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Acute hepatic failure	0	0	1	0	0	0	1	0	1	1
Immune system disorders	*Subtotal*	*Subtotal*	*1*	*2*	*0*	*0*	*1*	*3*	*0*	*0*	*3*	*4*
	Allergic conditions NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Hypersensitivity	0	1	0	0	0	1	0	0	1	1
	Immune and associated conditions NEC	*Subtotal*	*1*	*2*	*0*	*0*	*1*	*2*	*0*	*0*	*3*	*3*
		Immunisation reaction	1	2	0	0	1	2	0	0	3	3
Infections and infestations	*Subtotal*	*Subtotal*	*5*	*7*	*2*	*1*	*5*	*8*	*2*	*0*	*15*	*15*
	Abdominal and gastrointestinal infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Dysentery	0	0	1	0	0	0	1	0	1	1
	Candida infections	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Candida infection	1	0	0	0	1	0	0	0	1	1
	Coronavirus infections	*Subtotal*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*0*	*2*	*2*
		COVID-19	1	1	0	0	1	1	0	0	2	2
	Herpes viral infections	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Oral herpes	0	1	0	0	0	1	0	0	1	1
	Infections NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*1*	*1*
		Respiratory tract infection	0	0	0	1	0	1	0	0	1	1
	Influenza viral infections	*Subtotal*	*0*	*4*	*0*	*0*	*0*	*4*	*0*	*0*	*4*	*4*
		Influenza	0	4	0	0	0	4	0	0	4	4
	Skin structures and soft tissue infections	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Pustule	0	1	0	0	0	1	0	0	1	1
	Upper respiratory tract infections	*Subtotal*	*3*	*0*	*0*	*0*	*3*	*0*	*0*	*0*	*3*	*3*
		Nasopharyngitis	2	0	0	0	2	0	0	0	2	2
		Rhinitis	1	0	0	0	1	0	0	0	1	1
	Viral infections NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Viral rash	0	0	1	0	0	0	1	0	1	1
Injury, poisoning and procedural complications	*Subtotal*	*Subtotal*	*161*	*39*	*35*	*11*	*180*	*52*	*22*	*7*	*246*	*261*
	Exposures associated with pregnancy, delivery and lactation	*Subtotal*	*145*	*19*	*32*	*9*	*162*	*22*	*21*	*6*	*205*	*211*
		Exposure during pregnancy	0	1	0	0	0	1	0	0	1	1
		Exposure via breast milk	136	15	24	3	149	16	15	2	178	182
		Foetal exposure during pregnancy	1	2	4	4	3	3	2	3	11	11
		Maternal exposure during breast feeding	10	1	3	1	10	1	3	1	15	15
		Maternal exposure during pregnancy	0	0	0	1	0	1	0	0	1	1
		Paternal exposure before pregnancy	0	0	1	0	0	0	1	0	1	1
	Intentional product use issues	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Intentional dose omission	1	0	0	0	1	0	0	0	1	1
	Medication errors, product use errors and issues NEC	*Subtotal*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*2*	*2*
		Medication error	0	2	0	0	0	2	0	0	2	2
	Muscle, tendon and ligament injuries	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Muscle rupture	0	0	0	1	0	0	0	1	1	1
	Off label uses	*Subtotal*	*1*	*11*	*0*	*1*	*1*	*13*	*0*	*0*	*13*	*14*
		Off label use	1	11	0	1	1	13	0	0	13	14
	Product administration errors and issues	*Subtotal*	*13*	*12*	*3*	*0*	*15*	*15*	*1*	*0*	*28*	*31*
		Accidental underdose	1	0	0	0	1	0	0	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand total	Events Grand total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Expired product administered	1	0	0	0	1	0	0	0	1	1
		Inappropriate schedule of product administration	0	4	0	0	0	4	0	0	4	4
		Incorrect product formulation administered	1	0	0	0	1	0	0	0	1	1
		Product administered to patient of inappropriate age	10	9	3	0	12	9	1	0	22	22
		Product administration error	0	2	0	0	0	2	0	0	2	2
	Skin injuries NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Contusion	1	0	0	0	1	0	0	0	1	1
Investigations	*Subtotal*	*Subtotal*	*3*	*9*	*4*	*2*	*4*	*14*	*6*	*1*	*18*	*25*
	Blood gas and acid base analyses	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Oxygen saturation decreased	0	0	0	1	0	0	0	1	1	1
	Central nervous system imaging procedures	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*2*	*0*	*1*	*2*
		Magnetic resonance imaging head	0	0	1	0	0	0	1	0	1	1
		Magnetic resonance imaging spinal	0	0	1	0	0	0	1	0	1	1
	ECG investigations	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Electrocardiogram	1	0	0	0	1	0	0	0	1	1
	Foetal and neonatal diagnostic procedures	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Foetal heart rate abnormal	0	0	1	0	0	0	1	0	1	1
	Heart rate and pulse investigations	*Subtotal*	*1*	*1*	*1*	*0*	*1*	*1*	*1*	*0*	*3*	*3*
		Heart rate increased	1	1	1	0	1	1	1	0	3	3
	Immunology analyses NEC	*Subtotal*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*2*	*2*
		Antibody test abnormal	0	1	0	0	0	1	0	0	1	1
		Antibody test negative	0	1	0	0	0	1	0	0	1	1
	Investigations NEC	*Subtotal*	*1*	*0*	*2*	*0*	*1*	*0*	*2*	*0*	*3*	*3*
		Blood test	1	0	1	0	1	0	1	0	2	2
		Laboratory test	0	0	1	0	0	0	1	0	1	1
	Physical examination procedures and organ system status	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Body temperature increased	1	0	0	0	1	0	0	0	1	1
	Tissue enzyme analyses NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*1*	*1*
		Blood lactate dehydrogenase increased	0	0	0	1	0	1	0	0	1	1
	Vascular tests NEC (incl blood pressure)	*Subtotal*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*2*	*2*
		Blood pressure increased	0	2	0	0	0	2	0	0	2	2
	Virus identification and serology	*Subtotal*	*0*	*6*	*0*	*0*	*0*	*8*	*0*	*0*	*6*	*8*
		SARS-CoV-2 antibody test negative	0	6	0	0	0	6	0	0	6	6
		SARS-CoV-2 test	0	1	0	0	0	1	0	0	1	1
		SARS-CoV-2 test negative	0	1	0	0	0	1	0	0	1	1
Metabolism and nutrition disorders	*Subtotal*	*Subtotal*	*9*	*4*	*8*	*3*	*12*	*4*	*6*	*3*	*24*	*25*
	Appetite disorders	*Subtotal*	*5*	*1*	*1*	*1*	*5*	*1*	*1*	*1*	*8*	*8*
		Decreased appetite	5	1	1	1	5	1	1	1	8	8
	General nutritional disorders NEC	*Subtotal*	*4*	*3*	*6*	*1*	*6*	*3*	*4*	*1*	*14*	*14*
		Feeding disorder	0	1	0	0	0	1	0	0	1	1
		Food aversion	0	0	1	0	0	0	1	0	1	1
		Neonatal insufficient breast milk syndrome	0	0	2	0	0	0	2	0	2	2
		Poor feeding infant	3	2	2	1	4	2	1	1	8	8
		Underweight	1	0	0	0	1	0	0	0	1	1
		Weight gain poor	0	0	1	0	1	0	0	0	1	1
	Hypoglycaemic conditions NEC	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*2*	*2*
		Hypoglycaemia	0	0	0	1	0	0	0	1	1	1
		Hypoglycaemia neonatal	0	0	1	0	0	0	1	0	1	1
	Total fluid volume decreased	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Dehydration	1	0	0	0	1	0	0	0	1	1
Musculoskeletal and connective tissue disorders	*Subtotal*	*Subtotal*	*19*	*16*	*3*	*1*	*22*	*22*	*3*	*0*	*39*	*47*
	Joint related disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Rotator cuff syndrome	0	1	0	0	0	1	0	0	1	1
	Joint related signs and symptoms	*Subtotal*	*7*	*3*	*1*	*0*	*7*	*3*	*1*	*0*	*11*	*11*
		Arthralgia	6	3	1	0	6	3	1	0	10	10

SOC	HLT	PT	# Cases				# Events				Cases Grand total	Events Grand total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Joint swelling	1	0	0	0	1	0	0	0	1	1
	Muscle pains	*Subtotal*	*9*	*4*	*1*	*1*	*9*	*5*	*1*	*0*	*15*	*15*
		Myalgia	9	4	1	1	9	5	1	0	15	15
	Musculoskeletal and connective tissue conditions NEC	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Growth retardation	1	0	0	0	1	0	0	0	1	1
		Mobility decreased	1	0	0	0	1	0	0	0	1	1
	Musculoskeletal and connective tissue pain and discomfort	*Subtotal*	*4*	*12*	*1*	*0*	*4*	*13*	*1*	*0*	*17*	*18*
		Back pain	0	1	0	0	0	1	0	0	1	1
		Limb discomfort	0	7	0	0	0	7	0	0	7	7
		Neck pain	0	1	0	0	0	1	0	0	1	1
		Pain in extremity	4	4	1	0	4	4	1	0	9	9
Nervous system disorders	*Subtotal*	*Subtotal*	*25*	*19*	*15*	*5*	*28*	*25*	*15*	*5*	*64*	*73*
	Central nervous system haemorrhages and cerebrovascular accidents	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Intraventricular haemorrhage neonatal	0	0	1	0	0	0	1	0	1	1
	Coordination and balance disturbances	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Balance disorder	0	0	1	0	0	0	1	0	1	1
	Disturbances in consciousness NEC	*Subtotal*	*5*	*3*	*2*	*2*	*5*	*3*	*2*	*2*	*12*	*12*
		Lethargy	2	0	0	1	2	0	0	1	3	3
		Somnolence	2	3	2	0	2	3	2	0	7	7
		Somnolence neonatal	1	0	0	0	1	0	0	0	1	1
		Syncope	0	0	0	1	0	0	0	1	1	1
	Dyskinesias and movement disorders NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Foetal movement disorder	0	0	1	0	0	0	1	0	1	1
	Facial cranial nerve disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Bell's palsy	0	0	1	0	0	0	1	0	1	1
	Headaches NEC	*Subtotal*	*15*	*11*	*4*	*1*	*15*	*11*	*4*	*1*	*31*	*31*
		Headache	15	11	4	1	15	11	4	1	31	31
	Migraine headaches	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Migraine	1	0	0	0	1	0	0	0	1	1
	Neurological signs and symptoms NEC	*Subtotal*	*4*	*4*	*1*	*1*	*4*	*4*	*1*	*1*	*10*	*10*
		Dizziness	4	4	0	0	4	4	0	0	8	8
		Fontanelle bulging	0	0	0	1	0	0	0	1	1	1
		Infant irritability	0	0	1	0	0	0	1	0	1	1
	Paraesthesias and dysaesthesias	*Subtotal*	*3*	*3*	*0*	*0*	*3*	*3*	*0*	*0*	*6*	*6*
		Burning sensation	0	1	0	0	0	1	0	0	1	1
		Hypoaesthesia	1	0	0	0	1	0	0	0	1	1
		Paraesthesia	2	2	0	0	2	2	0	0	4	4
	Seizures and seizure disorders NEC	*Subtotal*	*0*	*0*	*3*	*1*	*0*	*0*	*3*	*1*	*4*	*4*
		Febrile convulsion	0	0	0	1	0	0	0	1	1	1
		Seizure	0	0	3	0	0	0	3	0	3	3
	Sensory abnormalities NEC	*Subtotal*	*0*	*2*	*0*	*0*	*0*	*3*	*0*	*0*	*2*	*3*
		Neuralgia	0	1	0	0	0	1	0	0	1	1
		Sensory disturbance	0	1	0	0	0	2	0	0	1	2
	Sleep disturbances NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Sleep deficit	0	0	1	0	0	0	1	0	1	1
	Tremor (excl congenital)	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Tremor	0	1	0	0	0	1	0	0	1	1
Pregnancy, puerperium and perinatal conditions	*Subtotal*	*Subtotal*	*3*	*1*	*13*	*0*	*4*	*1*	*17*	*0*	*17*	*22*
	Amniotic fluid and cavity disorders of pregnancy NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Meconium in amniotic fluid	0	0	1	0	0	0	1	0	1	1
	Foetal complications NEC	*Subtotal*	*0*	*0*	*5*	*0*	*0*	*0*	*5*	*0*	*5*	*5*
		Foetal cardiac disorder	0	0	1	0	0	0	1	0	1	1
		Foetal hypokinesia	0	0	4	0	0	0	4	0	4	4
	Foetal growth complications	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Foetal macrosomia	0	0	1	0	0	0	1	0	1	1
	Foetal position and presentation abnormalities	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*

SOC	HLT	PT	# Cases				# Events				Cases Grand total	Events Grand total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Shoulder dystocia	0	0	1	0	0	0	1	0	1	1
	Gestational age and weight conditions	*Subtotal*	*1*	*1*	*5*	*0*	*1*	*1*	*6*	*0*	*7*	*8*
		Low birth weight baby	1	0	3	0	1	0	3	0	4	4
		Premature baby	0	1	3	0	0	1	3	0	4	4
	Labour onset and length abnormalities	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Premature delivery	1	0	0	0	1	0	0	0	1	1
	Neonatal hepatobiliary disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Jaundice neonatal	0	0	1	0	0	0	1	0	1	1
	Stillbirth and foetal death	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Foetal death	0	0	1	0	0	0	1	0	1	1
		Stillbirth	0	0	1	0	0	0	1	0	1	1
	Umbilical cord complications	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Umbilical cord short	1	0	0	0	1	0	0	0	1	1
		Umbilical granuloma	1	0	0	0	1	0	0	0	1	1
Product issues	*Subtotal*	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
	Product distribution and storage issues	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Product temperature excursion issue	1	0	0	0	1	0	0	0	1	1
Psychiatric disorders	*Subtotal*	*Subtotal*	*17*	*10*	*5*	*1*	*21*	*11*	*10*	*1*	*33*	*43*
	Abnormal behaviour NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Abnormal behaviour	1	0	0	0	1	0	0	0	1	1
	Anxiety disorders NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Separation anxiety disorder	0	0	1	0	0	0	1	0	1	1
	Anxiety symptoms	*Subtotal*	*2*	*2*	*0*	*0*	*3*	*2*	*0*	*0*	*4*	*5*
		Agitation	1	1	0	0	1	1	0	0	2	2
		Anxiety	1	0	0	0	1	0	0	0	1	1
		Nervousness	1	1	0	0	1	1	0	0	2	2
	Behaviour and socialisation disturbances	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Paranoia	0	0	1	0	0	0	1	0	1	1
	Confusion and disorientation	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Confusional state	1	0	0	0	1	0	0	0	1	1
	Delusional symptoms	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Delusion	0	0	1	0	0	0	1	0	1	1
	Disturbances in initiating and maintaining sleep	*Subtotal*	*5*	*5*	*0*	*0*	*5*	*5*	*0*	*0*	*10*	*10*
		Insomnia	5	5	0	0	5	5	0	0	10	10
	Dyssomnias	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Poor quality sleep	1	0	1	0	1	0	1	0	2	2
	Emotional and mood disturbances NEC	*Subtotal*	*5*	*2*	*1*	*0*	*5*	*2*	*1*	*0*	*8*	*8*
		Irritability	3	2	1	0	3	2	1	0	6	6
		Mood altered	2	0	0	0	2	0	0	0	2	2
	Hallucinations (excl sleep-related)	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Hallucination	0	0	1	0	0	0	1	0	1	1
		Hallucination, visual	1	0	0	0	1	0	0	0	1	1
	Increased physical activity levels	*Subtotal*	*2*	*1*	*0*	*1*	*2*	*1*	*0*	*1*	*4*	*4*
		Restlessness	2	1	0	1	2	1	0	1	4	4
	Mood disorders NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Listless	1	0	0	0	1	0	0	0	1	1
	Psychiatric elimination disorders	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Enuresis	0	1	0	0	0	1	0	0	1	1
	Psychotic disorder NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Psychotic disorder	0	0	1	0	0	0	1	0	1	1
	Sleep disorders NEC	*Subtotal*	*1*	*0*	*2*	*0*	*1*	*0*	*2*	*0*	*3*	*3*
		Sleep disorder	1	0	2	0	1	0	2	0	3	3
	Thinking disturbances	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Thinking abnormal	0	0	1	0	0	0	1	0	1	1
Renal and urinary disorders	*Subtotal*	*Subtotal*	*2*	*0*	*1*	*0*	*2*	*0*	*1*	*0*	*3*	*3*
	Renal failure and impairment	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*

SOC	HLT	PT	# Cases				# Events				Cases Grand total	Evemts Grand total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Renal impairment	1	0	0	0	1	0	0	0	1	1
	Renal structural abnormalities and trauma	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Pyelocaliectasis	0	0	1	0	0	0	1	0	1	1
	Urinary abnormalities	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Haematuria	1	0	0	0	1	0	0	0	1	1
Reproductive system and breast disorders	*Subtotal*	*Subtotal*	*2*	*3*	*0*	*0*	*3*	*5*	*0*	*0*	*5*	*8*
	Breast disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Breast enlargement	0	1	0	0	0	1	0	0	1	1
	Breast signs and symptoms	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Nipple exudate bloody	0	1	0	0	0	1	0	0	1	1
	Menstruation and uterine bleeding NEC	*Subtotal*	*0*	*2*	*0*	*0*	*0*	*3*	*0*	*0*	*2*	*3*
		Dysmenorrhoea	0	1	0	0	0	1	0	0	1	1
		Menstrual discomfort	0	1	0	0	0	1	0	0	1	1
		Menstruation irregular	0	1	0	0	0	1	0	0	1	1
	Menstruation with increased bleeding	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Heavy menstrual bleeding	2	0	0	0	2	0	0	0	2	2
	Uterine disorders NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Uterine haemorrhage	1	0	0	0	1	0	0	0	1	1
Respiratory, thoracic and mediastinal disorders	*Subtotal*	*Subtotal*	*10*	*3*	*12*	*3*	*17*	*3*	*15*	*3*	*28*	*38*
	Breathing abnormalities	*Subtotal*	*1*	*1*	*4*	*1*	*1*	*1*	*4*	*1*	*7*	*7*
		Dyspnoea	1	1	2	0	1	1	2	0	4	4
		Respiratory depression	0	0	1	0	0	0	1	0	1	1
		Respiratory distress	0	0	1	0	0	0	1	0	1	1
		Tachypnoea	0	0	0	1	0	0	0	1	1	1
	Bronchospasm and obstruction	*Subtotal*	*1*	*0*	*1*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Obstructive airways disorder	0	0	1	0	1	0	0	0	1	1
		Wheezing	1	0	0	0	1	0	0	0	1	1
	Coughing and associated symptoms	*Subtotal*	*4*	*1*	*2*	*0*	*5*	*1*	*2*	*0*	*7*	*8*
		Cough	4	1	2	0	5	1	2	0	7	8
	Nasal congestion and inflammations	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Nasal congestion	1	0	0	0	1	0	0	0	1	1
	Nasal disorders NEC	*Subtotal*	*2*	*1*	*0*	*0*	*2*	*1*	*0*	*0*	*3*	*3*
		Epistaxis	2	1	0	0	2	1	0	0	3	3
	Neonatal hypoxic conditions	*Subtotal*	*0*	*0*	*3*	*0*	*0*	*0*	*4*	*0*	*3*	*4*
		Infantile apnoea	0	0	1	0	0	0	1	0	1	1
		Neonatal hypoxia	0	0	1	0	0	0	1	0	1	1
		Neonatal respiratory distress syndrome	0	0	2	0	0	0	2	0	2	2
	Newborn respiratory disorders NEC	*Subtotal*	*1*	*0*	*2*	*1*	*1*	*0*	*3*	*1*	*4*	*5*
		Neonatal aspiration	0	0	2	0	0	0	2	0	2	2
		Neonatal dyspnoea	0	0	0	1	0	0	0	1	1	1
		Respiratory disorder neonatal	0	0	1	0	0	0	1	0	1	1
		Transient tachypnoea of the newborn	1	0	0	0	1	0	0	0	1	1
	Pharyngeal disorders (excl infections and neoplasms)	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Tonsillar hypertrophy	1	0	0	0	1	0	0	0	1	1
	Pneumothorax and pleural effusions NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Pneumothorax	0	0	1	0	0	0	1	0	1	1
	Respiratory tract disorders NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Respiratory tract congestion	1	0	0	0	1	0	0	0	1	1
	Upper respiratory tract signs and symptoms	*Subtotal*	*2*	*0*	*1*	*1*	*3*	*0*	*1*	*1*	*4*	*5*
		Oropharyngeal pain	0	0	0	1	0	0	0	1	1	1
		Rhinorrhoea	2	0	0	0	2	0	0	0	2	2
		Sneezing	1	0	1	0	1	0	1	0	2	2
Skin and subcutaneous tissue disorders	*Subtotal*	*Subtotal*	*21*	*15*	*2*	*2*	*23*	*22*	*2*	*0*	*40*	*47*
	Apocrine and eccrine gland disorders	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Hyperhidrosis	0	1	0	0	0	1	0	0	1	1
	Bullous conditions	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*

SOC	HLT	PT	# Cases				# Events				Cases Grand total	Events Grand total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Erythema multiforme	0	0	1	0	0	0	1	0	1	1
	Dermal and epidermal conditions NEC	*Subtotal*	*2*	*1*	*0*	*0*	*3*	*1*	*0*	*0*	*3*	*4*
		Pain of skin	1	0	0	0	1	0	0	0	1	1
		Skin burning sensation	0	1	0	0	0	1	0	0	1	1
		Skin warm	2	0	0	0	2	0	0	0	2	2
	Dermatitis and eczema	*Subtotal*	*0*	*2*	*1*	*0*	*0*	*2*	*1*	*0*	*3*	*3*
		Dermatitis allergic	0	1	1	0	0	1	1	0	2	2
		Perioral dermatitis	0	1	0	0	0	1	0	0	1	1
	Erythemas	*Subtotal*	*1*	*3*	*0*	*0*	*2*	*3*	*0*	*0*	*4*	*5*
		Erythema	1	3	0	0	2	3	0	0	4	5
	Papulosquamous conditions	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Lichen sclerosus	0	1	0	0	0	1	0	0	1	1
	Pruritus NEC	*Subtotal*	*1*	*3*	*0*	*0*	*1*	*3*	*0*	*0*	*4*	*4*
		Pruritus	1	3	0	0	1	3	0	0	4	4
	Rashes, eruptions and exanthems NEC	*Subtotal*	*14*	*7*	*0*	*2*	*14*	*10*	*0*	*0*	*23*	*24*
		Rash	13	7	0	1	13	9	0	0	21	22
		Rash erythematous	1	0	0	0	1	0	0	0	1	1
		Rash maculo-papular	0	0	0	1	0	1	0	0	1	1
	Skin vasomotor conditions	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Livedo reticularis	2	0	0	0	2	0	0	0	2	2
	Urticarias	*Subtotal*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*0*	*2*	*2*
		Urticaria	1	1	0	0	1	1	0	0	2	2
Social circumstances	*Subtotal*	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
	Disability issues	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Loss of personal independence in daily activities	0	0	1	0	0	0	1	0	1	1
Surgical and medical procedures	*Subtotal*	*Subtotal*	*2*	*14*	*1*	*2*	*2*	*15*	*1*	*1*	*19*	*19*
	Cardiac therapeutic procedures NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Cardioversion	0	0	1	0	0	0	1	0	1	1
	Therapeutic procedures NEC	*Subtotal*	*2*	*14*	*0*	*2*	*2*	*15*	*0*	*1*	*18*	*18*
		Interchange of vaccine products	2	14	0	2	2	15	0	1	18	18
Vascular disorders	*Subtotal*	*Subtotal*	*2*	*2*	*0*	*0*	*2*	*2*	*0*	*0*	*4*	*4*
	Haemorrhages NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Haemorrhage	0	1	0	0	0	1	0	0	1	1
	Peripheral vascular disorders NEC	*Subtotal*	*2*	*1*	*0*	*0*	*2*	*1*	*0*	*0*	*3*	*3*
		Flushing	1	0	0	0	1	0	0	0	1	1
		Hot flush	1	0	0	0	1	0	0	0	1	1
		Peripheral vascular disorder	0	1	0	0	0	1	0	0	1	1
Grand total			219	111	69	17	521	337	169	43	416	1,070

Appendix 11.30d Children: Details on event counts during the reporting period in the 5-11 years age group

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
Blood and lymphatic system disorders	*Subtotal*	*Subtotal*	*2*	*1*	*0*	*1*	*2*	*1*	*0*	*1*	*4*	*4*
	Lymphatic system disorders NEC	*Subtotal*	*2*	*1*	*0*	*0*	*2*	*1*	*0*	*0*	*3*	*3*
		Lymphadenitis	0	1	0	0	0	1	0	0	1	1
		Lymphadenopathy	2	0	0	0	2	0	0	0	2	2
	Thrombocytopenias	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Immune thrombocytopenia	0	0	0	1	0	0	0	1	1	1
Cardiac disorders	*Subtotal*	*Subtotal*	*0*	*0*	*1*	*2*	*2*	*0*	*0*	*2*	*3*	*4*
	Cardiac signs and symptoms NEC	*Subtotal*	*0*	*0*	*1*	*2*	*1*	*0*	*0*	*2*	*3*	*3*
		Palpitations	0	0	1	2	1	0	0	2	3	3
	Rate and rhythm disorders NEC	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Tachycardia	0	0	1	0	1	0	0	0	1	1
Eye disorders	*Subtotal*	*Subtotal*	*1*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*1*	*2*
	Visual impairment and blindness (excl colour blindness)	*Subtotal*	*1*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*1*	*2*
		Visual impairment	1	0	0	0	2	0	0	0	1	2
Gastrointestinal disorders	*Subtotal*	*Subtotal*	*1*	*4*	*0*	*3*	*2*	*4*	*0*	*6*	*8*	*12*
	Diarrhoea (excl infective)	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Diarrhoea	0	1	0	0	0	1	0	0	1	1
	Gastrointestinal and abdominal pains (excl oral and throat)	*Subtotal*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*2*	*2*
		Abdominal pain	0	1	0	0	0	1	0	0	1	1
		Abdominal pain upper	0	1	0	0	0	1	0	0	1	1
	Nausea and vomiting symptoms	*Subtotal*	*1*	*1*	*0*	*3*	*2*	*1*	*0*	*6*	*5*	*9*
		Nausea	1	0	0	3	1	0	0	3	4	4
		Vomiting	1	1	0	3	1	1	0	3	5	5
General disorders and administration site conditions	*Subtotal*	*Subtotal*	*17*	*24*	*1*	*3*	*44*	*36*	*0*	*4*	*45*	*84*
	Administration site reactions NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Administration site oedema	0	1	0	0	0	1	0	0	1	1
	Adverse effect absent	*Subtotal*	*3*	*1*	*0*	*0*	*3*	*1*	*0*	*0*	*4*	*4*
		No adverse event	3	1	0	0	3	1	0	0	4	4
	Asthenic conditions	*Subtotal*	*3*	*1*	*0*	*0*	*4*	*1*	*0*	*0*	*4*	*5*
		Asthenia	1	0	0	0	2	0	0	0	1	2
		Malaise	2	1	0	0	2	1	0	0	3	3
	Febrile disorders	*Subtotal*	*4*	*8*	*0*	*2*	*4*	*8*	*0*	*2*	*14*	*14*
		Pyrexia	4	8	0	2	4	8	0	2	14	14
	Feelings and sensations NEC	*Subtotal*	*2*	*0*	*0*	*1*	*4*	*0*	*0*	*1*	*3*	*5*
		Chills	1	0	0	1	1	0	0	1	2	2
		Feeling abnormal	2	0	0	0	2	0	0	0	2	2
		Feeling cold	1	0	0	0	1	0	0	0	1	1
	General signs and symptoms NEC	*Subtotal*	*1*	*1*	*1*	*0*	*2*	*1*	*0*	*0*	*3*	*3*
		Condition aggravated	0	0	1	0	1	0	0	0	1	1
		Swelling	0	1	0	0	0	1	0	0	1	1
		Unevaluable event	1	0	0	0	1	0	0	0	1	1
	Injection site reactions	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Injection site hypoaesthesia	1	0	0	0	1	0	0	0	1	1
	Pain and discomfort NEC	*Subtotal*	*2*	*8*	*0*	*1*	*2*	*10*	*0*	*1*	*11*	*13*
		Chest discomfort	0	2	0	0	0	2	0	0	2	2
		Chest pain	1	4	0	1	1	4	0	1	6	6
		Pain	1	3	0	0	1	3	0	0	4	4
		Tenderness	0	1	0	0	0	1	0	0	1	1
	Therapeutic and nontherapeutic responses	*Subtotal*	*2*	*3*	*0*	*0*	*3*	*3*	*0*	*0*	*5*	*6*
		Adverse event	2	0	0	0	3	0	0	0	2	3
		Therapy partial responder	0	3	0	0	0	3	0	0	3	3
	Vaccination site reactions	*Subtotal*	*7*	*5*	*0*	*0*	*21*	*11*	*0*	*0*	*12*	*32*
		Vaccination site erythema	4	4	0	0	4	4	0	0	8	8
		Vaccination site induration	2	0	0	0	2	0	0	0	2	2

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Vaccination site joint erythema	1	0	0	0	1	0	0	0	1	1
		Vaccination site pain	4	3	0	0	4	3	0	0	7	7
		Vaccination site pruritus	2	0	0	0	2	0	0	0	2	2
		Vaccination site reaction	2	0	0	0	2	0	0	0	2	2
		Vaccination site swelling	2	4	0	0	2	4	0	0	6	6
		Vaccination site warmth	4	0	0	0	4	0	0	0	4	4
Immune system disorders	*Subtotal*	*Subtotal*	*1*	*25*	*0*	*0*	*1*	*25*	*0*	*0*	*26*	*26*
	Immune and associated conditions NEC	*Subtotal*	*1*	*25*	*0*	*0*	*1*	*25*	*0*	*0*	*26*	*26*
		Immunisation reaction	1	25	0	0	1	25	0	0	26	26
Infections and infestations	*Subtotal*	*Subtotal*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*0*	*2*	*2*
	Coronavirus infections	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Suspected COVID-19	1	0	0	0	1	0	0	0	1	1
	Herpes viral infections	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Herpes zoster	0	1	0	0	0	1	0	0	1	1
Injury, poisoning and procedural complications	*Subtotal*	*Subtotal*	*39*	*23*	*3*	*2*	*49*	*34*	*0*	*2*	*67*	*85*
	Medication errors, product use errors and issues NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Medication error	0	0	0	1	0	0	0	1	1	1
	Non-site specific injuries NEC	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Fall	0	0	1	0	1	0	0	0	1	1
	Off label uses	*Subtotal*	*2*	*5*	*0*	*0*	*3*	*5*	*0*	*0*	*7*	*8*
		Off label use	2	5	0	0	3	5	0	0	7	8
	Product administration errors and issues	*Subtotal*	*38*	*19*	*2*	*1*	*45*	*27*	*0*	*0*	*60*	*72*
		Accidental underdose	1	2	0	0	1	2	0	0	3	3
		Expired product administered	0	1	0	0	0	1	0	0	1	1
		Inappropriate schedule of product administration	3	5	0	0	3	5	0	0	8	8
		Incorrect dose administered	1	0	0	0	1	0	0	0	1	1
		Product administered to patient of inappropriate age	37	17	2	1	39	18	0	0	57	57
		Product administration error	1	1	0	0	1	1	0	0	2	2
	Product prescribing errors and issues	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Product prescribing error	0	0	0	1	0	0	0	1	1	1
	Product storage errors and issues in the product use system	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Product storage error	0	1	0	0	0	1	0	0	1	1
	Underdoses NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Underdose	0	1	0	0	0	1	0	0	1	1
Investigations	*Subtotal*	*Subtotal*	*0*	*12*	*0*	*0*	*0*	*13*	*0*	*0*	*12*	*13*
	Immunology analyses NEC	*Subtotal*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*2*	*2*
		Antibody test abnormal	0	2	0	0	0	2	0	0	2	2
	Physical examination procedures and organ system status	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Menstruation normal	0	1	0	0	0	1	0	0	1	1
	Virus identification and serology	*Subtotal*	*0*	*9*	*0*	*0*	*0*	*10*	*0*	*0*	*9*	*10*
		SARS-CoV-2 antibody test	0	1	0	0	0	1	0	0	1	1
		SARS-CoV-2 antibody test negative	0	8	0	0	0	8	0	0	8	8
		SARS-CoV-2 test negative	0	1	0	0	0	1	0	0	1	1
Metabolism and nutrition disorders	*Subtotal*	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
	Appetite disorders	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Decreased appetite	1	0	0	0	1	0	0	0	1	1
Musculoskeletal and connective tissue disorders	*Subtotal*	*Subtotal*	*10*	*7*	*0*	*1*	*10*	*9*	*0*	*1*	*18*	*20*
	Muscle pains	*Subtotal*	*2*	*4*	*0*	*0*	*2*	*5*	*0*	*0*	*6*	*7*
		Myalgia	2	4	0	0	2	5	0	0	6	7
	Muscle weakness conditions	*Subtotal*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*2*	*2*
		Muscular weakness	0	1	0	1	0	1	0	1	2	2
	Musculoskeletal and connective tissue	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
	conditions NEC	Mobility decreased	1	0	0	0	1	0	0	0	1	1
	Musculoskeletal and connective tissue pain and discomfort	*Subtotal*	*6*	*3*	*0*	*0*	*6*	*3*	*0*	*0*	*9*	*9*
		Back pain	0	1	0	0	0	1	0	0	1	1
		Limb discomfort	1	0	0	0	1	0	0	0	1	1
		Pain in extremity	5	2	0	0	5	2	0	0	7	7
	Soft tissue disorders NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Groin pain	1	0	0	0	1	0	0	0	1	1
Nervous system disorders	*Subtotal*	*Subtotal*	*3*	*3*	*2*	*3*	*4*	*4*	*2*	*3*	*11*	*13*
	Disturbances in consciousness NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Lethargy	1	0	0	0	1	0	0	0	1	1
	Facial cranial nerve disorders	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*1*	*1*
		Facial paresis	0	0	0	1	0	1	0	0	1	1
	Headaches NEC	*Subtotal*	*1*	*3*	*0*	*1*	*1*	*3*	*0*	*1*	*5*	*5*
		Headache	1	3	0	0	1	3	0	0	4	4
		Tension headache	0	0	0	1	0	0	0	1	1	1
	Neurological signs and symptoms NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Dizziness	0	0	0	1	0	0	0	1	1	1
	Paraesthesias and dysaesthesias	*Subtotal*	*1*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*1*	*2*
		Hypoaesthesia	1	0	0	0	1	0	0	0	1	1
		Paraesthesia	1	0	0	0	1	0	0	0	1	1
	Paralysis and paresis (excl cranial nerve)	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Paraparesis	0	0	0	1	0	0	0	1	1	1
	Seizures and seizure disorders NEC	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Seizure	0	0	2	0	0	0	2	0	2	2
Reproductive system and breast disorders	*Subtotal*	*Subtotal*	*0*	*2*	*0*	*0*	*0*	*3*	*0*	*0*	*2*	*3*
	Menstruation and uterine bleeding NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Menstruation irregular	0	1	0	0	0	1	0	0	1	1
	Reproductive tract signs and symptoms NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*2*	*0*	*0*	*1*	*2*
		Genital erythema	0	1	0	0	0	1	0	0	1	1
		Genital swelling	0	1	0	0	0	1	0	0	1	1
Respiratory, thoracic and mediastinal disorders	*Subtotal*	*Subtotal*	*1*	*0*	*1*	*1*	*1*	*0*	*1*	*1*	*3*	*3*
	Breathing abnormalities	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Respiratory depression	0	0	1	0	0	0	1	0	1	1
	Bronchospasm and obstruction	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Asthma	0	0	0	1	0	0	0	1	1	1
	Coughing and associated symptoms	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Cough	1	0	0	0	1	0	0	0	1	1
Skin and subcutaneous tissue disorders	*Subtotal*	*Subtotal*	*0*	*8*	*0*	*2*	*0*	*11*	*0*	*3*	*10*	*14*
	Dermatitis and eczema	*Subtotal*	*0*	*3*	*0*	*0*	*0*	*3*	*0*	*0*	*3*	*3*
		Dermatitis atopic	0	1	0	0	0	1	0	0	1	1
		Prurigo	0	2	0	0	0	2	0	0	2	2
	Pruritus NEC	*Subtotal*	*0*	*2*	*0*	*2*	*0*	*2*	*0*	*2*	*4*	*4*
		Pruritus	0	2	0	2	0	2	0	2	4	4
	Rashes, eruptions and exanthems NEC	*Subtotal*	*0*	*4*	*0*	*1*	*0*	*5*	*0*	*1*	*5*	*6*
		Rash	0	3	0	1	0	4	0	1	4	5
		Rash pruritic	0	1	0	0	0	1	0	0	1	1
	Urticarias	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Urticaria	0	1	0	0	0	1	0	0	1	1
Surgical and medical procedures	*Subtotal*	*Subtotal*	*1*	*11*	*0*	*0*	*1*	*11*	*0*	*0*	*12*	*12*
	Immunisations	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		COVID-19 immunisation	1	0	0	0	1	0	0	0	1	1
	Therapeutic procedures NEC	*Subtotal*	*0*	*11*	*0*	*0*	*0*	*11*	*0*	*0*	*11*	*11*
		Interchange of vaccine products	0	11	0	0	0	11	0	0	11	11
Vascular disorders	*Subtotal*	*Subtotal*	*2*	*0*	*0*	*1*	*2*	*0*	*0*	*1*	*3*	*3*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
	Peripheral vascular disorders NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Cyanosis	1	0	0	0	1	0	0	0	1	1
	Phlebitis NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Phlebitis superficial	0	0	0	1	0	0	0	1	1	1
	Vascular hypotensive disorders	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Hypotension	1	0	0	0	1	0	0	0	1	1
Grand total			47	83	3	14	122	152	3	24	147	301

Appendix 11.30e Children: Details on event counts during the reporting period in the 12-17 years age group

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
Blood and lymphatic system disorders	*Subtotal*	*Subtotal*	*69*	*45*	*15*	*13*	*74*	*46*	*15*	*13*	*142*	*148*
	Anaemias NEC	*Subtotal*	*2*	*0*	*2*	*1*	*3*	*0*	*1*	*1*	*5*	*5*
		Anaemia	2	0	1	1	3	0	0	1	4	4
		Microcytic anaemia	0	0	1	0	0	0	1	0	1	1
	Leukocytoses NEC	*Subtotal*	*0*	*0*	*2*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Hyperleukocytosis	0	0	1	0	0	0	1	0	1	1
		Lymphocytosis	0	0	1	0	1	0	0	0	1	1
	Lymphatic system disorders NEC	*Subtotal*	*67*	*45*	*7*	*5*	*70*	*46*	*5*	*5*	*124*	*126*
		Lymph node pain	0	1	0	0	0	1	0	0	1	1
		Lymphadenitis	2	2	0	0	2	2	0	0	4	4
		Lymphadenopathy	65	43	7	5	68	43	5	5	120	121
	Marrow depression and hypoplastic anaemias	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Pancytopenia	0	0	0	1	0	0	0	1	1	1
	Thrombocytopenias	*Subtotal*	*0*	*0*	*7*	*6*	*0*	*0*	*7*	*6*	*13*	*13*
		Immune thrombocytopenia	0	0	1	2	0	0	1	2	3	3
		Thrombocytopenia	0	0	4	4	0	0	4	4	8	8
		Thrombosis with thrombocytopenia syndrome	0	0	2	0	0	0	2	0	2	2
	Thrombocytoses	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Thrombocytosis	0	0	1	0	0	0	1	0	1	1
Cardiac disorders	*Subtotal*	*Subtotal*	*23*	*21*	*143*	*55*	*34*	*24*	*155*	*56*	*242*	*269*
	Cardiac disorders NEC	*Subtotal*	*2*	*1*	*1*	*0*	*2*	*1*	*1*	*0*	*4*	*4*
		Cardiac disorder	1	1	1	0	1	1	1	0	3	3
		Cardiovascular disorder	1	0	0	0	1	0	0	0	1	1
	Cardiac signs and symptoms NEC	*Subtotal*	*12*	*6*	*14*	*2*	*15*	*6*	*11*	*3*	*34*	*35*
		Cardiac discomfort	0	0	0	1	0	0	0	1	1	1
		Palpitations	12	6	14	2	15	6	11	2	34	34
	Ischaemic coronary artery disorders	*Subtotal*	*0*	*0*	*1*	*2*	*0*	*0*	*1*	*2*	*3*	*3*
		Angina pectoris	0	0	1	1	0	0	1	1	2	2
		Myocardial infarction	0	0	0	1	0	0	0	1	1	1
	Myocardial disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Cardiomegaly	0	1	0	0	0	1	0	0	1	1
	Noninfectious myocarditis	*Subtotal*	*1*	*1*	*98*	*36*	*1*	*1*	*100*	*36*	*136*	*138*
		Myocarditis	1	1	73	23	1	1	74	23	98	99
		Myopericarditis	0	0	25	13	0	0	26	13	38	39
	Noninfectious pericarditis	*Subtotal*	*2*	*0*	*21*	*8*	*2*	*0*	*21*	*8*	*31*	*31*
		Pericarditis	2	0	21	8	2	0	21	8	31	31
	Rate and rhythm disorders NEC	*Subtotal*	*9*	*12*	*15*	*8*	*12*	*13*	*14*	*7*	*44*	*46*
		Arrhythmia	2	1	4	0	2	1	4	0	7	7
		Bradycardia	0	0	2	1	0	0	2	1	3	3
		Cardiac flutter	0	0	1	0	0	0	1	0	1	1
		Extrasystoles	1	1	0	0	1	1	0	0	2	2
		Tachycardia	7	10	8	7	8	11	7	6	32	32
		Tachycardia paroxysmal	1	0	0	0	1	0	0	0	1	1
	Supraventricular arrhythmias	*Subtotal*	*1*	*0*	*3*	*1*	*2*	*1*	*3*	*0*	*5*	*6*
		Atrial tachycardia	0	0	1	0	0	0	1	0	1	1
		Sinus arrhythmia	0	0	0	1	0	1	0	0	1	1
		Sinus bradycardia	1	0	0	0	1	0	0	0	1	1
		Sinus tachycardia	0	0	1	0	0	0	1	0	1	1
		Supraventricular tachycardia	0	0	2	0	1	0	1	0	2	2
	Ventricular arrhythmias and cardiac arrest	*Subtotal*	*0*	*1*	*4*	*0*	*0*	*1*	*4*	*0*	*5*	*5*
		Cardiac arrest	0	0	3	0	0	0	3	0	3	3
		Ventricular extrasystoles	0	1	0	0	0	1	0	0	1	1
		Ventricular tachycardia	0	0	1	0	0	0	1	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
Congenital, familial and genetic disorders	*Subtotal*	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
	Congenital disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Aplasia	0	0	0	1	0	0	0	1	1	1
Ear and labyrinth disorders	*Subtotal*	*Subtotal*	*17*	*18*	*12*	*5*	*19*	*19*	*11*	*7*	*52*	*56*
	Ear disorders NEC	*Subtotal*	*6*	*0*	*2*	*1*	*7*	*0*	*1*	*1*	*9*	*9*
		Ear discomfort	0	0	0	1	0	0	0	1	1	1
		Ear pain	5	0	2	0	6	0	1	0	7	7
		Ear swelling	1	0	0	0	1	0	0	0	1	1
	Hearing losses	*Subtotal*	*1*	*1*	*6*	*1*	*1*	*1*	*6*	*1*	*9*	*9*
		Deafness	0	0	1	1	0	0	1	1	2	2
		Deafness transitory	0	0	1	0	0	0	1	0	1	1
		Hypoacusis	1	1	4	0	1	1	4	0	6	6
	Hyperacusia	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Hyperacusis	2	0	0	0	2	0	0	0	2	2
	Inner ear signs and symptoms	*Subtotal*	*9*	*18*	*4*	*4*	*9*	*18*	*4*	*5*	*35*	*36*
		Tinnitus	1	2	0	3	1	2	0	3	6	6
		Vertigo	8	16	4	2	8	16	4	2	30	30
Endocrine disorders	*Subtotal*	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
	Acute and chronic thyroiditis	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Silent thyroiditis	1	0	0	0	1	0	0	0	1	1
Eye disorders	*Subtotal*	*Subtotal*	*28*	*10*	*22*	*3*	*45*	*11*	*26*	*3*	*63*	*85*
	Conjunctival infections, irritations and inflammations	*Subtotal*	*1*	*0*	*2*	*0*	*3*	*0*	*1*	*0*	*3*	*4*
		Conjunctival hyperaemia	0	0	2	0	2	0	1	0	2	3
		Conjunctival oedema	1	0	0	0	1	0	0	0	1	1
	Eyelid movement disorders	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Blepharospasm	0	0	2	0	0	0	2	0	2	2
	Iris and uveal tract infections, irritations and inflammations	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Uveitis	0	0	1	0	0	0	1	0	1	1
	Lacrimation disorders	*Subtotal*	*2*	*1*	*0*	*0*	*2*	*1*	*0*	*0*	*3*	*3*
		Dry eye	0	1	0	0	0	1	0	0	1	1
		Lacrimation increased	2	0	0	0	2	0	0	0	2	2
	Lid, lash and lacrimal infections, irritations and inflammations	*Subtotal*	*2*	*2*	*1*	*0*	*2*	*2*	*1*	*0*	*5*	*5*
		Erythema of eyelid	1	0	0	0	1	0	0	0	1	1
		Eyelid oedema	0	1	1	0	0	1	1	0	2	2
		Swelling of eyelid	1	1	0	0	1	1	0	0	2	2
	Ocular disorders NEC	*Subtotal*	*7*	*1*	*3*	*1*	*8*	*1*	*2*	*1*	*12*	*12*
		Eye pain	2	1	2	0	3	1	1	0	5	5
		Eye swelling	3	0	1	0	3	0	1	0	4	4
		Periorbital swelling	2	0	0	1	2	0	0	1	3	3
	Ocular infections, inflammations and associated manifestations	*Subtotal*	*5*	*1*	*2*	*0*	*6*	*1*	*1*	*0*	*8*	*8*
		Eye irritation	1	0	2	0	2	0	1	0	3	3
		Ocular hyperaemia	4	1	0	0	4	1	0	0	5	5
	Ocular nerve and muscle disorders	*Subtotal*	*0*	*0*	*2*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Eye movement disorder	0	0	1	0	1	0	0	0	1	1
		Strabismus	0	0	1	0	0	0	1	0	1	1
	Ocular sensation disorders	*Subtotal*	*5*	*1*	*0*	*0*	*5*	*1*	*0*	*0*	*6*	*6*
		Asthenopia	1	0	0	0	1	0	0	0	1	1
		Photophobia	4	1	0	0	4	1	0	0	5	5
	Optic disc abnormalities NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Papilloedema	0	0	1	0	0	0	1	0	1	1
	Pupil disorders	*Subtotal*	*1*	*1*	*1*	*0*	*2*	*1*	*0*	*0*	*3*	*3*
		Mydriasis	1	1	1	0	2	1	0	0	3	3
	Visual disorders NEC	*Subtotal*	*7*	*4*	*11*	*2*	*9*	*4*	*13*	*2*	*24*	*28*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Diplopia	1	0	5	1	1	0	5	1	7	7
		Vision blurred	7	4	9	1	8	4	8	1	21	21
	Visual field disorders	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Visual field defect	1	0	0	0	1	0	0	0	1	1
	Visual impairment and blindness (excl colour blindness)	*Subtotal*	*3*	*0*	*6*	*0*	*6*	*0*	*3*	*0*	*9*	*9*
		Blindness	0	0	1	0	0	0	1	0	1	1
		Visual impairment	3	0	5	0	6	0	2	0	8	8
Gastrointestinal disorders	*Subtotal*	*Subtotal*	*196*	*134*	*60*	*44*	*293*	*172*	*52*	*50*	*434*	*567*
	Colitis (excl infective)	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*2*	*2*
		Colitis ulcerative	0	0	1	0	0	0	1	0	1	1
		Enterocolitis haemorrhagic	0	0	0	1	0	0	0	1	1	1
	Dental disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Teething	0	1	0	0	0	1	0	0	1	1
	Diarrhoea (excl infective)	*Subtotal*	*16*	*14*	*5*	*2*	*19*	*14*	*2*	*2*	*37*	*37*
		Diarrhoea	16	14	5	2	19	14	2	2	37	37
	Dyspeptic signs and symptoms	*Subtotal*	*2*	*0*	*1*	*0*	*3*	*0*	*0*	*0*	*3*	*3*
		Dyspepsia	2	0	1	0	3	0	0	0	3	3
	Gastrointestinal and abdominal pains (excl oral and throat)	*Subtotal*	*27*	*27*	*11*	*8*	*30*	*27*	*8*	*8*	*73*	*73*
		Abdominal pain	17	21	7	7	18	21	6	7	52	52
		Abdominal pain lower	0	2	0	0	0	2	0	0	2	2
		Abdominal pain upper	10	4	4	1	12	4	2	1	19	19
	Gastrointestinal atonic and hypomotility disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Gastrooesophageal reflux disease	0	1	0	0	0	1	0	0	1	1
	Gastrointestinal disorders NEC	*Subtotal*	*2*	*7*	*0*	*0*	*2*	*7*	*0*	*0*	*9*	*9*
		Gastrointestinal disorder	2	7	0	0	2	7	0	0	9	9
	Gastrointestinal inflammatory disorders NEC	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Enteritis	0	0	1	0	1	0	0	0	1	1
	Gastrointestinal mucosal dystrophies and secretion disorders	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Hyperchlorhydria	1	0	0	0	1	0	0	0	1	1
	Gastrointestinal signs and symptoms NEC	*Subtotal*	*6*	*2*	*1*	*0*	*7*	*2*	*0*	*0*	*9*	*9*
		Abdominal discomfort	3	2	0	0	3	2	0	0	5	5
		Dysphagia	2	0	1	0	3	0	0	0	3	3
		Odynophagia	1	0	0	0	1	0	0	0	1	1
	Intestinal haemorrhages	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Intestinal haematoma	0	0	1	0	0	0	1	0	1	1
	Nausea and vomiting symptoms	*Subtotal*	*156*	*94*	*46*	*34*	*206*	*109*	*35*	*34*	*330*	*384*
		Infantile spitting up	0	1	0	0	0	1	0	0	1	1
		Nausea	107	50	30	17	119	52	19	16	204	206
		Retching	0	2	0	0	0	2	0	0	2	2
		Vomiting	79	52	24	20	87	54	16	18	175	175
	Non-site specific gastrointestinal haemorrhages	*Subtotal*	*1*	*0*	*1*	*1*	*1*	*0*	*1*	*1*	*3*	*3*
		Haematemesis	0	0	0	1	0	0	0	1	1	1
		Haematochezia	1	0	1	0	1	0	1	0	2	2
	Oral dryness and saliva altered	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Salivary hypersecretion	0	0	1	0	1	0	0	0	1	1
	Oral soft tissue disorders NEC	*Subtotal*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*2*	*2*
		Cheilitis	0	2	0	0	0	2	0	0	2	2
	Oral soft tissue signs and symptoms	*Subtotal*	*5*	*2*	*3*	*1*	*8*	*2*	*2*	*2*	*11*	*14*
		Hypoaesthesia oral	0	1	2	1	1	1	1	1	4	4
		Lip discolouration	0	0	1	0	0	0	1	0	1	1
		Lip erythema	0	1	0	0	0	1	0	0	1	1
		Lip pain	1	0	0	0	1	0	0	0	1	1
		Lip pruritus	1	0	0	0	1	0	0	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Oral mucosal blistering	1	0	0	0	1	0	0	0	1	1
		Oral mucosal erythema	1	0	0	0	1	0	0	0	1	1
		Oral pain	1	0	0	1	1	0	0	1	2	2
		Paraesthesia oral	2	0	0	0	2	0	0	0	2	2
	Oral soft tissue swelling and oedema	*Subtotal*	*8*	*2*	*1*	*2*	*9*	*4*	*1*	*1*	*13*	*15*
		Lip oedema	3	1	0	1	3	1	0	1	5	5
		Lip swelling	3	1	1	1	3	3	1	0	6	7
		Mouth swelling	1	0	0	0	1	0	0	0	1	1
		Palatal oedema	1	0	0	0	1	0	0	0	1	1
		Palatal swelling	1	0	0	0	1	0	0	0	1	1
	Stomatitis and ulceration	*Subtotal*	*3*	*1*	*0*	*0*	*4*	*1*	*0*	*0*	*4*	*5*
		Aphthous ulcer	2	0	0	0	2	0	0	0	2	2
		Mouth ulceration	1	1	0	0	1	1	0	0	2	2
		Stomatitis	1	0	0	0	1	0	0	0	1	1
	Tongue signs and symptoms	*Subtotal*	*1*	*2*	*1*	*1*	*1*	*2*	*1*	*1*	*5*	*5*
		Swollen tongue	1	1	0	0	1	1	0	0	2	2
		Tongue discolouration	0	1	0	0	0	1	0	0	1	1
		Tongue eruption	0	0	1	0	0	0	1	0	1	1
		Tongue pruritus	0	0	0	1	0	0	0	1	1	1
General disorders and administration site conditions	*Subtotal*	*Subtotal*	*1,386*	*785*	*198*	*130*	*2,165*	*1,434*	*257*	*195*	*2,499*	*4,051*
	Administration site reactions NEC	*Subtotal*	*4*	*5*	*0*	*1*	*4*	*5*	*0*	*1*	*10*	*10*
		Administration site erythema	2	0	0	0	2	0	0	0	2	2
		Administration site induration	0	1	0	0	0	1	0	0	1	1
		Administration site inflammation	1	0	0	0	1	0	0	0	1	1
		Administration site joint erythema	0	1	0	0	0	1	0	0	1	1
		Administration site lymphadenopathy	1	1	0	0	1	1	0	0	2	2
		Administration site pain	0	1	0	1	0	1	0	1	2	2
		Administration site pruritus	0	1	0	0	0	1	0	0	1	1
	Adverse effect absent	*Subtotal*	*486*	*32*	*0*	*0*	*486*	*32*	*0*	*0*	*518*	*518*
		No adverse event	486	32	0	0	486	32	0	0	518	518
	Application and instillation site reactions	*Subtotal*	*5*	*1*	*0*	*0*	*5*	*1*	*0*	*0*	*6*	*6*
		Application site erythema	1	1	0	0	1	1	0	0	2	2
		Application site pain	3	0	0	0	3	0	0	0	3	3
		Application site reaction	1	0	0	0	1	0	0	0	1	1
	Asthenic conditions	*Subtotal*	*229*	*154*	*60*	*32*	*293*	*175*	*50*	*34*	*475*	*552*
		Asthenia	47	76	18	12	51	76	14	13	153	154
		Fatigue	147	58	29	13	157	60	21	12	247	250
		Malaise	78	38	21	10	85	39	15	9	147	148
	Body temperature altered	*Subtotal*	*0*	*0*	*6*	*0*	*0*	*0*	*6*	*0*	*6*	*6*
		Hyperthermia	0	0	5	0	0	0	5	0	5	5
		Hypothermia	0	0	1	0	0	0	1	0	1	1
	Death and sudden death	*Subtotal*	*0*	*0*	*3*	*3*	*0*	*0*	*3*	*3*	*6*	*6*
		Death	0	0	3	3	0	0	3	3	6	6
	Febrile disorders	*Subtotal*	*389*	*399*	*98*	*69*	*417*	*408*	*80*	*65*	*955*	*970*
		Hyperpyrexia	5	0	9	8	5	0	9	8	22	22
		Pyrexia	384	399	89	61	412	408	71	57	933	948
	Feelings and sensations NEC	*Subtotal*	*95*	*77*	*20*	*9*	*109*	*78*	*12*	*10*	*201*	*209*
		Chills	69	67	11	8	75	67	6	8	155	156
		Feeling abnormal	19	3	4	0	20	3	3	0	26	26
		Feeling cold	4	3	3	0	6	3	1	0	10	10
		Feeling hot	4	4	3	1	6	4	1	1	12	12
		Feeling jittery	1	0	0	0	1	0	0	0	1	1
		Hunger	0	0	0	1	0	0	0	1	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Sensation of foreign body	0	0	1	0	0	0	1	0	1	1
		Sense of oppression	1	0	0	0	1	0	0	0	1	1
		Thirst	0	1	0	0	0	1	0	0	1	1
	Gait disturbances	*Subtotal*	*4*	*0*	*3*	*0*	*4*	*0*	*3*	*0*	*7*	*7*
		Gait disturbance	4	0	3	0	4	0	3	0	7	7
	General signs and symptoms NEC	*Subtotal*	*100*	*181*	*16*	*11*	*110*	*233*	*10*	*10*	*308*	*363*
		Adhesion	2	0	0	0	2	0	0	0	2	2
		Concomitant disease aggravated	1	0	0	0	1	0	0	0	1	1
		Condition aggravated	1	1	4	1	2	1	3	1	7	7
		Crying	0	1	0	0	0	1	0	0	1	1
		Developmental delay	2	0	0	0	2	0	0	0	2	2
		Exercise tolerance decreased	0	0	1	1	0	0	1	1	2	2
		General physical health deterioration	1	1	0	0	1	1	0	0	2	2
		Ill-defined disorder	0	0	1	0	0	0	1	0	1	1
		Illness	5	0	1	0	6	0	0	0	6	6
		Induration	0	26	0	0	0	26	0	0	26	26
		Influenza like illness	18	31	6	2	22	31	2	2	57	57
		Local reaction	1	91	1	0	2	92	0	0	93	94
		Multiple organ dysfunction syndrome	0	0	1	0	0	0	1	0	1	1
		Nonspecific reaction	1	0	0	0	1	0	0	0	1	1
		Performance status decreased	1	0	1	0	1	0	1	0	2	2
		Peripheral swelling	13	6	2	2	15	7	1	1	23	24
		Physical deconditioning	1	0	0	0	1	0	0	0	1	1
		Swelling	7	69	0	5	7	69	0	5	81	81
		Swelling face	3	3	0	1	3	5	0	0	7	8
		Unevaluable event	44	0	0	0	44	0	0	0	44	44
	Inflammations	*Subtotal*	*0*	*3*	*2*	*0*	*0*	*3*	*2*	*0*	*5*	*5*
		Inflammation	0	3	2	0	0	3	2	0	5	5
	Infusion site reactions	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Infusion site rash	1	0	0	0	1	0	0	0	1	1
	Injection site reactions	*Subtotal*	*82*	*45*	*8*	*6*	*119*	*53*	*6*	*6*	*141*	*184*
		Injected limb mobility decreased	1	0	0	2	1	0	0	2	3	3
		Injection site cyst	2	0	0	0	2	0	0	0	2	2
		Injection site erythema	18	9	1	0	18	10	1	0	28	29
		Injection site haematoma	1	1	0	0	1	1	0	0	2	2
		Injection site hypoaesthesia	2	0	0	0	2	0	0	0	2	2
		Injection site induration	2	1	0	0	2	1	0	0	3	3
		Injection site inflammation	5	0	0	0	5	0	0	0	5	5
		Injection site mass	1	0	0	0	1	0	0	0	1	1
		Injection site oedema	5	0	1	0	5	0	1	0	6	6
		Injection site pain	49	28	6	1	52	28	3	1	84	84
		Injection site paraesthesia	0	0	0	1	0	0	0	1	1	1
		Injection site pruritus	6	0	0	0	6	0	0	0	6	6
		Injection site rash	1	0	1	0	1	0	1	0	2	2
		Injection site reaction	8	6	0	2	8	6	0	2	16	16
		Injection site swelling	7	3	0	0	8	3	0	0	10	11
		Injection site urticaria	1	1	0	0	1	1	0	0	2	2
		Injection site vesicles	1	1	0	0	1	1	0	0	2	2
		Injection site warmth	5	2	0	0	5	2	0	0	7	7
	Mass conditions NEC	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Mass	1	0	0	0	1	0	0	0	1	1
		Nodule	1	0	0	0	1	0	0	0	1	1
	Oedema NEC	*Subtotal*	*11*	*3*	*4*	*2*	*11*	*3*	*5*	*2*	*20*	*21*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Face oedema	2	0	1	0	2	0	1	0	3	3
		Localised oedema	3	0	1	1	3	0	1	1	5	5
		Oedema	3	1	0	0	3	1	0	0	4	4
		Oedema peripheral	3	2	3	1	3	2	3	1	9	9
	Pain and discomfort NEC	*Subtotal*	*100*	*288*	*63*	*38*	*126*	*295*	*58*	*39*	*489*	*518*
		Axillary pain	14	5	1	0	14	5	1	0	20	20
		Chest discomfort	16	6	9	5	19	6	6	5	36	36
		Chest pain	39	37	56	22	49	38	47	21	154	155
		Discomfort	2	1	0	0	2	1	0	0	3	3
		Facial pain	0	1	0	0	0	1	0	0	1	1
		Pain	34	243	6	13	37	244	4	13	296	298
		Tenderness	5	0	0	0	5	0	0	0	5	5
	Therapeutic and nontherapeutic responses	*Subtotal*	*6*	*1*	*2*	*12*	*8*	*1*	*0*	*12*	*21*	*21*
		Adverse drug reaction	0	0	0	1	0	0	0	1	1	1
		Adverse event	1	0	0	1	1	0	0	1	2	2
		Adverse reaction	1	0	0	0	1	0	0	0	1	1
		Idiosyncratic drug reaction	0	0	1	0	1	0	0	0	1	1
		Immediate post-injection reaction	1	0	1	0	2	0	0	0	2	2
		No reaction on previous exposure to drug	2	1	0	0	2	1	0	0	3	3
		Therapeutic response unexpected	1	0	0	0	1	0	0	0	1	1
		Vaccination failure	0	0	0	10	0	0	0	10	10	10
	Trophic disorders	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Metaplasia	0	0	0	1	0	0	0	1	1	1
	Ulcers NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Ulcer	0	1	0	0	0	1	0	0	1	1
	Vaccination site reactions	*Subtotal*	*302*	*121*	*21*	*8*	*470*	*146*	*22*	*12*	*452*	*650*
		Extensive swelling of vaccinated limb	2	4	0	0	2	4	0	0	6	6
		Vaccination site anaesthesia	0	1	0	0	0	1	0	0	1	1
		Vaccination site bruising	1	0	0	0	1	0	0	0	1	1
		Vaccination site discolouration	2	0	0	0	2	0	0	0	2	2
		Vaccination site discomfort	1	5	0	0	1	5	0	0	6	6
		Vaccination site erythema	65	13	2	1	66	14	1	1	81	82
		Vaccination site hypoaesthesia	2	0	1	0	2	0	1	0	3	3
		Vaccination site induration	2	1	0	1	2	1	0	1	4	4
		Vaccination site inflammation	11	3	0	1	11	3	0	1	15	15
		Vaccination site joint erythema	1	0	0	0	1	0	0	0	1	1
		Vaccination site lymphadenopathy	7	8	0	1	7	8	0	1	16	16
		Vaccination site macule	3	1	0	1	3	1	0	1	5	5
		Vaccination site mass	9	0	0	0	9	0	0	0	9	9
		Vaccination site movement impairment	4	0	1	0	4	0	1	0	5	5
		Vaccination site oedema	31	3	2	0	31	4	2	0	36	37
		Vaccination site pain	185	64	13	5	197	65	8	5	267	275
		Vaccination site paraesthesia	0	1	0	0	0	1	0	0	1	1
		Vaccination site plaque	3	1	0	0	3	1	0	0	4	4
		Vaccination site pruritus	20	4	2	0	20	4	2	0	26	26
		Vaccination site rash	29	4	1	0	29	4	1	0	34	34
		Vaccination site reaction	18	15	4	1	20	15	2	1	38	38
		Vaccination site swelling	30	11	3	0	32	11	3	0	44	46
		Vaccination site urticaria	3	2	0	0	3	2	0	0	5	5
		Vaccination site warmth	24	2	1	1	24	2	1	1	28	28
Hepatobiliary disorders	*Subtotal*	*Subtotal*	*2*	*1*	*5*	*0*	*3*	*1*	*4*	*0*	*8*	*8*
	Cholestasis and jaundice	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Jaundice	1	0	0	0	1	0	0	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
	Hepatic and hepatobiliary disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Liver disorder	0	1	0	0	0	1	0	0	1	1
	Hepatic enzymes and function abnormalities	*Subtotal*	*0*	*0*	*2*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Hepatic function abnormal	0	0	1	0	0	0	1	0	1	1
		Hypertransaminasaemia	0	0	1	0	1	0	0	0	1	1
	Hepatobiliary signs and symptoms	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Hepatomegaly	1	0	0	0	1	0	0	0	1	1
	Hepatocellular damage and hepatitis NEC	*Subtotal*	*0*	*0*	*3*	*0*	*0*	*0*	*3*	*0*	*3*	*3*
		Hepatic cytolysis	0	0	2	0	0	0	2	0	2	2
		Hepatitis acute	0	0	1	0	0	0	1	0	1	1
Immune system disorders	*Subtotal*	*Subtotal*	*24*	*226*	*24*	*28*	*25*	*244*	*23*	*29*	*302*	*321*
	Allergic conditions NEC	*Subtotal*	*5*	*29*	*2*	*3*	*5*	*29*	*2*	*3*	*39*	*39*
		Hypersensitivity	5	29	1	3	5	29	1	3	38	38
		Type I hypersensitivity	0	0	1	0	0	0	1	0	1	1
	Allergies to foods, food additives, drugs and other chemicals	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Food allergy	0	0	0	1	0	0	0	1	1	1
	Anaphylactic and anaphylactoid responses	*Subtotal*	*1*	*1*	*13*	*3*	*1*	*1*	*13*	*3*	*18*	*18*
		Anaphylactic reaction	1	1	9	3	1	1	9	3	14	14
		Anaphylactic shock	0	0	4	0	0	0	4	0	4	4
	Autoimmune disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Autoimmune disorder	0	0	0	1	0	0	0	1	1	1
	Immune and associated conditions NEC	*Subtotal*	*18*	*212*	*9*	*22*	*19*	*214*	*8*	*21*	*261*	*262*
		Haemophagocytic lymphohistiocytosis	0	0	1	0	0	0	1	0	1	1
		Immunisation reaction	18	212	4	20	19	214	3	19	254	255
		Multisystem inflammatory syndrome in children	0	0	3	2	0	0	3	2	5	5
		Vaccine associated enhanced disease	0	0	1	0	0	0	1	0	1	1
Infections and infestations	*Subtotal*	*Subtotal*	*36*	*43*	*27*	*19*	*42*	*44*	*24*	*21*	*125*	*131*
	Abdominal and gastrointestinal infections	*Subtotal*	*0*	*1*	*4*	*1*	*0*	*1*	*4*	*2*	*6*	*7*
		Abdominal abscess	0	0	0	1	0	0	0	1	1	1
		Appendicitis	0	0	2	0	0	0	2	0	2	2
		Appendicitis perforated	0	0	0	1	0	0	0	1	1	1
		Dysentery	0	1	2	0	0	1	2	0	3	3
	Bacterial infections NEC	*Subtotal*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*2*	*2*
		Arthritis bacterial	0	0	0	1	0	0	0	1	1	1
		Cellulitis	0	1	0	0	0	1	0	0	1	1
	Borrelial infections	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Erythema migrans	1	0	0	0	1	0	0	0	1	1
	Cardiac infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Myocarditis infectious	0	0	1	0	0	0	1	0	1	1
	Central nervous system and spinal infections	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Myelitis	0	0	0	1	0	0	0	1	1	1
	Chlamydial infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Chlamydial infection	0	0	1	0	0	0	1	0	1	1
	Coronavirus infections	*Subtotal*	*4*	*3*	*2*	*13*	*5*	*3*	*1*	*13*	*22*	*22*
		Asymptomatic COVID-19	0	1	0	0	0	1	0	0	1	1
		COVID-19	4	2	2	12	5	2	1	12	20	20
		COVID-19 pneumonia	0	0	0	1	0	0	0	1	1	1
	Cytomegaloviral infections	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Cytomegalovirus infection	0	0	1	0	1	0	0	0	1	1
	Dental and oral soft tissue infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Sialoadenitis	0	0	1	0	0	0	1	0	1	1
	Ear infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Ear infection	0	0	1	0	0	0	1	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
	Epstein-Barr viral infections	*Subtotal*	*1*	*2*	*1*	*0*	*1*	*2*	*1*	*0*	*4*	*4*
		Epstein-Barr virus infection	0	2	0	0	0	2	0	0	2	2
		Hepatitis infectious mononucleosis	0	0	1	0	0	0	1	0	1	1
		Infectious mononucleosis	1	0	0	0	1	0	0	0	1	1
	Female reproductive tract infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Vulvitis	0	0	1	0	0	0	1	0	1	1
	Flaviviral infections	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Dengue fever	0	1	0	0	0	1	0	0	1	1
	Herpes viral infections	*Subtotal*	*9*	*9*	*3*	*0*	*9*	*9*	*3*	*0*	*21*	*21*
		Genital herpes	1	1	0	0	1	1	0	0	2	2
		Herpes simplex	1	0	0	0	1	0	0	0	1	1
		Herpes zoster	5	6	1	0	5	6	1	0	12	12
		Herpes zoster oticus	0	0	1	0	0	0	1	0	1	1
		Herpes zoster reactivation	1	0	0	0	1	0	0	0	1	1
		Oral herpes	1	2	1	0	1	2	1	0	4	4
	Infections NEC	*Subtotal*	*2*	*2*	*1*	*0*	*2*	*2*	*1*	*0*	*5*	*5*
		Abscess	0	2	0	0	0	2	0	0	2	2
		Abscess limb	1	0	0	0	1	0	0	0	1	1
		Infection	1	0	0	0	1	0	0	0	1	1
		Localised infection	0	0	1	0	0	0	1	0	1	1
	Influenza viral infections	*Subtotal*	*3*	*2*	*3*	*1*	*3*	*2*	*3*	*1*	*9*	*9*
		Influenza	3	2	3	1	3	2	3	1	9	9
	Lower respiratory tract and lung infections	*Subtotal*	*0*	*0*	*1*	*1*	*1*	*0*	*1*	*1*	*2*	*3*
		Bronchitis	0	0	1	0	1	0	0	0	1	1
		Pneumonia	0	0	1	1	0	0	1	1	2	2
	Male reproductive tract infections	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Orchitis	0	1	0	0	0	1	0	0	1	1
	Neisseria infections	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Gonorrhoea	0	0	1	0	0	0	1	0	1	1
	Skin structures and soft tissue infections	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Dermo-hypodermitis	0	0	1	0	0	0	1	0	1	1
		Skin infection	1	0	0	0	1	0	0	0	1	1
	Tuberculous infections	*Subtotal*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*2*	*2*
		Disseminated Bacillus Calmette-Guerin infection	0	1	0	0	0	1	0	0	1	1
		Erythema induratum	0	0	1	0	0	0	1	0	1	1
	Upper respiratory tract infections	*Subtotal*	*14*	*20*	*5*	*2*	*17*	*20*	*2*	*2*	*41*	*41*
		Nasopharyngitis	8	16	3	1	9	16	2	1	28	28
		Rhinitis	5	4	0	1	5	4	0	1	10	10
		Sinusitis	1	0	2	0	3	0	0	0	3	3
	Vascular infections	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Lymphangitis	0	1	0	0	0	1	0	0	1	1
	Viral infections NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Viral infection	1	0	0	0	1	0	0	0	1	1
Injury, poisoning and procedural complications	*Subtotal*	*Subtotal*	*4,294*	*160*	*58*	*7*	*4,612*	*182*	*15*	*6*	*4,519*	*4,815*
	Abdominal and gastrointestinal injuries NEC	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Lip injury	0	0	1	0	1	0	0	0	1	1
	Bone and joint injuries NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Joint injury	0	0	1	0	0	0	1	0	1	1
	Cerebral injuries NEC	*Subtotal*	*0*	*0*	*3*	*0*	*0*	*0*	*3*	*0*	*3*	*3*
		Brain herniation	0	0	1	0	0	0	1	0	1	1
		Concussion	0	0	2	0	0	0	2	0	2	2
	Conditions caused by cold	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Chillblains	0	1	0	0	0	1	0	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
	Exposures associated with pregnancy, delivery and lactation	*Subtotal*	*13*	*0*	*2*	*0*	*15*	*0*	*0*	*0*	*15*	*15*
		Exposure during pregnancy	5	0	1	0	6	0	0	0	6	6
		Maternal exposure during breast feeding	1	0	0	0	1	0	0	0	1	1
		Maternal exposure during pregnancy	7	0	1	0	8	0	0	0	8	8
	Intentional product use issues	*Subtotal*	*5*	*0*	*0*	*0*	*5*	*0*	*0*	*0*	*5*	*5*
		Intentional dose omission	1	0	0	0	1	0	0	0	1	1
		Intentional product use issue	4	0	0	0	4	0	0	0	4	4
	Limb fractures and dislocations	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Tibia fracture	0	0	0	1	0	0	0	1	1	1
	Medication errors, product use errors and issues NEC	*Subtotal*	*20*	*1*	*0*	*1*	*21*	*1*	*0*	*1*	*22*	*23*
		Circumstance or information capable of leading to medication error	1	0	0	0	1	0	0	0	1	1
		Medication error	7	0	0	1	7	0	0	1	8	8
		Product use issue	3	0	0	0	3	0	0	0	3	3
		Vaccination error	8	1	0	0	8	1	0	0	9	9
		Wrong patient	1	0	0	0	1	0	0	0	1	1
		Wrong technique in product usage process	1	0	0	0	1	0	0	0	1	1
	Non-site specific injuries NEC	*Subtotal*	*4*	*3*	*10*	*2*	*11*	*3*	*3*	*2*	*19*	*19*
		Animal bite	0	0	0	1	0	0	0	1	1	1
		Fall	2	0	10	1	9	0	3	1	13	13
		Injury	2	2	0	0	2	2	0	0	4	4
		Wound	0	1	0	0	0	1	0	0	1	1
	Off label uses	*Subtotal*	*93*	*1*	*5*	*0*	*96*	*1*	*2*	*0*	*99*	*99*
		Off label use	93	1	5	0	96	1	2	0	99	99
	Overdoses NEC	*Subtotal*	*1*	*7*	*1*	*0*	*2*	*7*	*0*	*0*	*9*	*9*
		Overdose	1	7	1	0	2	7	0	0	9	9
	Product administration errors and issues	*Subtotal*	*4,250*	*150*	*42*	*2*	*4,430*	*165*	*3*	*1*	*4,444*	*4,599*
		Accidental overdose	2	0	1	0	3	0	0	0	3	3
		Accidental underdose	2	0	2	0	4	0	0	0	4	4
		Expired product administered	25	5	0	0	25	5	0	0	30	30
		Extra dose administered	1	0	0	0	1	0	0	0	1	1
		Inappropriate schedule of product administration	73	5	0	0	73	5	0	0	78	78
		Incomplete course of vaccination	4	0	0	0	4	0	0	0	4	4
		Incorrect dose administered	6	0	0	0	6	0	0	0	6	6
		Incorrect product administration duration	1	0	0	0	1	0	0	0	1	1
		Incorrect product formulation administered	17	1	0	0	17	1	0	0	18	18
		Incorrect route of product administration	2	0	0	0	2	0	0	0	2	2
		Poor quality product administered	1	8	0	0	1	8	0	0	9	9
		Product administered at inappropriate site	4	0	0	0	4	0	0	0	4	4
		Product administered by wrong person	1	0	0	0	1	0	0	0	1	1
		Product administered to patient of inappropriate age	4,185	144	39	2	4,226	145	3	1	4,370	4,375
		Product administration error	9	0	0	0	9	0	0	0	9	9
		Product dose omission issue	35	0	0	0	35	0	0	0	35	35
		Wrong patient received product	2	0	0	0	2	0	0	0	2	2
		Wrong product administered	16	1	0	0	16	1	0	0	17	17
	Product dispensing errors and issues	*Subtotal*	*3*	*0*	*0*	*0*	*3*	*0*	*0*	*0*	*3*	*3*
		Drug dispensed to wrong patient	2	0	0	0	2	0	0	0	2	2
		Product dispensing issue	1	0	0	0	1	0	0	0	1	1
	Product preparation errors and issues	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Product preparation issue	2	0	0	0	2	0	0	0	2	2
	Product selection errors and issues	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Product selection error	2	0	0	0	2	0	0	0	2	2
	Product storage errors and issues in the product use system	*Subtotal*	*13*	*1*	*0*	*0*	*13*	*1*	*0*	*0*	*14*	*14*
		Product storage error	13	1	0	0	13	1	0	0	14	14
	Site specific injuries NEC	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Face injury	0	0	1	0	0	0	1	0	1	1
		Limb injury	0	0	1	0	0	0	1	0	1	1
	Skin injuries NEC	*Subtotal*	*3*	*0*	*3*	*0*	*6*	*0*	*1*	*0*	*6*	*7*
		Contusion	3	0	2	0	4	0	1	0	5	5
		Skin abrasion	0	0	1	0	1	0	0	0	1	1
		Skin laceration	0	0	1	0	1	0	0	0	1	1
	Underdoses NEC	*Subtotal*	*4*	*0*	*0*	*0*	*4*	*0*	*0*	*0*	*4*	*4*
		Intentional underdose	1	0	0	0	1	0	0	0	1	1
		Underdose	3	0	0	0	3	0	0	0	3	3
	Vaccination related complications	*Subtotal*	*1*	*3*	*0*	*1*	*1*	*3*	*0*	*1*	*5*	*5*
		Reaction to previous exposure to any vaccine	1	0	0	0	1	0	0	0	1	1
		Vaccination complication	0	3	0	1	0	3	0	1	4	4
Investigations	*Subtotal*	*Subtotal*	*33*	*21*	*27*	*9*	*39*	*25*	*41*	*9*	*90*	*114*
	Autoimmunity analyses	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*2*	*0*	*1*	*2*
		Antinuclear antibody	0	0	1	0	0	0	1	0	1	1
		Rheumatoid factor	0	0	1	0	0	0	1	0	1	1
	Blood counts NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Full blood count	0	0	1	0	0	0	1	0	1	1
	Carbohydrate tolerance analyses (incl diabetes)	*Subtotal*	*2*	*0*	*1*	*0*	*3*	*0*	*0*	*0*	*3*	*3*
		Blood glucose abnormal	0	0	1	0	1	0	0	0	1	1
		Blood glucose decreased	1	0	0	0	1	0	0	0	1	1
		Blood glucose increased	1	0	0	0	1	0	0	0	1	1
	Cardiac auscultatory investigations	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Cardiac murmur	1	0	0	0	1	0	0	0	1	1
	Cardiac function diagnostic procedures	*Subtotal*	*1*	*0*	*2*	*0*	*1*	*0*	*2*	*0*	*3*	*3*
		Cardiovascular function test abnormal	1	0	0	0	1	0	0	0	1	1
		Echocardiogram	0	0	1	0	0	0	1	0	1	1
		Venous pressure jugular	0	0	1	0	0	0	1	0	1	1
	Cell marker analyses	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		HLA-B*27 positive	1	0	0	0	1	0	0	0	1	1
	Chemistry analyses NEC	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Inflammatory marker increased	1	0	1	0	1	0	1	0	2	2
	Coagulation and bleeding analyses	*Subtotal*	*0*	*1*	*1*	*1*	*0*	*2*	*1*	*1*	*3*	*4*
		Blood fibrinogen increased	0	1	0	0	0	1	0	0	1	1
		Fibrin D dimer increased	0	1	0	1	0	1	0	1	2	2
		Protein C increased	0	0	1	0	0	0	1	0	1	1
	ECG investigations	*Subtotal*	*1*	*0*	*5*	*0*	*1*	*0*	*6*	*0*	*6*	*7*
		Electrocardiogram	0	0	1	0	0	0	1	0	1	1
		Electrocardiogram abnormal	1	0	0	0	1	0	0	0	1	1
		Electrocardiogram change	0	0	1	0	0	0	1	0	1	1
		Electrocardiogram QT prolonged	0	0	1	0	0	0	1	0	1	1
		Electrocardiogram ST segment abnormal	0	0	1	0	0	0	1	0	1	1
		Electrocardiogram ST segment elevation	0	0	1	0	0	0	1	0	1	1
		Electrocardiogram T wave inversion	0	0	1	0	0	0	1	0	1	1
	Haematological analyses NEC	*Subtotal*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*2*	*2*
		Red blood cell sedimentation rate	0	0	1	0	0	0	1	0	1	1
		Red blood cell sedimentation rate increased	0	1	0	0	0	1	0	0	1	1
	Heart rate and pulse investigations	*Subtotal*	*5*	*4*	*5*	*4*	*7*	*4*	*4*	*4*	*18*	*19*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Heart rate abnormal	1	0	0	0	1	0	0	0	1	1
		Heart rate increased	4	3	4	3	5	3	3	3	14	14
		Heart rate irregular	1	1	1	1	1	1	1	1	4	4
	Hepatobiliary function diagnostic procedures	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*2*	*0*	*1*	*2*
		Alanine aminotransferase increased	0	0	1	0	0	0	1	0	1	1
		Aspartate aminotransferase increased	0	0	1	0	0	0	1	0	1	1
	Imaging procedures NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Ultrasound scan	0	0	1	0	0	0	1	0	1	1
	Investigations NEC	*Subtotal*	*1*	*1*	*1*	*0*	*1*	*1*	*1*	*0*	*3*	*3*
		Blood test abnormal	1	0	0	0	1	0	0	0	1	1
		Laboratory test	0	0	1	0	0	0	1	0	1	1
		Polymerase chain reaction	0	1	0	0	0	1	0	0	1	1
	Metabolism tests NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		N-terminal prohormone brain natriuretic peptide increased	0	0	1	0	0	0	1	0	1	1
	Microbiology and serology tests NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Blood culture	0	0	1	0	0	0	1	0	1	1
	Physical examination procedures and organ system status	*Subtotal*	*2*	*3*	*4*	*1*	*2*	*3*	*4*	*1*	*10*	*10*
		Body temperature abnormal	0	1	0	0	0	1	0	0	1	1
		Body temperature decreased	1	0	1	0	1	0	1	0	2	2
		Body temperature increased	1	2	1	0	1	2	1	0	4	4
		Grip strength decreased	0	0	1	0	0	0	1	0	1	1
		Respiratory rate increased	0	0	1	0	0	0	1	0	1	1
		Weight decreased	0	0	0	1	0	0	0	1	1	1
	Pituitary analyses anterior	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*2*	*0*	*0*	*1*	*2*
		Blood thyroid stimulating hormone decreased	0	1	0	0	0	1	0	0	1	1
		Blood thyroid stimulating hormone increased	0	1	0	0	0	1	0	0	1	1
	Platelet analyses	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Platelet count increased	1	0	0	0	1	0	0	0	1	1
	Protein analyses NEC	*Subtotal*	*1*	*0*	*2*	*0*	*1*	*0*	*2*	*0*	*3*	*3*
		C-reactive protein	0	0	1	0	0	0	1	0	1	1
		C-reactive protein increased	1	0	1	0	1	0	1	0	2	2
	Red blood cell analyses	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Haemoglobin decreased	1	0	0	0	1	0	0	0	1	1
	Respiratory tract and thoracic imaging procedures	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Chest X-ray	0	0	1	0	0	0	1	0	1	1
	Skeletal and cardiac muscle analyses	*Subtotal*	*1*	*0*	*7*	*2*	*1*	*0*	*8*	*2*	*10*	*11*
		Blood creatine phosphokinase increased	0	0	1	0	0	0	1	0	1	1
		Troponin I increased	0	0	3	0	0	0	3	0	3	3
		Troponin increased	0	0	3	2	0	0	4	2	5	6
		Troponin T	1	0	0	0	1	0	0	0	1	1
	Thyroid analyses	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Thyroid hormones increased	0	1	0	0	0	1	0	0	1	1
	Tissue enzyme analyses NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Blood lactate dehydrogenase increased	0	0	1	0	0	0	1	0	1	1
	Vascular tests NEC (incl blood pressure)	*Subtotal*	*13*	*9*	*1*	*0*	*14*	*9*	*0*	*0*	*23*	*23*
		Blood pressure decreased	3	1	1	0	4	1	0	0	5	5
		Blood pressure increased	10	8	0	0	10	8	0	0	18	18
	Virus identification and serology	*Subtotal*	*2*	*2*	*1*	*1*	*2*	*2*	*1*	*1*	*6*	*6*
		SARS-CoV-2 test negative	1	0	0	0	1	0	0	0	1	1
		SARS-CoV-2 test positive	1	2	1	1	1	2	1	1	5	5
	White blood cell analyses	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		White blood cell count decreased	1	0	0	0	1	0	0	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
Metabolism and nutrition disorders	*Subtotal*	*Subtotal*	*25*	*11*	*5*	*10*	*28*	*11*	*2*	*11*	*51*	*52*
	Appetite disorders	*Subtotal*	*19*	*11*	*1*	*7*	*20*	*11*	*0*	*7*	*38*	*38*
		Decreased appetite	18	11	1	7	19	11	0	7	37	37
		Increased appetite	1	0	0	0	1	0	0	0	1	1
	Diabetes mellitus (incl subtypes)	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Type 1 diabetes mellitus	0	0	0	1	0	0	0	1	1	1
	Diabetic complications NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Diabetic ketoacidosis	0	0	0	1	0	0	0	1	1	1
	General nutritional disorders NEC	*Subtotal*	*3*	*0*	*1*	*1*	*4*	*0*	*0*	*1*	*5*	*5*
		Abnormal loss of weight	1	0	0	0	1	0	0	0	1	1
		Cachexia	0	0	0	1	0	0	0	1	1	1
		Feeding disorder	2	0	1	0	3	0	0	0	3	3
	Hyperglycaemic conditions NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Hyperglycaemia	0	0	1	0	0	0	1	0	1	1
	Hypoglycaemic conditions NEC	*Subtotal*	*3*	*0*	*1*	*0*	*3*	*0*	*1*	*0*	*4*	*4*
		Hypoglycaemia	3	0	1	0	3	0	1	0	4	4
	Total fluid volume decreased	*Subtotal*	*0*	*0*	*1*	*1*	*1*	*0*	*0*	*1*	*2*	*2*
		Dehydration	0	0	1	1	1	0	0	1	2	2
Musculoskeletal and connective tissue disorders	*Subtotal*	*Subtotal*	*323*	*225*	*62*	*25*	*412*	*358*	*56*	*32*	*635*	*858*
	Arthropathies NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Arthritis	0	1	0	0	0	1	0	0	1	1
	Bone related signs and symptoms	*Subtotal*	*3*	*3*	*3*	*1*	*5*	*3*	*1*	*1*	*10*	*10*
		Bone pain	2	2	2	1	3	2	1	1	7	7
		Pain in jaw	0	1	1	0	1	1	0	0	2	2
		Spinal pain	1	0	0	0	1	0	0	0	1	1
	Joint related signs and symptoms	*Subtotal*	*53*	*131*	*15*	*9*	*61*	*131*	*12*	*9*	*208*	*213*
		Arthralgia	53	129	15	8	59	129	12	8	205	208
		Joint stiffness	0	1	0	1	0	1	0	1	2	2
		Joint swelling	2	1	0	0	2	1	0	0	3	3
	Lupus erythematosus (incl subtypes)	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Systemic lupus erythematosus	0	0	1	0	0	0	1	0	1	1
	Muscle pains	*Subtotal*	*102*	*150*	*16*	*12*	*106*	*150*	*12*	*12*	*280*	*280*
		Myalgia	102	150	16	12	106	150	12	12	280	280
	Muscle related signs and symptoms NEC	*Subtotal*	*9*	*4*	*2*	*1*	*10*	*4*	*2*	*1*	*16*	*17*
		Muscle spasms	8	4	1	1	8	4	1	1	14	14
		Muscle tightness	2	0	0	0	2	0	0	0	2	2
		Muscle twitching	0	0	1	0	0	0	1	0	1	1
	Muscle tone abnormalities	*Subtotal*	*2*	*0*	*1*	*1*	*2*	*0*	*1*	*1*	*4*	*4*
		Muscle rigidity	1	0	1	1	1	0	1	1	3	3
		Torticollis	1	0	0	0	1	0	0	0	1	1
	Muscle weakness conditions	*Subtotal*	*12*	*1*	*8*	*3*	*15*	*1*	*6*	*3*	*24*	*25*
		Muscular weakness	12	1	8	3	15	1	6	3	24	25
	Musculoskeletal and connective tissue conditions NEC	*Subtotal*	*8*	*3*	*3*	*0*	*9*	*3*	*2*	*0*	*14*	*14*
		Mobility decreased	4	0	1	0	4	0	1	0	5	5
		Musculoskeletal stiffness	4	3	2	0	5	3	1	0	9	9
	Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	*Subtotal*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*2*	*2*
		Facial asymmetry	0	1	1	0	0	1	1	0	2	2
	Musculoskeletal and connective tissue pain and discomfort	*Subtotal*	*186*	*57*	*28*	*6*	*202*	*64*	*17*	*5*	*277*	*288*
		Back pain	8	5	2	2	9	6	1	1	17	17
		Limb discomfort	3	6	1	0	4	6	0	0	10	10
		Musculoskeletal chest pain	1	0	0	1	2	0	0	1	2	3
		Musculoskeletal pain	1	3	0	0	1	3	0	0	4	4
		Neck pain	2	6	2	0	2	6	2	0	10	10

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Pain in extremity	174	43	23	3	184	43	14	3	243	244
	Soft tissue disorders NEC	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Axillary mass	1	0	0	0	1	0	0	0	1	1
		Soft tissue mass	1	0	0	0	1	0	0	0	1	1
	Tendon disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Enthesopathy	0	0	1	0	0	0	1	0	1	1
Nervous system disorders	*Subtotal*	*Subtotal*	*444*	*388*	*186*	*122*	*570*	*449*	*243*	*177*	*1,140*	*1,439*
	Abnormal reflexes	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Hyporeflexia	0	0	1	0	0	0	1	0	1	1
	Abnormal sleep-related events	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Sleep paralysis	1	0	0	0	1	0	0	0	1	1
	Absence seizures	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*2*	*2*
		Petit mal epilepsy	0	0	1	1	0	0	1	1	2	2
	Acute polyneuropathies	*Subtotal*	*0*	*0*	*1*	*3*	*0*	*0*	*1*	*3*	*4*	*4*
		Guillain-Barre syndrome	0	0	1	3	0	0	1	3	4	4
	Autonomic nervous system disorders	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Autonomic nervous system imbalance	0	0	1	0	1	0	0	0	1	1
	Central nervous system haemorrhages and cerebrovascular accidents	*Subtotal*	*0*	*0*	*3*	*1*	*0*	*0*	*3*	*2*	*4*	*5*
		Cerebral haemorrhage	0	0	2	0	0	0	2	0	2	2
		Intraventricular haemorrhage	0	0	0	1	0	0	0	1	1	1
		Reversible ischaemic neurological deficit	0	0	1	0	0	0	1	0	1	1
		Subarachnoid haemorrhage	0	0	0	1	0	0	0	1	1	1
	Cerebrovascular venous and sinus thrombosis	*Subtotal*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*	*2*
		Cerebral venous thrombosis	0	0	0	1	0	0	0	1	1	1
		Transverse sinus thrombosis	0	0	0	1	0	0	0	1	1	1
	Chronic polyneuropathies	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Chronic inflammatory demyelinating polyradiculoneuropathy	0	0	0	1	0	0	0	1	1	1
	Coma states	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Coma	0	0	1	0	0	0	1	0	1	1
	Coordination and balance disturbances	*Subtotal*	*4*	*3*	*3*	*3*	*4*	*3*	*4*	*3*	*13*	*14*
		Balance disorder	2	2	2	0	2	2	2	0	6	6
		Cerebellar syndrome	0	0	0	1	0	0	0	1	1	1
		Coordination abnormal	1	0	0	0	1	0	0	0	1	1
		Dysstasia	1	1	0	1	1	1	0	1	3	3
		Nystagmus	0	0	2	1	0	0	2	1	3	3
	Cranial nerve disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Paresis cranial nerve	0	0	0	1	0	0	0	1	1	1
	Disturbances in consciousness NEC	*Subtotal*	*32*	*40*	*75*	*32*	*38*	*40*	*72*	*34*	*179*	*184*
		Altered state of consciousness	0	0	2	0	0	0	2	0	2	2
		Depressed level of consciousness	0	0	4	2	0	0	4	2	6	6
		Lethargy	2	1	1	1	3	1	0	1	5	5
		Loss of consciousness	5	5	21	16	5	5	21	16	47	47
		Somnolence	10	5	3	0	11	5	2	0	18	18
		Syncope	15	29	47	15	19	29	43	15	106	106
	Dyskinesias and movement disorders NEC	*Subtotal*	*5*	*1*	*1*	*2*	*5*	*1*	*1*	*2*	*9*	*9*
		Dyskinesia	2	0	0	0	2	0	0	0	2	2
		Foetal movement disorder	1	0	0	0	1	0	0	0	1	1
		Motor dysfunction	1	0	1	2	1	0	1	2	4	4
		Movement disorder	0	1	0	0	0	1	0	0	1	1
		Psychomotor hyperactivity	1	0	0	0	1	0	0	0	1	1
	Dystonias	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Dystonia	0	1	0	0	0	1	0	0	1	1
	Encephalitis NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Immune-mediated encephalitis	0	0	1	0	0	0	1	0	1	1
	Encephalopathies NEC	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Encephalopathy	0	0	2	0	0	0	2	0	2	2
	Facial cranial nerve disorders	*Subtotal*	*2*	*1*	*8*	*6*	*2*	*1*	*8*	*6*	*17*	*17*
		Bell's palsy	0	0	2	2	0	0	2	2	4	4
		Facial paralysis	1	1	6	3	1	1	6	3	11	11
		Facial paresis	1	0	0	1	1	0	0	1	2	2
	Generalised tonic-clonic seizures	*Subtotal*	*0*	*0*	*2*	*1*	*0*	*0*	*2*	*2*	*3*	*4*
		Generalised tonic-clonic seizure	0	0	2	1	0	0	2	2	3	4
	Headaches NEC	*Subtotal*	*275*	*295*	*61*	*54*	*290*	*296*	*48*	*54*	*685*	*688*
		Headache	275	295	61	54	290	296	48	54	685	688
	Increased intracranial pressure disorders	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Idiopathic intracranial hypertension	0	0	0	1	0	0	0	1	1	1
	Memory loss (excl dementia)	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Memory impairment	1	0	1	0	1	0	1	0	2	2
	Mental impairment (excl dementia and memory loss)	*Subtotal*	*3*	*1*	*5*	*2*	*3*	*1*	*5*	*2*	*11*	*11*
		Cognitive disorder	0	0	1	0	0	0	1	0	1	1
		Disturbance in attention	3	1	4	2	3	1	4	2	10	10
	Migraine headaches	*Subtotal*	*4*	*5*	*1*	*6*	*4*	*5*	*2*	*6*	*16*	*17*
		Hemiplegic migraine	0	0	1	1	0	0	1	1	2	2
		Migraine	4	4	1	2	4	4	1	2	11	11
		Migraine with aura	0	1	0	2	0	1	0	2	3	3
		Status migrainosus	0	0	0	1	0	0	0	1	1	1
	Muscle tone abnormal	*Subtotal*	*1*	*4*	*2*	*2*	*1*	*4*	*2*	*2*	*9*	*9*
		Hypertonia	0	0	1	2	0	0	1	2	3	3
		Hypotonia	1	4	1	0	1	4	1	0	6	6
	Narcolepsy and hypersomnia	*Subtotal*	*1*	*1*	*2*	*1*	*1*	*1*	*2*	*1*	*5*	*5*
		Hypersomnia	1	1	2	1	1	1	2	1	5	5
	Nervous system disorders NEC	*Subtotal*	*1*	*0*	*3*	*0*	*1*	*0*	*3*	*0*	*4*	*4*
		Nervous system disorder	0	0	3	0	0	0	3	0	3	3
		Psychomotor skills impaired	1	0	0	0	1	0	0	0	1	1
	Neurological signs and symptoms NEC	*Subtotal*	*124*	*58*	*46*	*16*	*146*	*62*	*29*	*15*	*244*	*252*
		Clonus	0	0	0	1	0	0	0	1	1	1
		Dizziness	92	49	29	12	102	51	21	10	182	184
		Dizziness postural	1	1	0	0	1	1	0	0	2	2
		Head discomfort	0	1	0	0	0	1	0	0	1	1
		Presyncope	34	9	16	4	43	9	7	4	63	63
		Unresponsive to stimuli	0	0	1	0	0	0	1	0	1	1
	Neuromuscular disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Hypotonic-hyporesponsive episode	0	0	0	1	0	0	0	1	1	1
	Neuromuscular junction dysfunction	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Myasthenia gravis crisis	1	0	0	0	1	0	0	0	1	1
	Olfactory nerve disorders	*Subtotal*	*6*	*1*	*2*	*0*	*6*	*1*	*2*	*0*	*9*	*9*
		Anosmia	5	0	1	0	5	0	1	0	6	6
		Parosmia	1	1	1	0	1	1	1	0	3	3
	Optic nerve disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Optic neuritis	0	0	0	1	0	0	0	1	1	1
	Paraesthesias and dysaesthesias	*Subtotal*	*34*	*11*	*20*	*8*	*43*	*13*	*20*	*8*	*73*	*84*
		Burning sensation	1	0	1	2	1	0	1	2	4	4
		Dysaesthesia	1	0	1	0	1	0	1	0	2	2
		Formication	0	0	1	0	0	0	1	0	1	1
		Hemihypoaesthesia	0	0	0	1	0	0	0	1	1	1
		Hyperaesthesia	2	1	1	0	2	1	1	0	4	4

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Hypoaesthesia	22	6	10	2	24	6	9	2	40	41
		Paraesthesia	14	5	8	4	15	6	7	3	31	31
	Paralysis and paresis (excl cranial nerve)	*Subtotal*	*0*	*0*	*2*	*2*	*0*	*0*	*2*	*2*	*4*	*4*
		Hemiparesis	0	0	1	1	0	0	1	1	2	2
		Monoplegia	0	0	1	0	0	0	1	0	1	1
		Paralysis	0	0	0	1	0	0	0	1	1	1
	Partial simple seizures NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Simple partial seizures	0	0	1	0	0	0	1	0	1	1
	Peripheral neuropathies NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Neuropathy peripheral	0	0	1	0	0	0	1	0	1	1
	Seizures and seizure disorders NEC	*Subtotal*	*2*	*7*	*20*	*16*	*2*	*7*	*20*	*16*	*45*	*45*
		Change in seizure presentation	0	0	1	0	0	0	1	0	1	1
		Clonic convulsion	0	0	2	0	0	0	2	0	2	2
		Epilepsy	0	1	3	2	0	1	3	2	6	6
		Febrile convulsion	0	1	1	1	0	1	1	1	3	3
		Partial seizures	0	0	0	1	0	0	0	1	1	1
		Seizure	2	5	12	11	2	5	12	11	30	30
		Status epilepticus	0	0	0	1	0	0	0	1	1	1
		Tonic convulsion	0	0	1	0	0	0	1	0	1	1
	Sensory abnormalities NEC	*Subtotal*	*7*	*5*	*3*	*3*	*8*	*5*	*2*	*3*	*18*	*18*
		Ageusia	4	1	2	0	5	1	1	0	7	7
		Dysgeusia	0	1	0	0	0	1	0	0	1	1
		Electric shock sensation	1	0	0	0	1	0	0	0	1	1
		Hypogeusia	1	0	0	0	1	0	0	0	1	1
		Intercostal neuralgia	0	0	0	1	0	0	0	1	1	1
		Neuralgia	0	2	0	0	0	2	0	0	2	2
		Restless legs syndrome	0	0	0	1	0	0	0	1	1	1
		Sensory disturbance	0	0	0	1	0	0	0	1	1	1
		Taste disorder	1	1	1	0	1	1	1	0	3	3
	Sleep disturbances NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Sudden onset of sleep	1	0	0	0	1	0	0	0	1	1
	Speech and language abnormalities	*Subtotal*	*4*	*0*	*1*	*1*	*4*	*0*	*1*	*1*	*6*	*6*
		Dysarthria	2	0	0	0	2	0	0	0	2	2
		Language disorder	1	0	0	1	1	0	0	1	2	2
		Slow speech	0	0	1	0	0	0	1	0	1	1
		Speech disorder	1	0	0	0	1	0	0	0	1	1
	Structural brain disorders NEC	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Brain injury	0	0	1	0	0	0	1	0	1	1
		Cerebral ventricular rupture	0	0	1	0	0	0	1	0	1	1
	Tremor (excl congenital)	*Subtotal*	*5*	*8*	*4*	*7*	*7*	*8*	*3*	*7*	*24*	*25*
		Intention tremor	0	0	1	0	0	0	1	0	1	1
		Resting tremor	0	0	1	0	0	0	1	0	1	1
		Tremor	5	8	3	7	7	8	1	7	23	23
Pregnancy, puerperium and perinatal conditions	*Subtotal*	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
	Abortions spontaneous	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Abortion spontaneous	0	0	1	0	0	0	1	0	1	1
Product issues	*Subtotal*	*Subtotal*	*5*	*8*	*0*	*0*	*6*	*8*	*0*	*0*	*13*	*14*
	Device issues NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Device connection issue	1	0	0	0	1	0	0	0	1	1
	Device physical property and chemical issues	*Subtotal*	*1*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*1*	*2*
		Needle issue	1	0	0	0	1	0	0	0	1	1
		Syringe issue	1	0	0	0	1	0	0	0	1	1
	Product distribution and storage issues	*Subtotal*	*2*	*8*	*0*	*0*	*2*	*8*	*0*	*0*	*10*	*10*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Inappropriate release of product for distribution	1	0	0	0	1	0	0	0	1	1
		Product temperature excursion issue	1	8	0	0	1	8	0	0	9	9
	Product quality issues NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Product substitution issue	1	0	0	0	1	0	0	0	1	1
Psychiatric disorders	*Subtotal*	*Subtotal*	*25*	*27*	*15*	*11*	*30*	*32*	*15*	*14*	*78*	*91*
	Abnormal behaviour NEC	*Subtotal*	*1*	*0*	*3*	*1*	*2*	*0*	*2*	*1*	*5*	*5*
		Abnormal behaviour	0	0	1	0	1	0	0	0	1	1
		Behaviour disorder	1	0	0	0	1	0	0	0	1	1
		Staring	0	0	2	1	0	0	2	1	3	3
	Affect alterations NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Affect lability	0	0	1	0	0	0	1	0	1	1
	Anxiety symptoms	*Subtotal*	*5*	*17*	*2*	*2*	*5*	*17*	*2*	*2*	*26*	*26*
		Agitation	0	0	0	2	0	0	0	2	2	2
		Anxiety	3	15	1	0	3	15	1	0	19	19
		Immunisation stress-related response	0	2	0	0	0	2	0	0	2	2
		Nervousness	2	0	0	0	2	0	0	0	2	2
		Stress	0	0	1	0	0	0	1	0	1	1
	Confusion and disorientation	*Subtotal*	*4*	*3*	*2*	*4*	*4*	*3*	*2*	*4*	*13*	*13*
		Confusional state	4	3	2	4	4	3	2	4	13	13
	Deliria	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Delirium	0	0	1	0	0	0	1	0	1	1
	Delusional disorders	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Alice in wonderland syndrome	0	0	1	0	1	0	0	0	1	1
	Depressive disorders	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Depression	0	0	0	1	0	0	0	1	1	1
	Disturbances in initiating and maintaining sleep	*Subtotal*	*4*	*3*	*0*	*0*	*4*	*4*	*0*	*0*	*7*	*8*
		Initial insomnia	1	1	0	0	1	1	0	0	2	2
		Insomnia	2	3	0	0	2	3	0	0	5	5
		Middle insomnia	1	0	0	0	1	0	0	0	1	1
	Dyssomnias	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Poor quality sleep	1	0	1	0	1	0	1	0	2	2
	Emotional and mood disturbances NEC	*Subtotal*	*4*	*1*	*0*	*1*	*5*	*1*	*0*	*1*	*6*	*7*
		Dysphoria	2	0	0	0	3	0	0	0	2	3
		Emotional distress	1	0	0	0	1	0	0	0	1	1
		Irritability	1	1	0	1	1	1	0	1	3	3
	Fear symptoms and phobic disorders (incl social phobia)	*Subtotal*	*0*	*2*	*0*	*2*	*0*	*2*	*0*	*3*	*4*	*5*
		Aerophobia	0	0	0	1	0	0	0	1	1	1
		Fear	0	1	0	0	0	1	0	0	1	1
		Hydrophobia	0	0	0	1	0	0	0	1	1	1
		Phonophobia	0	1	0	1	0	1	0	1	2	2
	Fluctuating mood symptoms	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Mood swings	1	0	0	0	1	0	0	0	1	1
	Hallucinations (excl sleep-related)	*Subtotal*	*0*	*1*	*1*	*0*	*0*	*2*	*1*	*0*	*2*	*3*
		Hallucination	0	0	1	0	0	0	1	0	1	1
		Hallucination, auditory	0	1	0	0	0	1	0	0	1	1
		Hallucination, visual	0	1	0	0	0	1	0	0	1	1
	Increased physical activity levels	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Restlessness	0	1	0	0	0	1	0	0	1	1
	Mood disorders NEC	*Subtotal*	*0*	*1*	*1*	*0*	*1*	*1*	*0*	*0*	*2*	*2*
		Apathy	0	1	0	0	0	1	0	0	1	1
		Listless	0	0	1	0	1	0	0	0	1	1
	Panic attacks and disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Panic reaction	0	0	1	0	0	0	1	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
	Parasomnias	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Sleep terror	1	0	0	0	1	0	0	0	1	1
		Somnambulism	0	0	1	0	0	0	1	0	1	1
	Perception disturbances NEC	*Subtotal*	*0*	*0*	*1*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Jamais vu	0	0	1	0	1	0	0	0	1	1
	Psychiatric symptoms NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Psychiatric symptom	0	0	1	0	0	0	1	0	1	1
	Sleep disorders NEC	*Subtotal*	*3*	*0*	*0*	*0*	*3*	*0*	*0*	*0*	*3*	*3*
		Sleep disorder	3	0	0	0	3	0	0	0	3	3
	Somatic symptom disorders	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Conversion disorder	0	0	1	0	0	0	1	0	1	1
	Suicidal and self-injurious behaviour	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Suicide attempt	0	0	0	1	0	0	0	1	1	1
	Thinking disturbances	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Thinking abnormal	1	0	0	0	1	0	0	0	1	1
	Tic disorders	*Subtotal*	*0*	*1*	*1*	*1*	*0*	*1*	*1*	*1*	*3*	*3*
		Tic	0	1	1	1	0	1	1	1	3	3
Renal and urinary disorders	*Subtotal*	*Subtotal*	*4*	*3*	*8*	*6*	*5*	*4*	*13*	*8*	*21*	*30*
	Bladder and urethral symptoms	*Subtotal*	*3*	*2*	*4*	*1*	*4*	*2*	*4*	*1*	*10*	*11*
		Dysuria	2	2	1	0	2	2	1	0	5	5
		Incontinence	0	0	1	0	0	0	1	0	1	1
		Micturition urgency	0	0	0	1	0	0	0	1	1	1
		Pollakiuria	0	0	1	0	0	0	1	0	1	1
		Urinary incontinence	0	0	2	0	1	0	1	0	2	2
		Urinary retention	1	0	0	0	1	0	0	0	1	1
	Glomerulonephritis and nephrotic syndrome	*Subtotal*	*0*	*1*	*1*	*4*	*0*	*1*	*2*	*4*	*6*	*7*
		Glomerulonephritis	0	0	0	2	0	0	0	2	2	2
		IgA nephropathy	0	0	1	1	0	0	1	1	2	2
		Nephrotic syndrome	0	1	0	1	0	1	0	1	2	2
		Post infection glomerulonephritis	0	0	1	0	0	0	1	0	1	1
	Renal failure and impairment	*Subtotal*	*0*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*2*	*2*
		Acute kidney injury	0	0	1	1	0	0	1	1	2	2
	Urinary abnormalities	*Subtotal*	*1*	*0*	*4*	*2*	*1*	*1*	*5*	*2*	*7*	*9*
		Chromaturia	1	0	0	0	1	0	0	0	1	1
		Haematuria	0	0	3	2	0	1	3	1	5	5
		Myoglobinuria	0	0	1	0	0	0	1	0	1	1
		Proteinuria	0	0	1	1	0	0	1	1	2	2
	Urinary tract signs and symptoms NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Renal pain	0	0	1	0	0	0	1	0	1	1
Reproductive system and breast disorders	*Subtotal*	*Subtotal*	*57*	*56*	*6*	*6*	*91*	*92*	*5*	*11*	*125*	*199*
	Breast disorders NEC	*Subtotal*	*2*	*1*	*0*	*0*	*2*	*1*	*0*	*0*	*3*	*3*
		Breast mass	1	0	0	0	1	0	0	0	1	1
		Gynaecomastia	1	1	0	0	1	1	0	0	2	2
	Breast infections and inflammations	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Breast inflammation	1	0	0	0	1	0	0	0	1	1
	Breast signs and symptoms	*Subtotal*	*4*	*1*	*0*	*0*	*4*	*1*	*0*	*0*	*5*	*5*
		Breast engorgement	0	1	0	0	0	1	0	0	1	1
		Breast pain	1	0	0	0	1	0	0	0	1	1
		Breast swelling	1	0	0	0	1	0	0	0	1	1
		Breast tenderness	1	0	0	0	1	0	0	0	1	1
		Nipple pain	1	0	0	0	1	0	0	0	1	1
	Menstruation and uterine bleeding NEC	*Subtotal*	*29*	*29*	*3*	*4*	*41*	*41*	*2*	*7*	*65*	*91*
		Dysmenorrhoea	4	8	0	0	4	8	0	0	12	12

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Intermenstrual bleeding	6	4	1	1	8	5	0	0	12	13
		Menstrual discomfort	0	1	0	0	0	1	0	0	1	1
		Menstrual disorder	18	10	1	3	20	12	1	5	32	38
		Menstruation irregular	9	15	1	2	9	15	1	2	27	27
	Menstruation with decreased bleeding	*Subtotal*	*17*	*24*	*0*	*2*	*17*	*25*	*0*	*2*	*43*	*44*
		Amenorrhoea	9	14	0	2	9	14	0	2	25	25
		Hypomenorrhoea	0	4	0	0	0	4	0	0	4	4
		Menstruation delayed	3	5	0	0	3	5	0	0	8	8
		Oligomenorrhoea	5	2	0	0	5	2	0	0	7	7
	Menstruation with increased bleeding	*Subtotal*	*16*	*18*	*1*	*2*	*20*	*22*	*0*	*2*	*37*	*44*
		Heavy menstrual bleeding	12	14	1	2	13	16	0	2	29	31
		Menometrorrhagia	0	1	0	0	0	1	0	0	1	1
		Polymenorrhoea	7	5	0	0	7	5	0	0	12	12
	Ovarian and fallopian tube cysts and neoplasms	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Ovarian cyst	1	0	0	0	1	0	0	0	1	1
	Penile disorders NEC (excl erection and ejaculation)	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Penile pain	1	0	0	0	1	0	0	0	1	1
	Reproductive tract disorders NEC (excl neoplasms)	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Genital ulceration	1	0	1	0	1	0	1	0	2	2
	Reproductive tract signs and symptoms NEC	*Subtotal*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*2*	*2*
		Pelvic pain	0	2	0	0	0	2	0	0	2	2
	Scrotal disorders NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Varicocele	0	0	1	0	0	0	1	0	1	1
	Testicular and epididymal disorders NEC	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Testicular pain	0	0	1	0	0	0	1	0	1	1
	Vulvovaginal disorders NEC	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Vaginal haemorrhage	2	0	0	0	2	0	0	0	2	2
	Vulvovaginal signs and symptoms	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Vaginal discharge	1	0	0	0	1	0	0	0	1	1
Respiratory, thoracic and mediastinal disorders	*Subtotal*	*Subtotal*	*86*	*68*	*51*	*29*	*123*	*80*	*55*	*35*	*234*	*293*
	Breathing abnormalities	*Subtotal*	*36*	*34*	*35*	*16*	*43*	*35*	*29*	*17*	*121*	*124*
		Dyspnoea	30	33	34	15	37	33	27	16	112	113
		Hyperventilation	6	0	1	0	6	0	1	0	7	7
		Respiration abnormal	0	0	0	1	0	0	0	1	1	1
		Respiratory distress	0	0	1	0	0	0	1	0	1	1
		Respiratory fatigue	0	2	0	0	0	2	0	0	2	2
	Bronchospasm and obstruction	*Subtotal*	*4*	*3*	*5*	*5*	*5*	*3*	*4*	*5*	*17*	*17*
		Asthma	1	0	2	2	2	0	1	2	5	5
		Asthmatic crisis	0	0	1	1	0	0	1	1	2	2
		Bronchospasm	1	2	0	1	1	2	0	1	4	4
		Wheezing	2	1	2	1	2	1	2	1	6	6
	Coughing and associated symptoms	*Subtotal*	*14*	*16*	*6*	*4*	*15*	*17*	*6*	*4*	*40*	*42*
		Cough	14	16	5	4	15	17	4	3	39	39
		Haemoptysis	0	0	1	1	0	0	1	1	2	2
		Productive cough	0	0	1	0	0	0	1	0	1	1
	Laryngeal spasm, oedema and obstruction	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Laryngeal oedema	0	1	0	0	0	1	0	0	1	1
	Lower respiratory tract signs and symptoms	*Subtotal*	*1*	*0*	*1*	*1*	*1*	*0*	*1*	*1*	*3*	*3*
		Hiccups	0	0	0	1	0	0	0	1	1	1
		Pulmonary pain	1	0	1	0	1	0	1	0	2	2
	Nasal congestion and inflammations	*Subtotal*	*3*	*2*	*2*	*0*	*4*	*2*	*1*	*0*	*7*	*7*
		Nasal congestion	3	2	2	0	4	2	1	0	7	7
	Nasal disorders NEC	*Subtotal*	*11*	*4*	*2*	*3*	*12*	*4*	*1*	*3*	*20*	*20*

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Epistaxis	10	4	2	3	11	4	1	3	19	19
		Nasal oedema	1	0	0	0	1	0	0	0	1	1
	Pharyngeal disorders (excl infections and neoplasms)	*Subtotal*	*1*	*1*	*1*	*0*	*1*	*1*	*1*	*0*	*3*	*3*
		Pharyngeal oedema	0	1	0	0	0	1	0	0	1	1
		Pharyngeal swelling	1	0	1	0	1	0	1	0	2	2
	Pulmonary oedemas	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Pulmonary congestion	0	0	1	0	0	0	1	0	1	1
	Pulmonary thrombotic and embolic conditions	*Subtotal*	*0*	*1*	*1*	*2*	*0*	*1*	*1*	*2*	*4*	*4*
		Pulmonary embolism	0	1	1	2	0	1	1	2	4	4
	Respiratory signs and symptoms NEC	*Subtotal*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*2*	*2*
		Painful respiration	0	1	1	0	0	1	1	0	2	2
	Respiratory tract disorders NEC	*Subtotal*	*0*	*0*	*3*	*0*	*1*	*0*	*2*	*0*	*3*	*3*
		Lung disorder	0	0	1	0	1	0	0	0	1	1
		Respiratory disorder	0	0	1	0	0	0	1	0	1	1
		Respiratory tract oedema	0	0	1	0	0	0	1	0	1	1
	Upper respiratory tract signs and symptoms	*Subtotal*	*31*	*14*	*9*	*2*	*41*	*15*	*7*	*3*	*56*	*66*
		Dysphonia	2	1	0	0	2	1	0	0	3	3
		Increased viscosity of upper respiratory secretion	0	1	0	0	0	1	0	0	1	1
		Nasal discomfort	0	1	0	0	0	1	0	0	1	1
		Oropharyngeal discomfort	1	0	1	0	1	0	1	0	2	2
		Oropharyngeal pain	22	10	7	1	25	10	5	1	40	41
		Rhinorrhoea	8	1	1	0	9	1	0	0	10	10
		Sneezing	1	0	1	0	2	0	0	0	2	2
		Throat irritation	2	1	0	1	2	1	0	2	4	5
		Throat tightness	0	0	1	0	0	0	1	0	1	1
Skin and subcutaneous tissue disorders	*Subtotal*	*Subtotal*	*167*	*157*	*48*	*28*	*218*	*187*	*47*	*33*	*400*	*485*
	Alopecias	*Subtotal*	*2*	*3*	*0*	*0*	*2*	*4*	*0*	*0*	*5*	*6*
		Alopecia	1	2	0	0	1	2	0	0	3	3
		Alopecia areata	1	2	0	0	1	2	0	0	3	3
	Angioedemas	*Subtotal*	*1*	*0*	*7*	*3*	*1*	*0*	*7*	*3*	*11*	*11*
		Angioedema	0	0	7	2	0	0	7	2	9	9
		Circumoral swelling	1	0	0	1	1	0	0	1	2	2
	Apocrine and eccrine gland disorders	*Subtotal*	*12*	*5*	*6*	*2*	*14*	*5*	*4*	*2*	*25*	*25*
		Cold sweat	3	4	3	0	5	4	1	0	10	10
		Hyperhidrosis	9	1	2	0	9	1	2	0	12	12
		Night sweats	0	0	1	2	0	0	1	2	3	3
	Bullous conditions	*Subtotal*	*4*	*4*	*8*	*1*	*4*	*4*	*8*	*1*	*17*	*17*
		Blister	3	1	0	0	3	1	0	0	4	4
		Dermatitis bullous	0	0	1	0	0	0	1	0	1	1
		Erythema multiforme	1	3	6	1	1	3	6	1	11	11
		SJS-TEN overlap	0	0	1	0	0	0	1	0	1	1
	Dermal and epidermal conditions NEC	*Subtotal*	*16*	*2*	*1*	*1*	*16*	*2*	*1*	*1*	*20*	*20*
		Pain of skin	4	0	0	0	4	0	0	0	4	4
		Papule	1	0	0	0	1	0	0	0	1	1
		Skin burning sensation	2	0	1	0	2	0	1	0	3	3
		Skin discolouration	1	0	0	0	1	0	0	0	1	1
		Skin disorder	1	1	0	0	1	1	0	0	2	2
		Skin reaction	6	1	0	1	6	1	0	1	8	8
		Skin warm	1	0	0	0	1	0	0	0	1	1
	Dermatitis and eczema	*Subtotal*	*6*	*3*	*0*	*1*	*6*	*3*	*0*	*1*	*10*	*10*
		Dermatitis	2	1	0	0	2	1	0	0	3	3
		Dermatitis allergic	2	0	0	1	2	0	0	1	3	3
		Dermatitis atopic	1	0	0	0	1	0	0	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
		Eczema	1	0	0	0	1	0	0	0	1	1
		Neurodermatitis	0	1	0	0	0	1	0	0	1	1
		Skin irritation	0	1	0	0	0	1	0	0	1	1
	Dermatitis ascribed to specific agent	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Drug eruption	0	0	1	0	0	0	1	0	1	1
	Erythemas	*Subtotal*	*29*	*61*	*5*	*4*	*30*	*62*	*5*	*3*	*99*	*100*
		Erythema	29	61	5	4	30	62	5	3	99	100
	Exfoliative conditions	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Skin exfoliation	1	0	0	0	1	0	0	0	1	1
	Granulomatous and deep cutaneous inflammatory conditions	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Granuloma annulare	0	0	1	0	0	0	1	0	1	1
	Panniculitides	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Erythema nodosum	0	0	1	0	0	0	1	0	1	1
	Papulosquamous conditions	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Pityriasis rosea	1	0	0	0	1	0	0	0	1	1
	Photosensitivity and photodermatosis conditions	*Subtotal*	*2*	*0*	*0*	*1*	*2*	*0*	*0*	*1*	*3*	*3*
		Photosensitivity reaction	2	0	0	1	2	0	0	1	3	3
	Pruritus NEC	*Subtotal*	*24*	*22*	*3*	*2*	*25*	*23*	*2*	*1*	*51*	*51*
		Pruritus	24	22	3	2	25	23	2	1	51	51
	Psoriatic conditions	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Psoriasis	0	1	0	0	0	1	0	0	1	1
	Purpura and related conditions	*Subtotal*	*0*	*1*	*2*	*3*	*0*	*1*	*2*	*3*	*6*	*6*
		Ecchymosis	0	1	0	0	0	1	0	0	1	1
		Henoch-Schonlein purpura	0	0	2	1	0	0	2	1	3	3
		Petechiae	0	0	0	2	0	0	0	2	2	2
	Rashes, eruptions and exanthems NEC	*Subtotal*	*73*	*60*	*9*	*9*	*80*	*61*	*7*	*9*	*151*	*157*
		Nodular rash	0	0	1	0	0	0	1	0	1	1
		Rash	55	47	7	8	61	47	5	8	117	121
		Rash erythematous	4	0	0	0	4	0	0	0	4	4
		Rash macular	0	3	1	0	0	3	1	0	4	4
		Rash maculo-papular	5	4	0	0	5	4	0	0	9	9
		Rash papular	3	2	0	0	3	2	0	0	5	5
		Rash pruritic	6	3	0	1	6	3	0	1	10	10
		Rash scarlatiniform	1	0	0	0	1	0	0	0	1	1
		Rash vesicular	0	2	0	0	0	2	0	0	2	2
	Skin and subcutaneous tissue ulcerations	*Subtotal*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*1*	*1*
		Skin ulcer	0	0	1	0	0	0	1	0	1	1
	Skin cysts and polyps	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Dermal cyst	0	1	0	0	0	1	0	0	1	1
	Skin vasculitides	*Subtotal*	*0*	*0*	*2*	*1*	*0*	*0*	*2*	*1*	*3*	*3*
		Cutaneous vasculitis	0	0	1	1	0	0	1	1	2	2
		Hypersensitivity vasculitis	0	0	1	0	0	0	1	0	1	1
	Skin vasomotor conditions	*Subtotal*	*1*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	*2*	*2*
		Livedo reticularis	1	0	1	0	1	0	1	0	2	2
	Urticarias	*Subtotal*	*31*	*19*	*6*	*7*	*35*	*20*	*4*	*7*	*63*	*66*
		Mechanical urticaria	1	0	0	0	1	0	0	0	1	1
		Solar urticaria	1	0	0	0	1	0	0	0	1	1
		Urticaria	30	19	6	7	33	20	4	7	62	64
Social circumstances	*Subtotal*	*Subtotal*	*5*	*2*	*2*	*0*	*5*	*3*	*2*	*0*	*9*	*10*
	Disability issues	*Subtotal*	*5*	*1*	*1*	*0*	*5*	*1*	*1*	*0*	*7*	*7*
		Bedridden	1	0	0	0	1	0	0	0	1	1
		Impaired work ability	4	0	1	0	4	0	1	0	5	5
		Loss of personal independence in daily activities	0	1	0	0	0	1	0	0	1	1

SOC	HLT	PT	# Cases				# Events				Cases Grand Total	Events Grand Total
			Non Serious		Serious		Non Serious		Serious			
			Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period	Prior to Review Period	Review Period		
	Employment issues	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Sick leave	0	1	0	0	0	1	0	0	1	1
	Social issues NEC	*Subtotal*	*0*	*1*	*1*	*0*	*0*	*1*	*1*	*0*	*2*	*2*
		Impaired quality of life	0	1	0	0	0	1	0	0	1	1
		Patient uncooperative	0	0	1	0	0	0	1	0	1	1
Surgical and medical procedures	*Subtotal*	*Subtotal*	*61*	*6*	*8*	*3*	*64*	*6*	*5*	*3*	*78*	*78*
	Immunisations	*Subtotal*	*8*	*5*	*6*	*3*	*9*	*5*	*5*	*3*	*22*	*22*
		COVID-19 immunisation	8	5	6	3	9	5	5	3	22	22
	Therapeutic procedures NEC	*Subtotal*	*53*	*1*	*2*	*0*	*55*	*1*	*0*	*0*	*56*	*56*
		Interchange of vaccine products	53	1	2	0	55	1	0	0	56	56
Vascular disorders	*Subtotal*	*Subtotal*	*27*	*21*	*18*	*8*	*35*	*22*	*14*	*8*	*74*	*79*
	Blood pressure disorders NEC	*Subtotal*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*	*1*
		Blood pressure fluctuation	0	0	0	1	0	0	0	1	1	1
	Circulatory collapse and shock	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Circulatory collapse	0	0	1	0	0	0	1	0	1	1
		Peripheral circulatory failure	0	0	1	0	0	0	1	0	1	1
	Haemorrhages NEC	*Subtotal*	*1*	*3*	*1*	*1*	*1*	*3*	*1*	*1*	*6*	*6*
		Haematoma	1	3	1	1	1	3	1	1	6	6
	Non-site specific embolism and thrombosis	*Subtotal*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*0*	*2*	*2*
		Thrombosis	0	0	2	0	0	0	2	0	2	2
	Non-site specific vascular disorders NEC	*Subtotal*	*2*	*0*	*0*	*0*	*2*	*0*	*0*	*0*	*2*	*2*
		Capillary fragility	1	0	0	0	1	0	0	0	1	1
		Hyperaemia	1	0	0	0	1	0	0	0	1	1
	Peripheral embolism and thrombosis	*Subtotal*	*1*	*0*	*3*	*1*	*2*	*0*	*2*	*1*	*5*	*5*
		Pelvic venous thrombosis	0	0	0	1	0	0	0	1	1	1
		Superficial vein thrombosis	1	0	2	0	2	0	1	0	3	3
		Venous thrombosis limb	0	0	1	0	0	0	1	0	1	1
	Peripheral vascular disorders NEC	*Subtotal*	*7*	*6*	*1*	*1*	*7*	*6*	*1*	*1*	*15*	*15*
		Cyanosis	0	1	1	1	0	1	1	1	3	3
		Flushing	5	1	0	0	5	1	0	0	6	6
		Hot flush	2	3	0	0	2	3	0	0	5	5
		Peripheral vascular disorder	0	1	0	0	0	1	0	0	1	1
	Peripheral vasoconstriction, necrosis and vascular insufficiency	*Subtotal*	*1*	*4*	*1*	*1*	*1*	*4*	*1*	*1*	*7*	*7*
		Peripheral coldness	1	2	1	0	1	2	1	0	4	4
		Raynaud's phenomenon	0	2	0	1	0	2	0	1	3	3
	Site specific vascular disorders NEC	*Subtotal*	*10*	*5*	*8*	*2*	*16*	*5*	*4*	*2*	*25*	*27*
		Pallor	10	5	8	2	16	5	4	2	25	27
	Vascular hypertensive disorders NEC	*Subtotal*	*0*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	*1*
		Hypertension	0	1	0	0	0	1	0	0	1	1
	Vascular hypotensive disorders	*Subtotal*	*5*	*3*	*1*	*1*	*5*	*3*	*1*	*1*	*10*	*10*
		Hypotension	5	3	1	1	5	3	1	1	10	10
	Vasculitides NEC	*Subtotal*	*1*	*0*	*0*	*0*	*1*	*0*	*0*	*0*	*1*	*1*
		Vasculitis	1	0	0	0	1	0	0	0	1	1
Grand total			5,386	1,257	436	264	8,939	3,454	1,081	722	7,343	14,196

Appendix 12 Literature search strategies

12.1a Complete global literature search strategy

A literature search was performed in two major literature databases (EMBASE® and MEDLINE®) covering the period from 01 Jan 2022 to 18 Jun 2022. The literature search was completed in three parts.

Part one search related to the product (elasomeran/ or 2019-nCoV Vaccine mRNA-1273/ or (mRNA-1273 or "mRNA 1273" or mRNA1273 or "modernatx 1273" or "modernatx-1273" or "moderntx 1273" or "moderntx-1273" or m-1273 or "m 1273" or "Moderna Covid19 Vaccine" or "Moderna Covid-19 Vaccine" or "Moderna-Covid-19-Vaccine" or "Moderna Covid 19 Vaccine" or SPIKEVAX or Spike-vax or Elasomeran or "CX-024414" or "TAK-919" or "TAK 919" or TAK919) covered the active ingredient (messenger RNA) and included scientific literature available from conferences, non-clinical and clinical studies, and poster sessions.

Part two search covered all literature abstracts for the drug class (mRNA vaccine, SARS CoV-2 vaccine). The search covered an elaborate compilation of free text search terms which included numerous synonymous expressions and abbreviations.

Part three search covered multiple adverse event and therapeutic use terms including: (abnormal* or abortion* or abus* or acral or acroischemia or acute coronary syndrome* or acute disseminated encephalomyelitis or acute kidney injury or acute respiratory distress or adem or adr or adrs or adverse or adverse drug reaction or ageusia or agranulocyt* or allerg* or alopecia or amnionitis or anaemi* or anaphylact* or anaphylax* or anemi* or aneurysm* or angioedema or anomal* or anosmia or antenatal bleeding or "antibody-dependent" or antiphospholipid syndrome or antiphospholipid* or anxiety or aplas* or appendicitis or ARDS or arrhythm* or arthritis or aseptic meningitis or aspergillosis or asthma or asystole or ataxia or atrial fibrillation or atrial flutter or auto immun* or autoimmun* or autoimmune haemolytic anaemia or autoimmune haemolytic anemia or autops* or AV block or atypical ARDS or azotaemia or azotemia or Bell palsy or "Bell's palsy" or birth defect* or blind* or bone marrow failure or bradyarrhythmia* or bradycardia or brain involvement or breast feed* or breast milk or breastfed or breastfeed* or bullae or bullous or bundle branch block or carcinogen* or cardiac arrest or cardiac biopsy or cardiac injury or cardiac tamponade or cardiogenic or cardiogenic shock or cardiomegaly or cardiomyopathy or cardio vascular or cardiotox* or cardiovascular or case report* or case series or cataplexy or causal or cerebellitiis or cerebrovascular or cerebrovascular accident or "chickenpox-like" or Chilblain* or Chilblain like lesions or child* or chorioamnionitis or chronic fatigue syndrome or chronic hepatitis or chronic inflammat* or chronic liver disease or chronic neurological disease or chronic obstructive pulmonary disease or class effect or clinical pathological or clinicopathological or coagulopathy or coccidioidomycosis or coma or comatose or compassion* or complement activation or complement mediated or complication* or confusion* or congenital or contraindicat*

or convuls* or COPD or cor pulmonale or cranial nerve or Crohn* or cutaneous or cytokine release syndrome or cytokine storm or cytokine storm syndrome or cytotox* or deaf* or death* or deep vein thrombosis or dermatitis exfoliative* or dermatitis* or developmental delay or diabet* or DIC or diminished effect or disability or disabl* or disseminated intravascular coagulation or DRESS or drug diversion or drug eruption* or drug induced or "drug reaction with eosinophilia and systemic symptoms" or drug related or drug resistance or DVT or dysfunction or dysphagia or dysrhythmia* or effective* or efficacious* or efficacy or elder* or elevated creatinine kinase or embol* or emboli* or embryo or encephalit* or encephalomyelitis or encephalopathy or endometri* or endomyocardial biopsy or endothelial dysfunction or endotheliitis or epilep* or error* or erythema multiforme or erythema nodosum or erythroderma or event* or exanthem* or expanded access or expos* or facial paralysis or failure or "failure to thrive" or fatal* or fertility or fetal or fetus* or fibrillation or fibromyalgia or first case or focal deficit or foet* or follicular conjunctivitis or frail* or full term birth or fulminant or funisitis or gangrene or GBS or geriatric* or gestational diabetes or granulocytopen* or gravis or growth retardation or Guillain* or Guillain-Barre Syndrome or gustatory or haemoly* or haemolytic or haemolytic anaemia or haemophagocytic lymphohistiocytosis or haemorrhag* or harm* or hashimoto or heart failure or HELLP or hematochezia or hemolytic or hemophagocytic lymphohistiocytosis or hemorrhag* or hemostasis disorder* or hepat* or hepatotox* or hypercoagulability or hyperferritinaemi* or hyperferritinemi* or hyperinflammat* or hypersensitiv* or hypogeusia or hyponatremia or hyposmia or iatrogen* or idiopathic thrombocytopenic purpura or ileitis or immuno compromis* or immuno suppress* or immunocompromis* or immunocytotox* or immunopatholog* or immunosuppress* or immunotox* or in utero or incomplete abortion or induced or ineffective* or infan* or infarct* or infertil* or inflammat* or inflammatory bowel disease* or inflammatory bowel syndrome* or inflammatory multisystem syndrome or injection site* or injur* or interact* or intestinal perforation or intolerab* or intoleran* or intoxicat* or intrauterine infection or ischemia or ischemic or IBD or ITP or Kawasaki* or keratoconjunctivitis or kidney or Kounis syndrome or "lack of effect" or "lack of effectiveness" or "lack of efficacy" or "lack of response" or lactat* or lethal or leukoencephalopathy or livedo or livedoid or liver injur* or liver transplant* or lupus* or lupus anticoagulant or macrophage activation syndrome or macule* or macular or maculopapular or maladminist* or manifestation* or maternal or maternal morbidity or "maternal-fetal" or mediastinum or meningit* or meningoencephalitis or meningomyelitis or microangiopathy or micro angiopathy or microhaemorrhag* or microhemorrhag* or microthrombi or microthrombus or microvascular dysfunction or microvascular inflammation or Miller Fisher* or MIS-A or MIS-C or miscarriage* or missed abortion or misus* or morbidit* or morbilliform or mortality or mortem or "mother-to-newborn" or multi system inflammatory syndrome or multiple sclerosis or multisystem inflammatory syndrome or murine or musculoskeletal or mutagen* or

myastheni* or myelitis or myelitis transverse or myocardial* or myocarditis or myoclonus or myopathy or myopericarditis or myositis or named or narcolepsy or necrosis or necrot* or neonat* or nephritis or nephrotox* or nervous system or neuralgia or neuritis or neurodevelopmental or neuroinvasi* or neurologic* or neuropathy or neuropsychiatric or neurotox* or neurotrop* or neutropen* or neutropenic colitis or neutropenic infection or neutropenic sepsis or "not effective" or "not safe" or noxious or obesity or occupation* or "off-label" or olfactory or oncogene* or optic ischaemic neuropathy or optic neuritis or outcome* or overdos* or paediatric* or palsy or pancrea* or pancytopenia or papular or papule* or papulovesicular or paraesthesia or paresthesia or particular patient or patient or paediatric* or pericardial effusion or pericarditis or pericyte* or pernio or petechia* or pharmacotox* or pharmacovigilance or placenta* or plaque rupture or pneumomediastinum or pneumothorax or poison* or polyneuritis or polyneuropathy or postmortem or postpartum haemorrhage or postpartum hemorrhage or post viral fatigue syndrome or postural orthostatic tachycardia syndrome or preeclampsia or pregnan* or prematur* or preterm or preterm birth or progressive multifocal leukoencephalopathy or psychosis or pulmonary arterial hypertension or pulmonary embolism or pulmonary fibrosis or pulmonary hypertension or purpura or purpuric or pustular or pustule* or pustulosis or radiculitis or rash or rashes or reaction* or recall* or renal or reproduct* or respiratory or retinitis or "Reye's syndrome" or rhabdomyolysis or rheumatic or rheumatoid arthritis or rhomboencephalitis or right ventricular failure or risk* or safe* or seizure* or sensorineural hearing loss or sepsis or sequelae or serious* or severe* or severity or shock* or side effect or single organ cutaneous vasculitis or SJS or skin finding* or skin lesion* or "small for gestational age" or smell or spontaneous abortion or status epilepticus or STEMI or Stevens Johnson or Stevens Johnson syndrome or Still disease or "Still's disease" or stillbirth* or stillborn or stroke or subacute thyroiditis or subarachnoid or substance related disorder or sudden cardiac death or sudden death or sudden hearing loss or sudden vision loss or sudden visual loss or suicid* or "Sweet's syndrome" or systemic inflammatory response syndrome or tachyarrhythmia* or tachycardia or Takotsubo or "Tako-Tsubo" or taste or teratogen* or thrombo* or thrombocytopenia or thromboembol* or thromboprophylaxis or thrombotic thrombocytopenic purpura or thyroid* or tolerab* or toleran* or tolerat* or torsade de pointes or tox* or toxic epidermal necrolysis or toxic optic neuropathy or "transmission of an infectious agent" or transplant* or transverse myelitis or treatment emergent or treatment failure or ulcerative colitis or undesir* or unexpected or unintention* or unresponsive or unsafe* or untoward or unwanted or urticaria* or uterine infection or uveitis or vaccin* associated enhanced disease or vaccin* associated enhanced respiratory disease or vaccin* coadminist* or vaccination failure or vaccination site* or vaccine failure or vaccine induced or "varicella-like" or vascular inflammation or vascular leak* or vasculature or vasculit* or ventricular or ventricular fibrillation or vertical transmission or vesicle* or vesicular or vesiculobullous or viral meningitis or viral sepsis or vision

loss or visual loss or warning* or weakness or wide complex tachycardia or withdraw* or 2019 nCoV or 2019nCoV or 2019-nCoV or betacoronavirus or corona virus or coronaviridae or coronavirinae or coronavirus or "CoV 2" or cov19 or CoV2 or CoV-2 or "covi 19" or covi* or covi-19 or "covid 19" or covid19 or nCoV or novel corona* or novel CoV or "SARS COV 2" or SARS COV2 or SARS COV-2 or "SARSCOV 2" or "SARS-COV 2" or SARSCOV2 or SARSCOV-2 or SARS-COV-2 or SARS2))

12.1b List of journals used for local literature search

Journal name	Country
EWMA journal. Journal of the European Wound Management Association	UK
Immunisation against infectious disease/ Joint Committee on Vaccination and Immunisation.	UK
Journal of infection prevention.	UK
Disease Outbreak News.	Switzerland
Infectious disease reports.	Switzerland
Infektionskrankheiten in der Schweiz	Switzerland
Schweizerische Ärztezeitung	Switzerland
Swiss Medical Forum	Switzerland
COVID19 Swiss Taskforce	Switzerland
Swissmedic webpage	Switzerland
Swiss Medic Journal	Switzerland
2019 Novel Coronavirus Outbreak (COVID-19).	US
SAGE Journals. Journal of the American Biological Safety Association.	US
Clinical updates in infectious diseases/ National Foundation for Infectious	US
Infectious Disease News.	US
Infectious diseases and tropical medicine.	US
International Journal of Virology.	US
Current Treatment Options in Infectious Diseases	US
The Double Helix	US
The Internet Journal of Infectious Diseases	US
Journal of the Association of Medical Microbiology and Infectious Disease Canada.	Canada
Treatment Update	Canada
Canada Communicable Disease Report	Canada
Canadian Geriatrics Journal	Canada
Canadian Journal of Pain	Canada
Plastic Surgery (Previously known as The Canadian Journal of Plastic Surgery)	Canada
Canadian Medical Education Journal	Canada
Canadian Oncology Nursing Journal	Canada
The Journal of the Canadian Chiropractic Association	Canada
Canadian Journal of Community Mental Health	Canada
Chronicle of Neurology and Psychiatry	Canada
The Chronicle of Skin & Allergy	Canada
The Journal of the Canadian Rheumatology Association (CRAJ)	Canada
Physiotherapy Canada	Canada
Journal of Pharmacy and Nutrition Sciences	Canada
Surveillance of notifiable infectious diseases in Victoria/ Public Health/COVID-19	Australia

Journal name	Country
Australian Pharmacist	Australia
Medicine Safety Update - TGA	Australia
Medical Republic	Australia
Australian Doctor	Australia
Australian Prescriber	Australia
Australian Medical Journal	Australia
JATROS infectious diseases	Austria
ÖÄZ (Österreichische Ärztezeitung)	Austria
Arzneitelegramm	Germany
Arzt und Praxis	Austria
Universum Innere Medizin	Austria
Folia Pharmacotherapeutica	Belgium
Federal Agency for Medicines and Health Products (FAMHP)	Belgium
Revue de la Médecine Générale	Belgium
Huisarts Nu	Belgium
Minerva (Evidence-based Medicine)	Belgium
Vax info	Belgium
Acta microbiologica Bulgarica	Bulgaria
Medica Jadertina	Croatia
Liječničke novine	Croatia
Medix (paper)	Croatia
Agency for Medicinal Products and Medical Devices of Croatia	Croatia
Medicina Fluminensis	Croatia
Ygeia Gia Olous	Cyprus
Cyprus Nursing Chronicles Journal	Cyprus
Cyprus Journal of Medical Science	Cyprus
Statni ustav pro kontrolu leciv (SUKL)	Czech Republic
Farmakoterapie	Czech Republic
Medical Tribune	Czech Republic
Medicína pro praxi	Czech Republic
Nežádoucí účinky léčiv	Czech Republic
Månedsskrift for Almen Praksis	Denmark
LÃ¦gemagasinet	Denmark
Duodecim	Finland
Option/bio	France
Bulletin epidemiologique hebdomadaire	France
Clinical Therapeutics	France
Medecine Therapeutique / Pediatrie -Institutions-	France
Pharmacien Hospitalier et Clinicien (Le)	France
De la médecine factuelle à nos pratiques	France
Lettre de l Infectiologue (La)	France

Journal name	Country
Journal de pharmacie clinique	France
Adolescense	France
Annales françaises de médecine d'urgence.	France
Archives des maladies du coeur et des vaisseaux. Pratique.	France
Archives des maladies professionnelles et de l'environnement	France
Direction générale de la santé.	France
International Academy for Clinical Hematology	France
Les enfants du monde; revue du Comite français pour le Fonds des Nations unies	France
Ethics, medicine, and public health.	France
The journal of aging research & clinical practice.	France
The journal of nursing home research sciences.	France
La lettre du cardiologue	France
Meedecine theerapeutique peediatrie : MTP	France
Médecine tropicale et santé internationale.	France
Le Moniteur des pharmacies.	France
Le pharmacien hospitalier & clinicien.	France
Prescrire international.	France
International Union Against Tuberculosis and Lung Disease	France
Le quotidien du médecin.	France
Recherche & santé	France
Revue des maladies respiratoires actualités.	France
Toxicologie analytique et clinique.	France
World medical journal.	France
Epidemiologisches Bulletin.	Germany
Journal of paediatric infectious diseases.	Germany
GMS hygiene and infection control.	Germany
GMS infectious diseases.	Germany
Arzneimittelverordnung in der Praxis	Germany
Pharma Brief BUKO	Germany
The Federal Institute for Drugs and Medical Devices (Bundesinstitut fur Arzneimittel und Medizinprodukte, BfArm)	Germany
Iatriko Vima	Greece
Hospital Chronicles	Greece
Annales Clinicae Paediatricae Universitalis Atheniensis	Greece
Health Science Journal	Greece
Hellenic Iatriki	Greece
Immunológiai szemle	Hungary
Lege Artis Medicinae (LAM)	Hungary
Medicus Universalis	Hungary
Orvosi Hetilap	Hungary
Gyógyszerészi Hírlap	Hungary

Journal name	Country
European journal of microbiology & immunology	Hungary
Medicore	Ireland
Notiziario dell'Istituto superiore di sanita	Italy
Focus farmacovigilanza	Italy
SocietÃ italiana di medicina generale	Italy
Rivista di allergologia e immunologia paediatrica	Italy
Bollettino SIFO	Italy
Doctus	Latvia
State Agency of Medicines of Latvia	Latvia
Luxembourg Coronavairus Information	Luxembourg
Malta Medical Journal	Malta
Journal of Malta College of Family Doctors	Malta
Biosafety and health	Netherlands
Nederlands tijdschrift voor dermatologie & venereologie.	Netherlands
Norsk Farmasøytisk Tidsskrift	Norway
RELIS Nyhetsbrev	Norway
The journal of critical care medicine.	Poland
Choroby zakazne i zatrucia w Polsce	Poland
Revista portuguesa de doencas infecciosas.	Portugal
Infectio.ro	Romania
Scientia parasitologica	Romania
Germs	Romania
The journal of microbiology, biotechnology and food sciences	Slovakia
ISIS - Glasilo zdravniške zbornice	Slovenia
Medicinski razgledi - – medicinski razgledi society	Slovenia
Metas de Enfermería	Spain
Medicina General y de Familia	Spain
Index de Enfermería	Spain
Farmaceuticos Comunitarios	Spain
Dagens Medicin	Sweden
Acta Médica Colombiana	Colombia
Avances en Enfermería	Colombia
Biomédica	Colombia
Ciencia y Cuidado	Colombia
Revista Ciencias de La Salud	Colombia
Archivos de Medicina	Colombia
Revista Med	Colombia
Revista Médica de Risaralda	Colombia
Ces Medicina	Colombia
Revista Colombiana de Ciencias Químico Farmacéuticas	Colombia
Allergy, Asthma & Respiratory Disease	South Korea

Journal name	Country
Clinical and Experimental Emergency Medicine	South Korea
Korean Journal of Healthcare-associated Infection Control and Prevention	South Korea
Keimyung Medical Journal	South Korea
Allergy, Asthma & Immunology Research	South Korea
Annals of Child Neurology	South Korea
Annals of Clinical Neurophysiology	South Korea
Blood Research	South Korea
International Journal of Heart Failure	South Korea
International Neurourology Journal	South Korea
Journal of Bacteriology and Virology	South Korea
Journal of Cerebrovascular and Endovascular Neurosurgery	South Korea
Journal of Rheumatic Diseases	South Korea
Tuberculosis and Respiratory Diseases	South Korea
Korean Medical Journal	South Korea
Journal of Korean Medical Association	South Korea
Journal of the Korean Society of Radiology	South Korea
The Korean Journal of Medicine	South Korea
Google Scholar	Qatar
Google Scholar	Estonia
Google Scholar	Iceland
Google Scholar	Liechtenstein
Google Scholar	Lithuania
Google Scholar	Monaco
Google Scholar	Botswana

12.1c Literature search for medical topics

Search Strategy (e.g., Global, Local, EV MLM, SLR)

Database(s): **Embase, Ovid MEDLINE(R) ALL**

Search Strategy:

#	Searches	Notes
1	RNA vaccine/ae, ct, it, dt, to, pv, tm or SARS-CoV-2 vaccine/ae, ct, it, dt, to, pv, tm	Therapeutic class search in Embase thesaurus, focused on therapeutic use/adverse effects
2	(COVID-19 Vaccine/ae, tu, de, po, to or (exp Contraindications/ and COVID-19 Vaccine/)) use medall	Therapeutic class search in Medline thesaurus, focused on therapeutic use/adverse effects
3	((RNA vaccin* or mRNA vaccin* or messenger RNA vaccin* or mRNA platform therap* or messenger RNA platform therap* or mRNA inject* or messenger RNA inject*) adj14 (abnormal* or abortion* or abus* or acral or acroischemia or acute coronary syndrome* or acute disseminated encephalomyelitis or acute kidney injury or acute respiratory distress or adem or adr or adrs or adverse or adverse drug reaction or ageusia or agranulocyt* or allerg* or alopecia or amnionitis or anaemi* or anaphylact* or anaphylax* or anemi* or aneurysm* or angioedema or anomal* or anosmia or antenatal bleeding or "antibody-dependent" or antiphospholipid syndrome or antiphospholipid* or anxiety or aplas* or appendicitis or ARDS or arrhythm* or arthritis or aseptic meningitis or aspergillosis or asthma or asystole or ataxia or atrial fibrillation or atrial flutter or auto immun* or autoimmun* or autoimmune haemolytic anaemia or autoimmune haemolytic anemia or autops* or AV block or atypical ARDS or azotaemia or azotemia or Bell palsy or "Bell's palsy" or birth defect* or blind* or bone marrow failure or bradyarrhythmia* or bradycardia or brain involvement or breast feed* or breast milk or breastfed or breastfeed* or	Therapeutic class and mRNA platform search in title/abstract fields, focused on therapeutic use/adverse effects/client-requested terms of interest

	bullae or bullous or bundle branch block or carcinogen* or cardiac arrest or cardiac biopsy or cardiac injury or cardiac tamponade or cardiogenic or cardiogenic shock or cardiomegaly or cardiomyopathy or cardio vascular or cardiotox* or cardiovascular or case report* or case series or cataplexy or causal or cerebellitiis or cerebrovascular or cerebrovascular accident or "chickenpox-like" or Chilblain* or Chilblain like lesions or child* or chorioamnionitis or chronic fatigue syndrome or chronic hepatitis or chronic inflammat* or chronic liver disease or chronic neurological disease or chronic obstructive pulmonary disease or class effect or clinical pathological or clinicopathological or coagulopathy or coccidioidomycosis or coma or comatose or compassion* or complement activation or complement mediated or complication* or confusion* or congenital or contraindicat* or convuls* or COPD or cor pulmonale or cranial nerve or Crohn* or cutaneous or cytokine release syndrome or cytokine storm or cytokine storm syndrome or cytotox* or deaf* or death* or deep vein thrombosis or dermatitis exfoliative* or dermatitis* or developmental delay or diabet* or DIC or diminished effect or disability or disabl* or disseminated intravascular coagulation or DRESS or drug diversion or drug eruption* or drug induced or "drug reaction with eosinophilia and systemic symptoms" or drug related or drug resistance or DVT or dysfunction or dysphagia or dysrhythmia* or effective* or efficacious* or efficacy or elder* or elevated creatinine kinase or embol* or emboli* or embryo or encephalit* or encephalomyelitis or encephalopathy or endometri* or endomyocardial biopsy or endothelial dysfunction or endotheliitis or epilep* or error* or erythema multiforme or erythema nodosum or erythroderma or event* or exanthem* or expanded access or expos* or facial paralysis or failure or "failure to thrive" or fatal* or fertility or fetal or fetus* or fibrillation or fibromyalgia or first case or focal deficit or foet* or follicular conjunctivitis or frail* or full term birth or fulminant or funisitis or gangrene or GBS or geriatric* or gestational diabetes or granulocytopen* or gravis or growth retardation or Guillain* or Guillain-Barre Syndrome or gustatory or haemoly* or haemolytic or haemolytic anaemia or haemophagocytic lymphohistiocytosis or haemorrhag* or harm* or hashimoto or heart failure or HELLP or hematochezia or hemolytic or hemophagocytic lymphohistiocytosis or hemorrhag* or hemostasis disorder* or hepat* or hepatotox* or hypercoagulability or hyperferritinaemi* or hyperferritinemi* or hyperinflammat* or hypersensitiv* or		

	hypogeusia or hyponatremia or hyposmia or iatrogen* or idiopathic thrombocytopenic purpura or ileitis or immuno compromis* or immuno suppress* or immunocompromis* or immunocytotox* or immunopatholog* or immunosuppress* or immunotox* or in utero or incomplete abortion or induced or ineffective* or infan* or infarct* or infertil* or inflammat* or inflammatory bowel disease* or inflammatory bowel syndrome* or inflammatory multisystem syndrome or injection site* or injur* or interact* or intestinal perforation or intolerab* or intoleran* or intoxicat* or intrauterine infection or ischemia or ischemic or IBD or ITP or Kawasaki* or keratoconjunctivitis or kidney or Kounis syndrome or "lack of effect" or "lack of effectiveness" or "lack of efficacy" or "lack of response" or lactat* or lethal or leukoencephalopathy or livedo or livedoid or liver injur* or liver transplant* or lupus* or lupus anticoagulant or macrophage activation syndrome or macule* or macular or maculopapular or maladminist* or manifestation* or maternal or maternal morbidity or "maternal-fetal" or mediastinum or meningit* or meningoencephalitis or meningomyelitis or microangiopathy or micro angiopathy or microhaemorrhag* or microhemorrhag* or microthrombi or microthrombus or microvascular dysfunction or microvascular inflammation or Miller Fisher* or MIS-A or MIS-C or miscarriage* or missed abortion or misus* or morbidit* or morbilliform or mortality or mortem or "mother-to-newborn" or multi system inflammatory syndrome or multiple sclerosis or multisystem inflammatory syndrome or murine or musculoskeletal or mutagen* or myastheni* or myelitis or myelitis transverse or myocardial* or myocarditis or myoclonus or myopathy or myopericarditis or myositis or named or narcolepsy or necrosis or necrot* or neonat* or nephritis or nephrotox* or nervous system or neuralgia or neuritis or neurodevelopmental or neuroinvasi* or neurologic* or neuropathy or neuropsychiatric or neurotox* or neurotrop* or neutropen* or neutropenic colitis or neutropenic infection or neutropenic sepsis or "not effective" or "not safe" or noxious or obesity or occupation* or "off-label" or olfactory or oncogene* or optic ischaemic neuropathy or optic neuritis or outcome* or overdos* or paediatric* or palsy or pancrea* or pancytopenia or papular or papule* or papulovesicular or paraesthesia or paresthesia or particular patient or patient or paediatric* or pericardial effusion or pericarditis or pericyte* or pernio or petechia* or pharmacotox* or pharmacovigilance or placenta* or plaque rupture or		

	pneumomediastinum or pneumothorax or poison* or polyneuritis or polyneuropathy or postmortem or postpartum haemorrhage or postpartum hemorrhage or post viral fatigue syndrome or postural orthostatic tachycardia syndrome or preeclampsia or pregnan* or prematur* or preterm or preterm birth or progressive multifocal leukoencephalopathy or psychosis or pulmonary arterial hypertension or pulmonary embolism or pulmonary fibrosis or pulmonary hypertension or purpura or purpuric or pustular or pustule* or pustulosis or radiculitis or rash or rashes or reaction* or recall* or renal or reproduct* or respiratory or retinitis or "Reye's syndrome" or rhabdomyolysis or rheumatic or rheumatoid arthritis or rhomboencephalitis or right ventricular failure or risk* or safe* or seizure* or sensorineural hearing loss or sepsis or sequelae or serious* or severe* or severity or shock* or side effect or single organ cutaneous vasculitis or SJS or skin finding* or skin lesion* or "small for gestational age" or smell or spontaneous abortion or status epilepticus or STEMI or Stevens Johnson or Stevens Johnson syndrome or Still disease or "Still's disease" or stillbirth* or stillborn or stroke or subacute thyroiditis or subarachnoid or substance related disorder or sudden cardiac death or sudden death or sudden hearing loss or sudden vision loss or sudden visual loss or suicid* or "Sweet's syndrome" or systemic inflammatory response syndrome or tachyarrhythmia* or tachycardia or Takotsubo or "Tako-Tsubo" or taste or teratogen* or thrombo* or thrombocytopenia or thromboembol* or thromboprophylaxis or thrombotic thrombocytopenic purpura or thyroid* or tolerab* or toleran* or tolerat* or torsade de pointes or tox* or toxic epidermal necrolysis or toxic optic neuropathy or "transmission of an infectious agent" or transplant* or transverse myelitis or treatment emergent or treatment failure or ulcerative colitis or undesir* or unexpected or unintention* or unresponsive or unsafe* or untoward or unwanted or urticaria* or uterine infection or uveitis or vaccin* associated enhanced disease or vaccin* associated enhanced respiratory disease or vaccin* coadminist* or vaccination failure or vaccination site* or vaccine failure or vaccine induced or "varicella-like" or vascular inflammation or vascular leak* or vasculature or vasculit* or ventricular or ventricular fibrillation or vertical transmission or vesicle* or vesicular or vesiculobullous or viral meningitis or viral sepsis or vision loss or visual loss or warning* or weakness or wide complex tachycardia or withdraw* or 2019 nCoV or 2019nCoV or 2019-nCoV or betacoronavirus or		

	corona virus or coronaviridae or coronavirinae or coronavirus or "CoV 2" or cov19 or CoV2 or CoV-2 or "covi 19" or covi* or covi-19 or "covid 19" or covid19 or covid-19 or nCoV or novel corona* or novel CoV or "SARS COV 2" or SARS COV2 or SARS COV-2 or "SARSCOV 2" or "SARS-COV 2" or SARSCOV2 or SARSCOV-2 or SARS-COV-2 or SARS2)).ti,ab.		
4	elasomeran/ or 2019-nCoV Vaccine mRNA-1273/ or (mRNA-1273 or "mRNA 1273" or mRNA1273 or "modernatx 1273" or "modernatx-1273" or "moderntx 1273" or "moderntx-1273" or m-1273 or "m 1273" or "Moderna Covid19 Vaccine" or "Moderna Covid-19 Vaccine" or "Moderna-Covid-19-Vaccine" or "Moderna Covid 19 Vaccine" or SPIKEVAX or Spike-vax or Elasomeran or "CX-024414" or "TAK-919" or "TAK 919" or TAK919).ti,ab.	Product search in Embase/Medline thesaurus and title/abstract fields	
5	*severe acute respiratory syndrome/ae, ct, it, dt, to, pv, tm or *severe acute respiratory syndrome coronavirus 2/ae, ct, it, dt, to, pv, tm or *virus spike protein/ae, ct, it, dt, to, pv, tm or *virus capsid/ae, ct, it, dt, to, pv, tm	SARS/virus spike protein/virus capsid terms requested by client, searched in Embase thesaurus, focused on adverse effects	
6	(Severe Acute Respiratory Syndrome/ae, po, to or (exp Contraindications/ and Severe Acute Respiratory Syndrome/)) use medall	SARS search in Medline thesaurus, focused on adverse effects	
7	(or/1-6) and (2020:2050.(yr). or (2020:2050.(dt). or 2020:2050.(dc).))	All searches combined, narrowed to publications available in 2020 and after	

12.2 Scientific abstracts