PREPARED BY PFIZER INC

CDS EFFECTIVE DATE: 06-OCT-2022

Date of Superseded CDS: 8-Sep-2022

COVID-19 mRNA Vaccine

CORE DATA SHEET

VERSION 17

1. NAME OF THE MEDICINAL PRODUCT

COVID-19 mRNA Vaccine (nucleoside modified) and COMIRNATY are called TRADENAME.

{{COMIRNATY Bivalent Original and Omicron BA.1 15/15 micrograms per dose is called TRADENAME (Bivalent)}}.

{{COMIRNATY Bivalent Original and Omicron BA.4/BA.5 15/15 micrograms per dose is called TRADENAME (Bivalent)}}.

{{COMIRNATY Bivalent Original and Omicron BA.4/BA.5 5/5 micrograms per dose is called TRADENAME (Bivalent)}}.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[1,2,72,85,120]

*[Editorial guidance for countries: Select this text for the **PBS/Sucrose presentation, 30 micrograms/dose**.]*

TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap: This is a multidose vial and must be diluted before use. One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution (see Sections 4.2 and 6.6).

One dose (0.3 mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

TRADENAME is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Original).

For the full list of excipients, see Section 6.1.

*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 30 micrograms/dose**.]*

TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap: This is a multidose vial. One vial (2.25 mL) contains 6 doses of 0.3 mL (see Sections 4.2 and 6.6).

One dose (0.3 mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

TRADENAME is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Original).

For the full list of excipients, see Section 6.1.

*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 10 micrograms/dose**.]*

TRADENAME (for age 5 years to <12 years), orange cap: This is a multidose vial and must be diluted before use. One vial (1.3 mL) contains 10 doses of 0.2 mL after dilution (see Sections 4.2 and 6.6).

One dose (0.2 mL) contains 10 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

TRADENAME is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Original).

For the full list of excipients, see Section 6.1.

*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 3 micrograms/dose**.]*

TRADENAME (for age 6 months to <5 years), maroon cap: This is a multidose vial and must be diluted before use. One vial (0.4 mL) contains 10 doses of 0.2 mL after dilution (see Sections 4.2 and 6.6).

One dose (0.2 mL) contains 3 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

TRADENAME is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Original).

For the full list of excipients, see Section 6.1.

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 15/15 micrograms/dose**.]*

TRADENAME (Bivalent) (for age 12 years and older), grey cap: This is a multidose vial. One vial (2.25 mL) contains 6 doses of 0.3 mL (see Sections 4.2 and 6.6).

One dose (0.3 mL) contains 15/15 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

TRADENAME (Bivalent) is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Original and {{Omicron BA.1}} {{Omicron BA.4/BA.5}}).

For the full list of excipients, see Section 6.1.

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 5/5 micrograms/dose**.]*

TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap: This is a multidose vial and must be diluted before use. One vial (1.3 mL) contains 10 doses of 0.2 mL (see Sections 4.2 and 6.6).

One dose (0.2 mL) contains 5/5 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

TRADENAME (Bivalent) is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Original and Omicron BA.4/BA.5).

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM[2,3,72,85]

*[Editorial guidance for countries: Select this text for the **PBS/Sucrose presentation, 30 micrograms/dose**.]*

TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap: Concentrate for dispersion for injection.

*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 30 micrograms/dose**.]*

TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap: Dispersion for injection.

*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 10 micrograms/dose**.]*

TRADENAME (for age 5 years to <12 years), orange cap: Concentrate for dispersion for injection.

*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 3 micrograms/dose**.]*

TRADENAME (for age 6 months to <5 years), maroon cap: Concentrate for dispersion for injection.

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 15/15 micrograms/dose**.]*

TRADENAME (Bivalent) (for age 12 years and older), grey cap: Dispersion for injection.

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 5/5 micrograms/dose**.]*

TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap: Concentrate for dispersion for injection.

The vaccine is a white to off-white frozen solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

The following is a representative indication. Locally approved indications may differ.

Active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 virus, in individuals 6 months of age and older.[4,49,73,86]

4.2. Posology and method of administration

Posology

*[Editorial guidance for countries: Select this text for the **PBS/Sucrose presentation, 30 micrograms/dose**.]*
Or
*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 30 micrograms/dose**.]*

Individuals 12 years of age and older

TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap, or TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap, are administered intramuscularly as a primary series of 2 doses (0.3 mL each) at greater than or equal to 21 days (preferably 3 weeks) apart.[5,49]

Booster dose in individuals 12 years of age and older

A booster dose of TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap, or TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap, may be administered intramuscularly at least 5 months after the second dose in individuals 12 years of age and older.[71,87]

Subsequent doses of TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap, or TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap, may be administered to individuals 12 years of age and older at least 4 months after a previous booster dose of TRADENAME.[121]

Doses of TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap, concentrate for dispersion for injection (30 micrograms/dose) or TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap, dispersion for injection (30 micrograms/dose) vaccine are considered interchangeable.

TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap, or TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap, intended for individuals ages 12 years and older cannot be used for individuals age 5 years to <12 years.

Interchangeability

The interchangeability of TRADENAME with other COVID-19 vaccines to complete the primary vaccination series or the booster dose has not been established. Individuals who have received 1 dose of TRADENAME should receive a second dose of TRADENAME to complete the primary vaccination series and for any additional doses.

Individuals may not be protected until at least 7 days after their second dose of the vaccine.[6]

For further information on efficacy, see Section 5.1.

*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 10 micrograms/dose**.]*

Individuals 5 through <12 years of age

TRADENAME (for age 5 years to <12 years), orange cap, is administered intramuscularly after dilution as a primary series of 2 doses (0.2 mL) at greater than or equal to 21 days (preferably 3 weeks) apart.[73]

Booster dose in individuals 5 through <12 years of age

A booster dose of TRADENAME (for age 5 years to <12 years), orange cap, may be administered intramuscularly at least 6 months after the second dose in individuals 5 years through <12 years of age.[84]

TRADENAME (for age 5 years to <12 years), orange cap, cannot be used in individuals 12 years of age and older.

Interchangeability

The interchangeability of TRADENAME with other COVID-19 vaccines to complete the primary vaccination series has not been established. Individuals who have received 1 dose of TRADENAME should receive a second dose of TRADENAME to complete the primary vaccination series.

Individuals may not be protected until at least 7 days after their second dose of the vaccine.[6]

For further information on efficacy, see Section 5.1.

*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 3 micrograms/dose**.]*

Individuals 6 months through <5 years of age

TRADENAME (for age 6 months to <5 years), maroon cap, is administered intramuscularly after dilution as a primary series of 3 doses (0.2 mL). The initial 2 doses are administered 3 weeks apart followed by a third dose administered at least 8 weeks after the second dose.[86]

Individuals who will turn from 4 years to 5 years of age between their doses in the vaccination series should receive their age-appropriate dose at the time of the vaccination and the interval between doses is determined by the individual's age at the start of the vaccination series.[88]

TRADENAME (for age 6 months to <5 years), maroon cap, cannot be used in individuals 5 years of age and older.

Interchangeability

The interchangeability of TRADENAME with other COVID-19 vaccines to complete the primary vaccination series has not been established. Individuals who have received 1 dose of TRADENAME should receive a second and third dose of TRADENAME to complete the primary vaccination series.

Individuals may not be protected until at least 7 days after their second dose of the vaccine.[6]

For further information on efficacy, see Section 5.1.

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 15/15 micrograms/dose**.]*

Booster dose in individuals 12 years of age and older

A booster dose of TRADENAME (Bivalent) (for age 12 years and older), grey cap, may be administered intramuscularly at least 5 months after completing the primary series of TRADENAME. Subsequent doses of TRADENAME (Bivalent) (for age 12 years and older),

grey cap, may be administered to individuals 12 years of age and older at least 4 months after a previous booster dose of TRADENAME or TRADENAME (Bivalent) (for age 12 years and older), grey cap.

For further information on efficacy, see Section 5.1.

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 5/5 micrograms/dose**.]*

Booster dose in individuals 5 through <12 years of age

A booster dose of TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap, may be administered intramuscularly at least 4 months after the last prior dose in individuals 5 years through <12 years of age.[156]

TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap, cannot be used in individuals 12 years of age and older.

For further information on efficacy, see Section 5.1.

Pediatric population

The safety and efficacy of TRADENAME in individuals under 6 months of age have not yet been established. The safety and effectiveness of a booster dose of TRADENAME in individuals 16 through 17 years of age is based on safety and effectiveness data in adults at least 18 through 55 years of age.[71,86]

{{The safety and efficacy of TRADENAME (Bivalent) in children less than 5 years of age has not yet been established.}}

Geriatric population

Clinical studies of TRADENAME include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy.[7] Of the total number of TRADENAME recipients in Study 2 (N = 22,026), 16.5% (n = 3627) were 65 through 74 years of age and 4.2% (n = 925) were 75 years of age and older (see Section 5.1).[50]

The safety of a booster dose of TRADENAME in individuals 65 years of age and older is based on safety data in 12 booster dose recipients 65 through 85 years of age in Study 2, 306 booster dose recipients 18 through 55 years of age in Study 2, and 1,175 booster dose recipients 65 years of age and older in Study 4. The effectiveness of a booster dose of TRADENAME in individuals 65 years of age and older is based on effectiveness data in 306 booster dose recipients 18 through 55 years of age in Study 2, and an efficacy analysis from participants 16 years of age and older in 9,945 participants in Study 4.[71, 80]

Method of administration

*[Editorial guidance for countries: Select this text for the **PBS/Sucrose presentation, 30 micrograms/dose**.]*

Administer TRADENAME intramuscularly in the deltoid muscle.

Do not inject the vaccine intravascularly, subcutaneously, or intradermally.

After dilution, vials of TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap, contain 6 doses of 0.3 mL of vaccine.

Individuals 12 years of age and older

Low dead -volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

For instructions on the handling, dilution, and dose preparation of the vaccine before administration, see Section 6.6.

*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 30 micrograms/dose**.]*

Administer TRADENAME intramuscularly in the deltoid muscle.

Do not inject the vaccine intravascularly, subcutaneously, or intradermally.

Vials of TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap, contain 6 doses of 0.3 mL of vaccine.

Individuals 12 years of age and older

Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

For instructions on handling and dose preparation of the vaccine before administration, see Section 6.6.

*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 10 micrograms/dose**.]*

Administer TRADENAME intramuscularly in the deltoid muscle.

Do not inject the vaccine intravascularly, subcutaneously, or intradermally.

After dilution, vials of TRADENAME (for age 5 years to <12 years), orange cap, contain 10 doses of 0.2 mL of vaccine.

Individuals 5 through <12 years of age

Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

For instructions on the handling, dilution, and dose preparation of the vaccine before administration, see Section 6.6.

*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 3 micrograms/dose**.]*

In individuals 6 to less than 12 months of age, administer TRADENAME intramuscularly in the anterolateral aspect of the thigh. In individuals 1 years of age and older, administer TRADENAME intramuscularly in the anterolateral aspect of the thigh or the deltoid muscle.

Do not inject the vaccine intravascularly, subcutaneously, or intradermally.

After dilution, vials of TRADENAME (for age 6 months to <5 years), maroon cap, contain 10 doses of 0.2 mL of vaccine.

Individuals 6 months through <5 years of age

Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and content.

- Do not pool excess vaccine from multiple vials.

For instructions on the handling, dilution, and dose preparation of the vaccine before administration, see Section 6.6.

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 15/15 micrograms/dose**.]*

Administer TRADENAME (Bivalent) intramuscularly in the deltoid muscle.

Do not inject the vaccine intravascularly, subcutaneously, or intradermally.

Vials of TRADENAME (Bivalent) (for age 12 years and older), grey cap, contain 6 doses of 0.3 mL of vaccine.

Individuals 12 years of age and older

Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

For instructions on handling and dose preparation of the vaccine before administration, see Section 6.6.

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 5/5 micrograms/dose**.]*

Administer TRADENAME (Bivalent) intramuscularly in the deltoid muscle.

Do not inject the vaccine intravascularly, subcutaneously, or intradermally.

After dilution, vials of TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap, contain 10 doses of 0.2 mL of vaccine.

Individuals 5 through <12 years of age

Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial. Irrespective of the type of syringe and needle:
- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and content.

- Do not pool excess vaccine from multiple vials.

For instructions on the handling, dilution, and dose preparation of the vaccine before administration, see Section 6.6.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in Section 6.1.

4.4. Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

General recommendations

As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in case of a rare anaphylactic event following the administration of the vaccine.[9]

Very rare cases of myocarditis and pericarditis have been reported following vaccination with TRADENAME. Typically, the cases have occurred more often in younger men and after the second dose of the vaccine and within 14 days after vaccination. Based on accumulating data, the reporting rates of myocarditis and pericarditis after primary series in children ages 5 through <12 years are lower than in ages 12 through 17 years. Rates of myocarditis and pericarditis in booster doses do not appear to be higher than after the second dose in the primary series. The cases are generally mild and individuals tend to recover within a short time following standard treatment and rest. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis in vaccine recipients.[69,89]

The administration of TRADENAME {{or TRADENAME (Bivalent)}} should be postponed in individuals suffering from acute severe febrile illness.[9]

Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection, should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.[9]

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

Some individuals may have stress-related responses associated with the process of vaccination itself. Stress-related responses are temporary and resolve on their own. They may include dizziness, fainting, palpitations, increases in heart rate, alterations in blood pressure, feeling short of breath, tingling sensations, sweating and/or anxiety. Individuals should be advised to bring

symptoms to the attention of the vaccination provider for evaluation and precautions should be in place to avoid injury from fainting.[67]

As with any vaccine, vaccination with TRADENAME {{or TRADENAME (Bivalent)}} may not protect all vaccine recipients.

4.5. Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Do not mix TRADENAME {{or TRADENAME (Bivalent)}} with other vaccines/products in the same syringe.

4.6. Fertility, pregnancy and lactation

Pregnancy

There are limited amount of data from the use of TRADENAME in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition, or post-natal development (see Section 5.3).[10,11] Administration of TRADENAME in pregnancy should be considered when the potential benefits outweigh any potential risks for the mother and fetus.

{{No data are available yet regarding the use of TRADENAME (Bivalent) during pregnancy.}}

Lactation

It is unknown whether TRADENAME is excreted in human milk.

{{No data are available yet regarding the use of TRADENAME (Bivalent) during breast-feeding.}}

Fertility

It is unknown whether TRADENAME has an impact on fertility. Animal studies do not indicate direct or indirect harmful effects with respect to female fertility or reproductive toxicity (see Section 5.3).[10,11]

{{It is unknown whether TRADENAME (Bivalent) has an impact on fertility.}}

4.7. Effects on ability to drive and use machines

TRADENAME {{or TRADENAME (Bivalent)}} has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under Section 4.8 “Undesirable effects” may temporarily affect the ability to drive or use machines.

4.8. Undesirable effects

Summary of safety profile

The safety of TRADENAME was evaluated in participants 5 years of age and older in 3 clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America.[12,49] Study BNT162-01 (Study 1) enrolled 60 participants, 18 through 55 years of age and 36 participants, 56 through 85 years of age.[68] Study C4591001 (Study 2) enrolled approximately 46,000 participants,[41] 12 years of age or older.[12] Study C4591007 (Study 3) enrolled approximately 2,300 participants 5 through <12 years of age.[73] Study 3 also enrolled approximately 1,800 participants 2 through 4 years of age and 1,200 participants 6 months through 23 months of age.[86]

Additionally, 306 existing Phase 3 participants at least 18 through 55 years of age received a booster dose of TRADENAME approximately 6 months after the second dose in the non-placebo-controlled booster dose portion of Study 2. The overall safety profile for the booster dose was similar to that seen after 2 doses.[71]

In Study C4591031 (Study 4), a placebo-controlled booster study, 5,081 participants 16 years of age and older were recruited from Study 2 to receive a booster dose of TRADENAME at least 6 months after the second dose. The overall safety profile for the booster dose was similar to that seen after 2 doses.[80]

In a subset of Study 3 (Phase 2/3) participants, 401 participants 5 through <12 years of age received a booster dose of TRADENAME at least 5 months after completing the primary series. The overall safety profile for the booster dose was similar to that seen after the primary series.[84]

Participants 16 years of age and older – after 2 doses

In Study 2, a total of 22,026 participants 16 years of age or older received at least 1 dose of TRADENAME and a total of 22,021 participants 16 years of age or older received placebo.[50]

The most frequent adverse reactions in participants 16 years of age and older that received 2 doses (in order from highest to lowest frequencies) were injection site pain (>80%), fatigue (>60%), headache (>50%), myalgia (>40%), chills (>30%), arthralgia (>20%), pyrexia and injection site swelling (>10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination.[64] A lower frequency of reactogenicity events was associated with greater age.[15]

The safety profile in 545 participants receiving TRADENAME, that were seropositive for SARS-CoV-2 at baseline, was similar to that seen in the general population.[17,28,31]

Study 2 also included 200 participants with confirmed stable human immunodeficiency virus (HIV) infection. The safety profile of the participants receiving TRADENAME (n = 100) in the individuals with stable HIV infection was similar to that seen in the general population.[51]

Adolescents 12 through 15 years of age – after 2 doses[81]

In an analysis of long-term safety follow-up in Study 2, 2,260 adolescents (1,131 TRADENAME; 1,129 placebo) were 12 through 15 years of age. Of these, 1,559 adolescents (786 TRADENAME and 773 placebo) have been followed for ≥4 months after the second dose.[41,42] The safety evaluation in Study 2 is ongoing.

The most frequent adverse reactions in adolescents 12 through 15 years of age that received 2 doses were injection site pain (>90%), fatigue and headache (>70%), myalgia and chills (>40%), arthralgia and pyrexia (>20%).[43,44,45]

Children 5 through <12 years of age – after 2 doses[73]

In an analysis of Study 3 (Phase 2/3), 2,268 participants (1,518 TRADENAME 10 mcg; 750 placebo) were 5 through <12 years of age. Of these, 2,158 (95.1%) (1,444 TRADENAME 10 mcg and 714 placebo) participants have been followed for at least 2 months after the second dose. The safety evaluation in Study 3 is ongoing.

The most frequent adverse reactions in children 5 through <12 years of age that received 2 doses included injection site pain (>80%), fatigue (>50%), headache (>30%), injection site redness and swelling (>20%), myalgia and chills (>10%).

Children 2 through 4 years of age – after 3 doses[90,91,92]

In an analysis of Study 3 (Phase 2/3), 2,750 individuals (1,835 TRADENAME 3 mcg and 915 placebo) were 2 through 4 years age. Based on data in the blinded placebo-controlled follow-up period up to the cutoff date of April 29, 2022, 886 individuals 2 through 4 years of age who received a 3-dose primary course (606 TRADENAME 3 mcg and 280 placebo) have been followed a median of 1.4 months after the third dose.

The most frequent adverse reactions in children 2 through 4 years of age that received any primary series dose included pain at injection site and fatigue (>40%), injection site redness and fever (>10%).

Children 6 through 23 months of age – after 3 doses[93,94,95]

In an analysis of Study 3 (Phase 2/3), 1,776 individuals (1,178 TRADENAME 3 mcg and 598 placebo) were 6 through 23 months of age. Based on data in the blinded placebo-controlled follow-up period up to the cutoff date of April 29, 2022, 570 individuals 6 through 23 months of age who received a 3-dose primary course (386 TRADENAME 3 mcg and 184 placebo) have been followed for a median of 1.3 months after the third dose.

The most frequent adverse reactions in children 6 through 23 months of age that received any primary series dose included irritability (>60%), decrease appetite (>30%), tenderness at the injection site (>20%), injection site redness and fever (>10%).

Participants 12 years of age and older – after booster dose[71]

The safety of a booster dose of TRADENAME in participants 12 years of age and older is inferred from safety data from studies of a booster dose of TRADENAME in participants 16 years of age and older.

A subset from Study 2 (Phase 2/3) participants of 306 adults at least 18 through 55 years of age who completed the primary TRADENAME 2-dose course, received a booster dose of TRADENAME approximately 6 months (range of 4.8 to 8.0 months) after receiving Dose 2. Of these, 301 participants have been followed for ≥4 months after the booster dose of TRADENAME.[96]

The most frequent adverse reactions in participants 18 through 55 years of age were injection site pain (>80%), fatigue (>60%), headache (>40%), myalgia (>30%), chills and arthralgia (>20%).

In Study 4, a placebo-controlled booster study, participants 16 years of age and older recruited from Study 2 received a booster dose of TRADENAME (5,081 participants), or placebo (5,044 participants) at least 6 months after the second dose of TRADENAME. Overall, participants who received a booster dose, had a median follow-up time of 2.8 months (range 0.3 to 7.5 months) after the booster dose in the blinded placebo-controlled follow-up period to the cut-off date (8 February 2022).[80,97] Of these, 1281 participants (895 TRADENAME and 386 placebo) have been followed for ≥4 months after the booster dose of TRADENAME.[98]

Participants 12 years of age and older – after subsequent booster doses

The safety of a booster dose of TRADENAME in participants 12 years of age and older is inferred from safety data from studies of a booster dose of TRADENAME in participants 18 years of age and older.

A subset of 325 adults 18 to ≤55 years of age who had completed 3 doses of TRADENAME, received a booster (fourth dose) of TRADENAME (30 mcg) 90 to 180 days after receiving Dose 3.[122,123] Participants who received a booster (fourth dose) of TRADENAME (30 mcg) had a median follow-up time of 1.4 months.[124] The most frequent adverse reactions in these participants were injection site pain (>70%), fatigue (>60%), headache (>40%), myalgia and chills (>20%) and arthralgia (>10%).[125,126]

In a subset from Study 4 (Phase 3), 305 adults greater than 55 years of age who had completed 3 doses of TRADENAME, received a booster (fourth dose) of TRADENAME (30 mcg) 5.3 to 13.1 months after receiving Dose 3.[127,128] Participants who received a booster (fourth dose) of TRADENAME (30 mcg) had a median follow-up time of at least 1.7 months up to a data cutoff date of 16 May 2022.[129] The most frequent adverse reactions in participants greater than 55 years of age were injection site pain (>60%), fatigue (>40%), headache (>20%), myalgia and chills (>10%).[130,131,132]

Omicron-adapted TRADENAME – after a booster dose of TRADENAME (Bivalent, Original/Omicron BA.1) or monovalent Omicron BA.1 (fourth dose)

The safety of a booster dose of TRADENAME (Bivalent) in participants 5 years of age and older is inferred from safety data from studies of a booster dose of TRADENAME (Bivalent Original/Omicron BA.1) in individuals greater than 55 years of age and also safety data from studies of a booster dose of monovalent Omicron BA.1 in individuals 18 to ≤55 years of age.

Participants greater than 55 years of age – after a booster dose of TRADENAME (Bivalent, Original/Omicron BA.1)

In a subset from Study 4 (Phase 3), 305 adults greater than 55 years of age who had completed 3 doses of TRADENAME, received a booster (fourth dose) of TRADENAME (Bivalent, Original/Omicron BA.1) 15/15 mcg 4.7 to 11.5 months after receiving Dose 3.[133,134,135] Participants who received a booster (fourth dose) of TRADENAME (Bivalent, Original/Omicron BA.1) had a median follow-up time of at least 1.7 months up to a data cutoff date of 16 May 2022.[136,137]

The overall safety profile for the TRADENAME (Bivalent, Original/Omicron BA.1) booster (fourth dose) was similar to that seen after the TRADENAME booster (third dose). The most frequent adverse reactions in participants greater than 55 years of age were injection site pain (>50%), fatigue (>40%), headache (>30%), myalgia (>20%), chills and arthralgia (>10%). No new adverse reactions were identified for TRADENAME (Bivalent, Original/Omicron BA.1).[138,139]

Participants 18 to ≤55 years of age – after a booster dose of monovalent Omicron BA.1

A subset of 315 adults 18 to ≤55 years of age who had completed 3 doses of TRADENAME, received a booster (fourth dose) of Omicron BA.1 30 mcg (monovalent) 90 to 180 days after receiving Dose 3.[122,123] Participants who received a booster (fourth dose) of monovalent Omicron BA.1 had a median follow-up time of 1.4 months.[124] The most frequent adverse reactions in these participants were injection site pain (>70%), fatigue (>60%), headache (>40%), myalgia (>30%), chills (>30%) and arthralgia (>20%).[125,126]

Children 5 through <12 years of age – after booster dose[84]

In a subset from Study 3, a total of 401 children 5 through <12 years of age received a booster dose of TRADENAME 10 mcg at least 5 months (range of 5 to 9 months) after completing the primary series. The analysis of the Study 3 (Phase 2/3) subset is based on data up to the cut-off date of March 22, 2022 (median follow-up time of 1.3 months).

The most frequent adverse reactions in participants 5 through <12 years of age were injection site pain (>70%), fatigue (>40%), headache (>30%), myalgia, chills, injection site redness, and swelling (>10%).

The adverse reactions in the tables below apply to TRADENAME and TRADENAME (Bivalent) and all age groups unless specified otherwise.

Table 1. Adverse Drug Reactions (Clinical Trials)[13,14,16,64,80,86]

System Organ Class	Adverse Drug Reactions
Blood and lymphatic system disorders	Lymphadenopathy[a]
Metabolism and nutrition disorders	Decreased appetite
Psychiatric disorders	Irritability[c]
Nervous system disorders	Headache Lethargy
Gastrointestinal disorders	Nausea
Skin and subcutaneous tissue disorders	Hyperhidrosis Night sweats
Musculoskeletal and connective tissue disorders	Arthralgia Myalgia
General disorders and administration site conditions	Pyrexia[b] Chills Asthenia Malaise Fatigue Injection site pain Injection site tenderness[c] Injection site swelling Injection site redness

a. A higher frequency of lymphadenopathy was observed in participants 5 through <12 years of age in Study 3 (2.5% vs. 0.9%) and in participants 16 years of age and older in Study 4 (2.8% vs. 0.4%) receiving a booster dose compared to participants receiving 2 doses.[71,84]
b. A higher frequency of pyrexia was observed after the second dose compared to the first dose. The preferred term pyrexia is a cluster term covering also body temperature increased.
c. Irritability and injection site tenderness pertain to participants 6 through 23 months of age.[86]

Table 2. Adverse Drug Reactions (Post-authorization Experience)[38,64,80,89,155]

System Organ Class	Adverse Drug Reactions
Immune system disorders	Anaphylaxis Hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)
Nervous system disorders	Dizziness
Cardiac disorders	Myocarditis Pericarditis
Gastrointestinal disorders	Diarrhea Vomiting
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)[a]

a. A higher frequency of pain in extremity (1.1% vs. 0.8%) was observed in participants receiving a booster dose in Study 4 compared to participants receiving 2 doses.

4.9. Overdose

Participants who received 58 micrograms of TRADENAME in clinical trials did not report an increase in reactogenicity or adverse events.[18]

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacological class, therapeutic class

Vaccines
Refer to the current ATC code index for the appropriate code assignment for the pharmacologic and/or therapeutic class.

Mechanism of action

The nucleoside-modified messenger RNA in TRADENAME {{or TRADENAME (Bivalent)}} is formulated in lipid nanoparticles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.[19,20]

Efficacy

Study 2 is a multicenter, placebo-controlled efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥56-year stratum.[12] The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19.[12] Participants with pre-existing stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment,[21] were included as were participants with known stable infection with HIV, hepatitis C virus (HCV), or hepatitis B virus (HBV).[12]

Efficacy in participants 16 years of age and older – after 2 doses

In the Phase 2/3 portion of Study 2, based on data accrued through 14 November 2020, approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of TRADENAME or placebo. The efficacy analyses included participants that received their second vaccination within 19 to 42 days after their first vaccination. The majority (93.1%) of vaccine recipients received the second dose 19 days to 23 days after Dose 1.[52] Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.[12,27]

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the TRADENAME group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose.[22] Table 3 presents the specific demographic characteristics in the studied population.

Table 3. Demographics (Population for the Primary Efficacy Endpoint)[a,22]

	TRADENAME (N=18,242) n (%)	Placebo (N=18,379) n (%)
Sex		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
Age (years)		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)
Age group		
12 to 15 years	46 (0.3)	42 (0.2)
16 to 17 years	66 (0.4)	68 (0.4)
16 to 64 years	14,216 (77.9)	14,299 (77.8)
65 to 74 years	3176 (17.4)	3226 (17.6)
≥75 years	804 (4.4)	812 (4.4)
Race		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other[b]	534 (2.9)	516 (2.8)
Ethnicity		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
Comorbidities[c]		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

a. All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.
b. Includes multiracial and not reported.
c. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19.
   - Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
   - Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
   - Obesity (body mass index ≥30 kg/m^2)

- Diabetes (Type 1, Type 2, or gestational)
- Liver disease
- Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

At the time of the primary efficacy analysis, participants had been followed for symptomatic COVID-19 for at least 2214 person-years for the TRADENAME and at least 2222 person-years in the placebo group.[32]

There were no meaningful clinical differences in overall vaccine efficacy in participants who were at risk of severe COVID-19 including those with 1 or more comorbidities that increase the risk of severe COVID-19 [e.g., asthma, body mass index (BMI) ≥30 kg/m^2, chronic pulmonary disease, diabetes mellitus, hypertension].[23,24]

The vaccine efficacy information is presented in Table 4.

Table 4. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*,[34]			
Subgroup	**TRADENAME N[a]=18,198 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=18,325 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
All participants[e]	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6)[f]
16 to 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1)[g]
≥65 years	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9)[g]
65 to 74 years	1 0.406 (3074)	14 0.406 (3095)	92.9 (53.1, 99.8)[g]
≥75 years	0 0.102 (774)	5 0.106 (785)	100.0 (-13.1, 100.0)[g]

First COVID-19 occurrence from 7 days after Dose 2 in participants with or without* evidence of prior SARS-CoV-2 infection[28]			
Subgroup	TRADENAME N[a]=19,965 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=20,172 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)
All participants[e]	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3)[f]
16 to 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7)[g]
≥65 years	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9)[g]
65 to 74 years	1 0.424 (3239)	14 0.423 (3255)	92.9 (53.2, 99.8)[g]
≥75 years	0 0.106 (805)	5 0.109 (812)	100.0 (-12.1, 100.0)[g]

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).
Abbreviations: NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. No confirmed cases were identified in adolescents 12 to 15 years of age.
f. Two-sided credible interval for vaccine efficacy (VE) was calculated using a beta-binomial model with a beta (0.700102, 1) prior for $\theta=r(1-VE)/(1+r(1-VE))$, where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.
g. Two-sided confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

The subgroup analyses of vaccine efficacy including demographic characteristics is presented in Table 5.

Table 5. Subgroup Analyses of Vaccine Efficacy - Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 - Evaluable Efficacy Population[33]

Subgroup	TRADENAME Na=18,198 Cases n1b Surveillance Timec (n2d)	Placebo Na=18,325 Cases n1b Surveillance Timec (n2d)	Vaccine Efficacy % (95% CI)
Sex			
Female	5 1.090 (8536)	81 1.114 (8749)	93.7 (84.7, 98.0)
Male	3 1.124 (8875)	81 1.108 (8762)	96.4 (88.9, 99.3)
Ethnicity			
Hispanic or Latino	3 0.605 (4764)	53 0.600 (4746)	94.4 (82.7, 98.9)
Not Hispanic or Latino	5 1.596 (12,548)	109 1.608 (12,661)	95.4 (88.9, 98.5)
Race			
Black or African American	0 0.165 (1502)	7 0.164 (1486)	100.0 (31.2, 100.0)
White	7 1.889 (14,504)	146 1.903 (14,670)	95.2 (89.8, 98.1)
All others[f]	1 0.160 (1405)	9 0.155 (1355)	89.3 (22.6, 99.8)

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.
f. All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

Updated efficacy analyses were performed with additional confirmed COVID-19 cases accrued during blinded placebo-controlled follow-up through 13 March 2021, representing up to 6 months of follow-up after Dose 2 for participants in the efficacy population.

The updated vaccine efficacy information is presented in Table 6.

Table 6. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*,[53]			
Subgroup	**TRADENAME N[a]=20,998 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=21,096 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
All participants[f]	77 6.247 (20,712)	850 6.003 (20,713)	91.3 (89.0, 93.2)
16 through 64 years	70 4.859 (15,519)	710 4.654 (15,515)	90.6 (87.9, 92.7)
65 years and older	7 1.233 (4192)	124 1.202 (4226)	94.5 (88.3, 97.8)
65 through 74 years	6 0.994 (3350)	98 0.966 (3379)	94.1 (86.6, 97.9)
75 years and older	1 0.239 (842)	26 0.237 (847)	96.2 (76.9, 99.9)
First COVID-19 occurrence from 7 days after Dose 2 in participants with or without* evidence of prior SARS-CoV-2 infection[54]			
Subgroup	**TRADENAME N[a]=22,166 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=22,320 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
All participants[f]	81 6.509 (21,642)	873 6.274 (21,689)	91.1 (88.8, 93.0)
16 through 64 years	74 5.073 (16,218)	727 4.879 (16,269)	90.2 (87.6, 92.4)
65 years and older	7 1.267 (4315)	128 1.232 (4326)	94.7 (88.7, 97.9)
65 through 74 years	6 1.021 (3450)	102 0.992 (3468)	94.3 (87.1, 98.0)
75 years and older	1 0.246 (865)	26 0.240 (858)	96.2 (77.2, 99.9)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.
f. Included confirmed cases in participants 12 through 15 years of age: 0 in the TRADENAME group (both without and with or without evidence of prior SARS-CoV-2 infection); 16 and 18 in the placebo group (without and with or without evidence of prior SARS-CoV-2 infection, respectively).

The updated subgroup analyses of vaccine efficacy by demographic characteristics are presented in Table 7 and Table 8.

Table 7. Vaccine Efficacy– First COVID-19 Occurrence From 7 Days After Dose 2 – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 by Demographic Characteristics – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period[53]

Subgroup	TRADENAME N[a]=20,998 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=21,096 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
Sex			
Male	42 3.246 (10,637)	399 3.047 (10,433)	90.1 (86.4, 93.0)
Female	35 3.001 (10075)	451 2.956 (10,280)	92.4 (89.2, 94.7)
Ethnicity			
Hispanic or Latino	29 1.786 (5161)	241 1.711 (5120)	88.5 (83.0, 92.4)
Not Hispanic or Latino	47 4.429 (15,449)	609 4.259 (15,484)	92.6 (90.0, 94.6)
Race			
Black or African American	4 0.545 (1737)	48 0.527 (1737)	91.9 (78.0, 97.9)
White	67 5.208 (17,186)	747 5.026 (17,256)	91.3 (88.9, 93.4)
All others[f]	6 0.494 (1789)	55 0.451 (1720)	90.0 (76.9, 96.5)

Subgroup	TRADENAME N[a]=20,998 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=21,096 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
Country			
Argentina	15 1.012 (2600)	108 0.986 (2586)	86.5 (76.7, 92.7)
Brazil	12 0.406 (1311)	80 0.374 (1293)	86.2 (74.5, 93.1)
Germany	0 0.047 (236)	1 0.048 (242)	100.0 (-3874.2, 100.0)
South Africa	0 0.080 (291)	9 0.074 (276)	100.0 (53.5, 100.0)
Turkey	0 0.027 (228)	5 0.025 (222)	100.0 (-0.1, 100.0)
United States	50 4.674 (16,046)	647 4.497 (16,094)	92.6 (90.1, 94.5)

Notes: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting). Included confirmed cases in participants 12 through 15 years of age: 0 in the TRADENAME group; 16 in the placebo group.

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1,000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.
f. All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

Table 8. Vaccine Efficacy– First COVID-19 Occurrence From 7 Days After Dose 2 – Participants With or Without* Evidence of Infection Prior to 7 Days After Dose 2 by Demographic Characteristics – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period[54]

Subgroup	TRADENAME N[a]=22,166 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=22,320 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
Sex			
Male	44 3.376 (11,103)	411 3.181 (10,920)	89.9 (86.2, 92.8)
Female	37 3.133 (10,539)	462 3.093 (10,769)	92.1 (88.9, 94.5)
Ethnicity			
Hispanic or Latino	32 1.862 (5408)	245 1.794 (5391)	87.4 (81.8, 91.6)
Not Hispanic or Latino	48 4.615 (16,128)	628 4.445 (16,186)	92.6 (90.1, 94.6)
Race			
Black or African American	4 0.611 (1958)	49 0.601 (1985)	92.0 (78.1, 97.9)
White	69 5.379 (17,801)	768 5.191 (17,880)	91.3 (88.9, 93.3)
All others[f]	8 0.519 (1883)	56 0.481 (1824)	86.8 (72.1, 94.5)
Country			
Argentina	16 1.033 (2655)	110 1.017 (2670)	85.7 (75.7, 92.1)
Brazil	14 0.441 (1419)	82 0.408 (1401)	84.2 (71.9, 91.7)
Germany	0 0.047 (237)	1 0.048 (243)	100.0 (-3868.6, 100.0)
South Africa	0 0.099 (358)	10 0.096 (358)	100.0 (56.6, 100.0)
Turkey	0 0.029 (238)	6 0.026 (232)	100.0 (22.2, 100.0)
United States	51 4.861 (16,735)	664 4.678 (16,785)	92.6 (90.2, 94.6)

Notes: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting). Included confirmed cases in participants 12 through 15 years of age: 0 in the TRADENAME group; 18 in the placebo group.

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.
f. All others = American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

The subgroup analyses of vaccine efficacy by risk status in participants is presented in Table 9.

Table 9. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population[23]

Efficacy Endpoint Subgroup	TRADENAME N[a]=18,198 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=18,325 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2			
At risk[f]			
Yes	4 1.025 (8030)	86 1.025 (8029)	95.3 (87.7, 98.8)
No	4 1.189 (9381)	76 1.197 (9482)	94.7 (85.9, 98.6)
Age group (years) and at risk			
16 to 64 and not at risk	4 0.962 (7671)	69 0.964 (7701)	94.2 (84.4, 98.5)
16 to 64 and at risk	3 0.744 (5878)	74 0.746 (5917)	95.9 (87.6, 99.2)
≥65 and not at risk	0 0.227 (1701)	7 0.233 (1771)	100.0 (29.0, 100.0)
≥65 and at risk	1 0.281 (2147)	12 0.279 (2109)	91.7 (44.2, 99.8)
Obese[g]			
Yes	3 0.763 (6000)	67 0.782 (6103)	95.4 (86.0, 99.1)
No	5 1.451 (11,406)	95 1.439 (11,404)	94.8 (87.4, 98.3)

Efficacy Endpoint Subgroup	TRADENAME Na=18,198 Cases n1b Surveillance Timec (n2d)	Placebo Na=18,325 Cases n1b Surveillance Timec (n2d)	Vaccine Efficacy % (95% CIe)
Age group (years) and obese			
16 to 64 and not obese	4 1.107 (8811)	83 1.101 (8825)	95.2 (87.3, 98.7)
16 to 64 and obese	3 0.598 (4734)	60 0.609 (4789)	94.9 (84.4, 99.0)
≥65 and not obese	1 0.343 (2582)	12 0.338 (2567)	91.8 (44.5, 99.8)
≥65 and obese	0 0.165 (1265)	7 0.173 (1313)	100.0 (27.1, 100.0)

Abbreviations: BMI = body mass index; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

* Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. At risk is defined as having at least 1 of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥30 kg/m^2).
g. Obese is defined as BMI ≥30 kg/m^2.

The updated subgroup analyses of vaccine efficacy by risk status in participants followed up to 6 months after Dose 2 (with a cut-off date of 13 March 2021) are presented in Table 10 and Table 11.

Table 10. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants Without Evidence of Infection* Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period[55]

Subgroup	TRADENAME Na=20,998 Cases n1b Surveillance Timec (n2d)	Placebo Na=21,096 Cases n1b Surveillance Timec (n2d)	Vaccine Efficacy % (95% CI)e
First COVID-19 occurrence from 7 days after Dose 2f	77 6.247 (20,712)	850 6.003 (20,713)	91.3 (89.0, 93.2)

Subgroup	TRADENAME Na=20,998 Cases n1b Surveillance Timec (n2d)	Placebo Na=21,096 Cases n1b Surveillance Timec (n2d)	Vaccine Efficacy % (95% CI)e
At riskg			
Yes	35 2.797 (9167)	401 2.681 (9136)	91.6 (88.2, 94.3)
No	42 3.450 (11,545)	449 3.322 (11,577)	91.0 (87.6, 93.6)
Age group (years) and risk status			
16 through 64 and not at risk	41 2.776 (8887)	385 2.661 (8886)	89.8 (85.9, 92.8)
16 through 64 and at risk	29 2.083 (6632)	325 1.993 (6629)	91.5 (87.5, 94.4)
65 and older and not at risk	1 0.553 (1870)	53 0.546 (1922)	98.1 (89.2, 100.0)
65 and older and at risk	6 0.680 (2322)	71 0.656 (2304)	91.8 (81.4, 97.1)
Obeseh			
Yes	27 2.103 (6796)	314 2.050 (6875)	91.6 (87.6, 94.6)
No	50 4.143 (13,911)	536 3.952 (13,833)	91.1 (88.1, 93.5)
Age group (years) and obesity status			
16 through 64 and not obese	46 3.178 (10,212)	444 3.028 (10,166)	90.1 (86.6, 92.9)
16 through 64 and obese	24 1.680 (5303)	266 1.624 (5344)	91.3 (86.7, 94.5)
65 and older and not obese	4 0.829 (2821)	79 0.793 (2800)	95.2 (87.1, 98.7)
65 and older and obese	3 0.404 (1370)	45 0.410 (1426)	93.2 (78.9, 98.7)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

Subgroup	TRADENAME N[a]=20,998 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=21,096 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]

f. Included confirmed cases in participants 12 through 15 years of age: 0 in the TRADENAME group; 16 in the placebo group.
g. At risk is defined as having at least 1 of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥30 kg/m^2 or BMI ≥95th percentile [12 through 15 Years of age]).
h. Obese is defined as BMI ≥30 kg/m^2. For 12 through 15 years age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.

Table 11. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Participants With or Without* Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period[56]

Subgroup	TRADENAME N[a]=22,166 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=22,320 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
First COVID-19 occurrence from 7 days after Dose 2[f]	81 6.509 (21,642)	873 6.274 (21,689)	91.1 (88.8, 93.0)
At risk[g]			
Yes	36 2.925 (9601)	410 2.807 (9570)	91.6 (88.1, 94.2)
No	45 3.584 (12,041)	463 3.466 (12,119)	90.6 (87.2, 93.2)
Age group (years) and risk status			
16 through 64 and not at risk	44 2.887 (9254)	397 2.779 (9289)	89.3 (85.4, 92.4)
16 through 64 and at risk	30 2.186 (6964)	330 2.100 (6980)	91.3 (87.3, 94.2)
65 and older and not at risk	1 0.566 (1920)	55 0.559 (1966)	98.2 (89.6, 100.0)
65 and older and at risk	6 0.701 (2395)	73 0.672 (2360)	92.1 (82.0, 97.2)
Obese[h]			
Yes	28 2.207 (7139)	319 2.158 (7235)	91.4 (87.4, 94.4)
No	53 4.301 (14,497)	554 4.114 (14,448)	90.8 (87.9, 93.2)

Subgroup	TRADENAME N[a]=22,166 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=22,320 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
Age group (years) and obesity status			
16 through 64 and not obese	49 3.303 (10,629)	458 3.158 (10,614)	89.8 (86.2, 92.5)
16 through 64 and obese	25 1.768 (5584)	269 1.719 (5649)	91.0 (86.4, 94.3)
65 and older and not obese	4 0.850 (2899)	82 0.811 (2864)	95.3 (87.6, 98.8)
65 and older and obese	3 0.417 (1415)	46 0.420 (1462)	93.4 (79.5, 98.7)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Included confirmed cases in participants 12 to 15 years of age: 0 in the TRADENAME group; 18 in the placebo group.
g. At risk is defined as having at least 1 of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥30 kg/m^2 or BMI ≥95th percentile [12 through 15 years of age]).
h. Obese is defined as BMI ≥30 kg/m^2. For the 12 through 15 years of age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.

Efficacy against severe COVID-19 - after 2 doses

Secondary efficacy analyses suggested benefit of TRADENAME in preventing severe COVID-19.

As of 14 November 2020, efficacy against severe COVID-19 (as defined by the study protocol) occurring after the first dose was 88.9% (95% CI: 20.1, 99.7) (1 case in TRADENAME group and 9 cases in placebo group), with an estimated vaccine efficacy of 75.0% (95% CI: -152.6, 99.5) (1 case in TRADENAME group and 4 cases in placebo group) against severe COVID-19 occurring at least 7 days after Dose 2.[36] Efficacy against severe COVID-19, defined by the Centers for Disease Control and Prevention as hospitalization, admission to the Intensive Care Unit, intubation or mechanical ventilation, or death occurring after the first dose, was 92.9% (95% CI: 53.2, 99.8) (1 case in TRADENAME group and 14 cases in placebo group).[37]

As of 13 March 2021, vaccine efficacy against severe COVID-19 is presented only for participants with or without prior SARS-CoV-2 infection (Table 12) as the COVID-19 case counts in participants without prior SARS-CoV-2 infection were the same as those in participants with or without prior SARS-CoV-2 infection in both the TRADENAME and placebo groups.

Table 12. Vaccine Efficacy – First Severe COVID-19 Occurrence in Participants With or Without* Prior SARS-CoV-2 Infection Based on FDA† or Centers for Disease Control and Prevention (CDC)‡ Definition After Dose 1 or From 7 Days After Dose 2 in the Placebo-Controlled Follow-up

Vaccine Efficacy – First Severe COVID-19 Occurrence Based on FDA Definition[57,58]			
	TRADENAME Cases n1[a] Surveillance Time (n2[b])	**Placebo Cases n1[a] Surveillance Time (n2[b])**	**Vaccine Efficacy % (95% CI[c])**
After Dose 1[d]	1 8.439[e] (22,505)	30 8.288[e] (22,435)	96.7 (80.3, 99.9)
7 days after Dose 2[f]	1 6.522[g] (21,649)	21 6.404[g] (21,730)	95.3 (70.9, 99.9)
Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC Definition[59,60]			
	TRADENAME Cases n1[a] Surveillance Time (n2[b])	**Placebo Cases n1[a] Surveillance Time (n2[b])**	**Vaccine Efficacy % (95% CI[c])**
After Dose 1[d]	1 8.427[e] (22,473)	45 8.269[e] (22,394)	97.8 (87.2, 99.9)
7 days after Dose 2[f]	0 6.514[g] (21,620)	32 6.391[g] (21,693)	100 (88.0, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

† Severe illness from COVID-19 as defined by FDA is confirmed COVID-19 and presence of at least 1 of the following:[61]

- Clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths per minute, heart rate ≥125 beats per minute, saturation of oxygen ≤93% on room air at sea level, or ratio of arterial oxygen partial pressure to fractional inspired oxygen <300 mm Hg);
- Respiratory failure [defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation or extracorporeal membrane oxygenation (ECMO)];
- Evidence of shock (systolic blood pressure <90 mm Hg, diastolic blood pressure <60 mm Hg, or requiring vasopressors);
- Significant acute renal, hepatic, or neurologic dysfunction;
- Admission to an Intensive Care Unit;
- Death.

‡ Severe illness from COVID-19 as defined by CDC is confirmed COVID-19 and presence of at least 1 of the following:[61]

- Hospitalization;
- Admission to the Intensive Care Unit;

- Intubation or mechanical ventilation;
- Death.

a. n1 = Number of participants meeting the endpoint definition.
b. n2 = Number of participants at risk for the endpoint.
c. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.
d. Efficacy assessed based on the Dose 1 all-available efficacy (modified intention-to-treat) population that included all randomized participants who received at least 1 dose of study intervention.[62]
e. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
f. Efficacy assessed based on the evaluable efficacy (7 Days) population that included all eligible randomized participants who receive all dose(s) of study intervention as randomized within the predefined window, have no other important protocol deviations as determined by the clinician.[62]
g. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

Efficacy and immunogenicity in adolescents 12 to 15 years of age – after 2 doses

An analysis of Study 2 has been performed in adolescents 12 to 15 years of age up to a data cut-off date of 13 March 2021.

The vaccine efficacy information in adolescents 12 to 15 years of age is presented in Table 13.

Table 13. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, Without Evidence of Infection and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period, Adolescents 12 to 15 Years of Age Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 to 15 years of age without evidence of prior SARS-CoV-2 infection*,[46]			
	TRADENAME N[a]=1005 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=978 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
Adolescents 12 to 15 Years of Age	0 0.154 (1001)	16 0.147 (972)	100.0 (75.3, 100.0)

First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 to 15 years of age with or without* evidence of prior SARS-CoV-2 infection[47]			
	TRADENAME N[a]=1119 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=1110 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
Adolescents 12 to 15 Years of Age	0 0.170 (1109)	18 0.163 (1094)	100.0 (78.1, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

In Study 2 an analysis of SARS-CoV-2 neutralizing titers in a randomly selected subset of participants was performed to demonstrate non-inferior immune responses (within 1.5-fold) comparing adolescents 12 to 15 years of age to participants 16 through 25 years of age who had no serological or virological evidence of past SARS-CoV-2 infection. The immune response to TRADENAME in adolescents 12 to 15 years of age (n=190) was non-inferior to the immune response in participants 16 through 25 years of age (n=170), based on results for SARS-CoV-2 neutralizing titers at 1 month after Dose 2. The geometric mean titers (GMT) ratio of the adolescents 12 to 15 years of age group to the participants 16 through 25 years of age group was 1.76, with a 2-sided 95% CI of 1.47 to 2.10, meeting the 1.5-fold non-inferiority criterion (the lower bound of the 2-sided 95% CI for the geometric mean ratio [GMR] >0.67) which indicates a statistically greater response in the adolescents 12 to 15 years of age than that of participants 16 through 25 years of age.[48]

An updated efficacy analysis of Study 2 has been performed in approximately 2,260 adolescents 12 through 15 years of age evaluating confirmed COVID-19 cases accrued up to a data cut-off date of September 2, 2021, representing up to 6 months of follow-up after Dose 2 for participants in the efficacy population.[81]

The updated vaccine efficacy information in adolescents 12 through 15 years of age is presented in Table 14.

Table 14. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2: Without Evidence of Infection and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period, Adolescents 12 Through 15 Years of Age Evaluable Efficacy (7 Days) Population[81]

First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age without evidence of prior SARS-CoV-2 infection*			
	TRADENAME N[a]=1057 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=1030 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
Adolescents 12 through 15 years of age	0 0.343 (1043)	28 0.322 (1019)	100.0 (86.8, 100.0)
First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age with or without evidence of prior SARS-CoV-2 infection			
	TRADENAME N[a]=1119 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=1109 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
Adolescents 12 through 15 years of age	0 0.362 (1098)	30 0.345 (1088)	100.0 (87.5, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

Efficacy in children 5 through <12 years of age – after 2 doses

A descriptive efficacy analysis of Study 3 has been performed in 1,968 children 5 through <12 years of age without evidence of infection prior to 7 days after Dose 2. This analysis evaluated confirmed symptomatic COVID-19 cases accrued up to a data cut-off date of October 8, 2021.[82]

Table 15 presents the specific demographic characteristics in participants who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose.

Table 15. Demographics Characteristics – Participants Without Evidence of Infection Prior to 7 Days After Dose 2 – Phase 2/3 – 5 Through <12 Years of Age – Evaluable Efficacy Population[82]

	TRADENAME 10 mcg/dose (N[a]=1305) n[b] (%)	Placebo (N[a]=663) n[b] (%)
Sex		
Male	679 (52.0)	343 (51.7)
Female	626 (48.0)	320 (48.3)
Age at Vaccination		
Mean (SD)	8.2 (1.93)	8.1 (1.98)
Median	8.0	8.0
Min, max	(5, 11)	(5, 11)
Race		
White	1018 (78.0)	514 (77.5)
Black or African American	76 (5.8)	48 (7.2)
American Indian or Alaska Native	<1.0%	<1.0%
Asian	86 (6.6)	46 (6.9)
Native Hawaiian or other Pacific Islander	<1.0%	<1.0%
Other[c]	110 (8.4)	52 (7.8)
Ethnicity		
Hispanic or Latino	243 (18.6)	130 (19.6)
Not Hispanic or Latino	1059 (81.1)	533 (80.4)
Not reported	<1.0%	<1.0%
Comorbidities[d]		
Yes	262 (20.1)	133 (20.1)
No	1043 (79.9)	530 (79.9)

a. N = Number of participants in the specified group from the evaluable efficacy population with no evidence of SARS CoV-2 infection prior to 7 days after Dose 2. This value is the denominator for the percentage calculations. Evaluable efficacy population included all eligible randomized participants who received all vaccination(s) as randomized within the predefined window, had no other important protocol deviations as determined by the clinician.
b. n = Number of participants with the specified characteristic.
c. Includes multiracial and not reported.
d. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least 1 of the prespecified comorbidities based on MMWR 69(32);1081-1088 and/or obesity (BMI ≥95th percentile).

The descriptive vaccine efficacy results in children 5 through <12 years of age without evidence of prior SARS-CoV-2 infection are presented in Table 16. None of the cases accrued met criteria for severe COVID-19 or multisystem inflammatory syndrome in children (MIS-C). No cases of

COVID-19 were observed in either the vaccine group or the placebo group in participants with evidence of prior SARS-CoV-2 infection.[82]

Table 16. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2: Without Evidence of Infection Prior to 7 Days After Dose 2 – Phase 2/3 – Children 5 Through <12 Years of Age Evaluable Efficacy Population[82]

First COVID-19 occurrence from 7 days after Dose 2 in children 5 through <12 years of age without evidence of prior SARS-CoV-2 infection*			
	TRADENAME 10 mcg/dose N[a]=1305 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=663 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
Children 5 through 11 years of age	3 0.322 (1273)	16 0.159 (637)	90.7 (67.7, 98.3)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1,000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.

Immunogenicity in children 5 through <12 years of age – after 2 doses[73]

Study 3 is a Phase 1/2/3 study comprised of an open-label vaccine dose-finding portion (Phase 1) and a multicenter, multinational, randomized, saline placebo-controlled, observer-blind efficacy portion (Phase 2/3) that has enrolled participants 5 through <12 years of age.

In Study 3, an analysis of SARS-CoV-2 50% neutralizing titers (NT50) 1 month after Dose 2 in a randomly selected subset of participants demonstrated effectiveness by immunobridging of immune responses comparing children 5 through <12 years of age in the Phase 2/3 part of Study 3 to participants 16 through 25 years of age in the Phase 2/3 part of Study 2 who had no serological or virological evidence of past SARSCoV-2 infection up to 1 month after Dose 2, meeting the prespecified immunobridging criteria for both the GMR and the seroresponse difference with seroresponse defined as achieving at least 4-fold rise in SARS-CoV-2 NT50 from baseline (before Dose 1).

The ratio of the SARS-CoV-2 NT50 in children 5 through <12 years of age to that of young adults 16 through 25 years of age was 1.04 (2-sided 95% CI: 0.93, 1.18), as presented in Table 17.

Table 17. Summary of Geometric Mean Ratio for 50% Neutralizing Titer – Comparison of Children 5 Through <12 Years of Age (Study 3) to Participants 16 Through 25 Years of Age (Study 2) – Participants Without* Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population[73]

		TRADENAME			
		10 mcg/Dose 5 Through <12 Years n[a]=264	30 mcg/Dose 16 Through 25 Years n[a]=253	5 Through <12 Years/ 16 Through 25 Years	
Assay	Time Point[b]	GMT[c] (95% CI[c])	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])	Met Immunobridging Objective[e] (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)[f]	1 month after Dose 2	1197.6 (1106.1, 1296.6)	1146.5 (1045.5, 1257.2)	1.04 (0.93, 1.18)	Y

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

* Participants who had no serological or virological evidence (up to 1 month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and 1 month after Dose 2, SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 blood collection) and had no medical history of COVID-19 were included in the analysis.

a. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.

b. Protocol-specified timing for blood sample collection.

c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.

d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (Group 1[5 through <12 years of age] - Group 2 [16 through 25 years of age]) and the corresponding CI (based on the Student t distribution).

e. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67 and the point estimate of the GMR is ≥0.8.

f. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

Among participants without prior evidence of SARS-CoV-2 infection up to 1 month after Dose 2, 99.2% of children 5 through <12 years of age and 99.2% of participants 16 through 25 years of age had a seroresponse from before vaccination to 1 month after Dose 2. The difference in proportions of participants who had seroresponse between the 2 age groups (children – young adult) was 0.0% (2-sided 95% CI: -2.0%, 2.2%), as presented in Table 18.

Table 18. Difference in Percentages of Participants With Seroresponse – Participants Without* Evidence of Infection up to 1 Month After Dose 2 – Immunobridging Subset – Phase 2/3 – Comparison of 5 Through <12 Years of Age to Study 2 Phase 2/3 16 Through 25 Years of Age – Evaluable Immunogenicity Population[73]

		TRADENAME			
		Study 3 10 mcg/Dose 5 Through <12 Years N[a]=264	Study 2 30 mcg/Dose 16 Through 25 Years N[a]=253	5 Through <12 Years / 16 Through 25 Years	
Assay	Time Point[b]	n[c] (%) (95% CI[d])	n[c] (%) (95% CI[d])	Difference %[e] (95% CI[f])	Met Immunobridging Objective[g] (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)[h]	1 month after Dose 2	262 (99.2) (97.3, 99.9)	251 (99.2) (97.2, 99.9)	0.0 (-2.0, 2.2)	Y

Abbreviations: LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NT50 = 50% neutralizing titer 50; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Seroresponse is defined as achieving a ≥4-fold rise from baseline (before Dose 1). If the baseline measurement is below the LLOQ, a postvaccination assay result ≥4 × LLOQ is considered a seroresponse.

* Participants who had no serological or virological evidence (up to 1 month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and 1 month after Dose 2, SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2, and negative NAAT (nasal swab) at any unscheduled visit up to 1 month after Dose 2 blood collection) and had no medical history of COVID-19 were included in the analysis.

a. N = Number of participants with valid and determinate assay results both before vaccination and at 1 month after Dose 2. These values are the denominators for the percentage calculations.
b. Protocol-specified timing for blood sample collection.
c. n = Number of participants with seroresponse for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
e. Difference in proportions, expressed as a percentage (Group 1 [5 through <12 years of age] – Group 2 [16 through 25 years of age]).
f. 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
g. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the difference in proportions is greater than -10.0%.
h. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

Efficacy and immunogenicity in individuals 6 months through <5 years of age – 3-dose primary course[86]

A descriptive efficacy analysis was performed across the combined population of participants 6 months through <5 years of age based on cases confirmed among 992 participants in the TRADENAME group and 464 participants in the placebo group who received all 3 doses of study

intervention during the blinded follow-up period. The observed vaccine efficacy from at least 7 days after Dose 3 to the cutoff date (29 April 2022) was 80.3% (2-sided 95% CI: 13.9, 96.7) based on 3 cases in the TRADENAME group and 7 cases in the placebo group, adjusted for surveillance time (noting 2:1 randomization ratio).

Children 2 through 4 years of age – after 3 doses[86]

A descriptive efficacy analysis of Study 3 has been performed in participants 2 through 4 years of age. This analysis evaluated confirmed symptomatic COVID-19 cases accrued up to a data cutoff date of 29 April 2022.

Table 19 presents the specific demographic characteristics in participants 2 through 4 years of age who received 3 doses of TRADENAME (3 mcg modRNA) or placebo.

Table 19. Demographics Characteristics – Phase 2/3 – Participants 2 Through 4 Years of Age – Dose 3 All-Available Efficacy Population[99]

	TRADENAME 3 mcg/Dose (N[a]=606) n[b] (%)	**Placebo (N[a]=280) n[b] (%)**
Sex		
Male	290 (47.9)	124 (44.3)
Female	316 (52.1)	156 (55.7)
Age at Vaccination (years)		
Mean (SD)	2.9 (0.77)	2.9 (0.75)
Median	3.0	3.0
Min, max	(2, 4)	(2, 4)
Race		
White	455 (75.1)	219 (78.2)
Black or African American	29 (4.8)	13 (4.6)
American Indian or Alaska Native	0	2 (0.7)
Asian	64 (10.6)	26 (9.3)
Native Hawaiian or other Pacific Islander	1 (0.2)	0
Other[c]	57 (9.4)	20 (7.1)
Ethnicity		
Hispanic or Latino	77 (12.7)	36 (12.9)
Not Hispanic or Latino	528 (87.1)	244 (87.1)
Not reported	1 (0.2)	0
Comorbidities[d]		
Yes	71 (11.7)	42 (15.0)
No	535 (88.3)	238 (85.0)

Abbreviations: BMI = body mass, SD = standard deviation.

a. N = Number of participants in the specified group from the Dose 3 all-available efficacy population. This value is the denominator for the percentage calculations. Dose 3 all-available efficacy population included all randomized participants who received 3 doses of TRADENAME (3 mcg modRNA) or placebo.

b. n = Number of participants with the specified characteristic.
c. Includes multiracial and not reported.
d. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least 1 of the prespecified comorbidities based on Morbidity and Mortality Weekly Report 69(32);1081-1088 and/or obesity (BMI ≥95th percentile).

The descriptive vaccine efficacy results after Dose 3 in participants 2 through 4 years of age are presented in Table 20.

Table 20. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 3 - Phase 2/3 – Participants 2 Through 4 Years of Age – Dose 3 All-available Efficacy Population (Blinded Follow-up Period)[100]

	TRADENAME 3 mcg/Dose N[a]=606 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=280 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy (%) (95% CI[e])
First COVID-19 occurrence from 7 days after Dose 3	2 0.056 (481)	5 0.025 (209)	82.3 (-8.0, 98.3)

Abbreviation: VE = vaccine efficacy.
Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting; inability to eat/poor feeding).
a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 3 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Two-sided 95% confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

Additional evaluation of vaccine efficacy for cases confirmed at least 7 days after Dose 2 and before Dose 3 was performed. In the evaluable efficacy population in participants without prior evidence of SARS-CoV-2 infection before or during the vaccination regimen the observed vaccine efficacy from at least 7 days after Dose 2 and before Dose 3 was 35.9% (2-sided 95% CI: 11.0%, 53.7%). The vaccine efficacy in participants with or without prior evidence of SARS-CoV-2 infection before or during the vaccination regimen was similar.

Analysis of COVID-19 cases that excluded those involving coinfection with other respiratory pathogens did not meaningfully impact the estimated vaccine efficacy in this population.

Severe COVID-19 criteria (as described in the protocol, based on FDA definition and modified for children) were fulfilled for 7 cases (6 TRADENAME and 1 placebo) among participants 2 through 4 years of age, of which 5 of the 6 cases in the TRADENAME group fulfilled a single

criterion of increased heart rate or respiratory rate and 1 case in the placebo group fulfilled a single criterion of decreased peripheral oxygen saturation (88% on room air). None of the cases accrued met criteria for multisystem inflammatory syndrome in children (MIS-C).

Immunogenicity analyses have been performed in the immunobridging subset of 143 Study 3 participants 2 through 4 years of age without evidence of infection up to 1 month after Dose 3 based on a data cutoff date of 29 April 2022.

Table 21 presents the specific demographic characteristics in the studied evaluable immunogenicity population.

Table 21. Demographics Characteristics – Immunobridging Subset – Participants 2 Through 4 Years of Age (Study 3) and Participants 16 Through 25 Years of Age (Study 2) – Without Evidence of Infection -Evaluable Immunogenicity Population[101]

	TRADENAME 3 mcg/Dose 2 Through 4 Years of Age (N[a]=143) n[b] (%)	TRADENAME 30 mcg/Dose 16 Through 25 Years of Age (N[a]=170) n[b] (%)
Sex		
Male	63 (44.1)	79 (46.5)
Female	80 (55.9)	91 (53.5)
Age at Vaccination (years)		
Mean (SD)	2.7 (0.76)	21.2 (2.95)
Median	3.0	2.0
Min, max	(2, 4)	(16, 25)
Race		
White	99 (69.2)	130 (76.5)
Black or African American	8 (5.6)	15 (8.8)
American Indian or Alaska Native	0	3 (1.8)
Asian	16 (11.2)	13 (7.6)
Native Hawaiian or other Pacific Islander	0	1 (0.6)
Other[c]	20 (14.0)	8 (4.7)
Ethnicity		
Hispanic or Latino	16 (11.2)	51 (30.0)
Not Hispanic or Latino	126 (88.1)	119 (70.0)
Not reported	1 (0.7)	0

Note: Participants who had no serological or virological evidence (up to 1 month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at pre-Dose 1 and 1 month after Dose 2, SARS-CoV-2 not detected by NAAT [nasal swab] at pre-Dose 1 and pre-Dose 2, and negative NAAT [nasal swab] at any unscheduled visit up to 1 month after Dose 2 blood collection) and had no medical history of COVID-19 were included in the analysis.

a. N = Number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.

b. n = Number of participants with the specified characteristic.
c. Includes multiracial and not reported.

SARS-CoV-2 50% neutralizing antibody titers (NT50) were compared between an immunogenicity subset of Phase 2/3 participants 2 through 4 years of age from Study 3 at 1 month after the 3-dose primary course and a randomly selected subset from Study 2 (Phase 2/3) participants 16 through 25 years of age at 1 month after the 2-dose primary course, using a microneutralization assay against the reference strain (USA_WA1/2020). The primary immunobridging analyses compared the geometric mean titers (using a GMR) and the seroresponse (defined as achieving at least 4-fold rise in SARS-CoV-2 NT50 from before Dose 1) rates in the evaluable immunogenicity population of participants without evidence of prior SARS-CoV-2 infection up to 1 month after Dose 3 in participants 2 through 4 years of age and up to 1 month after Dose 2 in participants 16 through 25 years of age. The prespecified immunobridging criteria were met for both the GMR and the seroresponse difference (Table 22 and Table 23, respectively).

Table 22. SARS-CoV-2 GMTs (NT50) at 1 Month After Vaccination Course – Immunobridging Subset - Participants 2 Through 4 Years of Age (Study 3) 1 Month After Dose 3 and Participants 16 Through 25 Years of Age (Study 2) 1 Month After Dose 2 – Without Evidence of SARS-CoV-2 Infection – Evaluable Immunogenicity Population[102]

	TRADENAME		
	3 mcg/Dose 2 Through 4 Years of Age (1 month After Dose 3) n[a]=143	30 mcg/Dose 16 Through 25 Years of Age (1 Month After Dose 2) n[a]=170	GMR (95%CI) (2 Through 4 Years of Age/16 Through 25 Years of Age)[c,d]
Assay	GMT[b] (95% CI[b])	GMT[b] (95% CI[b])	
SARS-CoV-2 neutralization assay - NT50 (titer)[e]	1535.2 (1388.2, 1697.8)	1180.0 (1066.6, 1305.4)	1.30 (1.13, 1.50)

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants who had no serological or virological evidence [(up to 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood sample collection)] of past SARS-CoV-2 infection [i.e., N-binding antibody [serum] negative at Dose 1, Dose 3 (Study 3) and 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3), SARS-CoV-2 not detected by NAAT [nasal swab] at Dose 1, Dose 2, and Dose 3 (Study 3) study visits, and negative NAAT [nasal swab] at any unscheduled visit up to 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood collection] and had no medical history of COVID-19 were included in the analysis.
a. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
b. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.

c. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (2 to 4 years of age minus 16 to 25 years of age) and the corresponding CI (based on the Student t distribution).
d. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the GMR ratio is greater than 0.67 and the point estimate of the GMR is ≥0.8.
e. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

Table 23. Difference in Percentages of Participants With Seroresponse at 1 Month After Vaccination Course – Immunobridging Subset –Participants 2 Through 4 Years of Age (Study 3) 1 Month After Dose 3 and Participants 16 Through 25 Years of Age (Study 2) 1 Month After Dose 2 Without Evidence of Infection – Evaluable Immunogenicity Population[103]

	TRADENAME		
	3 mcg/Dose 2 Through 4 Years of Age (1 Month After Dose 3) N[a]=141	30 mcg/Dose 16 Through 25 Years of Age (1 Month After Dose 2) N[a]=170	Difference in Seroresponse Rates %[d] (95% CI[e]) (2 Through 4 Years of age Minus 16 Through 25 Years of Age)[f]
Assay	n[b] (%) (95% CI[c])	n[b] (%) (95% CI[c])	
SARS-CoV-2 neutralization assay - NT50 (titer)[g]	141 (100.0) (97.4, 100.0)	168 (98.8) (95.8, 99.9)	1.2 (-1.5, 4.2)

Abbreviations: LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NT50 = 50% neutralizing titer 50; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Seroresponse is defined as achieving a ≥4-fold rise from baseline (before Dose 1). If the baseline measurement is below the LLOQ, a postvaccination assay result ≥4 × LLOQ is considered a seroresponse.
Note: Participants who had no serological or virological evidence (up to 1 month after Dose 2 [(Study 2) or 1 month after Dose 3 (Study 3) blood sample collection)[of past SARS-CoV-2 infection [i.e., N-binding antibody [serum] negative at pre-Dose 1, pre-Dose 3 (Study 3) and 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3), SARS-CoV-2 not detected by NAAT [nasal swab] at pre-Dose 1, pre-Dose 2, and pre-Dose 3 (Study 3) study visits, and negative NAAT [nasal swab] at any unscheduled visit up to 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood collection] and had no medical history of COVID-19 were included in the analysis.
a. N = Number of participants with valid and determinate assay results both before vaccination and at 1 month after Dose 2. These values are the denominators for the percentage calculations.
b. n = Number of participants with seroresponse for the given assay at the given dose/sampling time point.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Difference in proportions, expressed as a percentage (2 through 4 years of age minus 16 through 25 years of age).
e. 2-sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
f. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the difference in proportions is greater than -10.0% provided that the immunobridging criteria based on GMR were met.
g. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

Using a non-validated fluorescence focus reduction neutralization test assay against the Omicron variant of SARS-CoV-2 (BA.1), the NT50 GMT at 1 month after Dose 3 among a subset of 34 study participants without evidence of prior SARS-CoV-2 infection (82.5 [2-sided 95% CI: 55.4, 122.9]) was increased compared to the NT50 GMT before Dose 3 (14.0 [2-sided 95% CI: 10.6, 18.5]).

An additional descriptive immunogenicity analysis was performed for participants 2 through 4 years of age who received a 3-dose course of TRADENAME in Study 3 (Phase 2/3), compared with a subset of participants 18 through 50 years of age in Study C4591017 (Phase 3) who had received a 2-dose primary course followed by a booster dose of TRADENAME 30 mcg. The comparator group (participants 18 through 50 years of age) in this analysis had a similar interval between TRADENAME Dose 2 and Dose 3 (median 13.0 weeks) as the participants 2 to 4 years of age (median 10.6 weeks). Among 34 participants 2 through 4 years of age without evidence of prior SARS-CoV-2 infection who received 3 doses of TRADENAME 3 mcg, neutralizing GMTs were 114.3 at 1-month post-Dose 3. Among 27 participants 18 through 50 years of age without evidence of prior SARS-CoV-2 infection who received 3 doses of TRADENAME 30 mcg, Omicron neutralizing GMTs were 164.2 at 1-month post-Dose 3.

Infants 6 through 23 months of age – after 3 doses[86]

A descriptive efficacy analysis of Study 3 has been performed in participants 6 through 23 months of age. This analysis evaluated confirmed symptomatic COVID-19 cases accrued up to a data cutoff date of 29 April 2022.

Table 24 presents the specific demographic characteristics in participants 6 through 23 months of age who received 3 doses of TRADENAME (3 mcg modRNA) or placebo.

Table 24. Demographics Characteristics – Phase 2/3 – Participants 6 Through 23 Months of Age – Dose 3 All-Available Efficacy Population[104]

	TRADENAME 3 mcg/Dose (N^a=386) n^b (%)	**Placebo (N^a=184) n^b (%)**
Sex		
Male	189 (49.0)	79 (42.9)
Female	197 (51.0)	105 (57.1)
Age at Vaccination (months)		
Mean (SD)	15.4 (4.92)	15.2 (5.14)
Median	16.0	15.5
Min, max	(6, 23)	(6, 23)

	TRADENAME 3 mcg/Dose (N[a]=386) n[b] (%)	Placebo (N[a]=184) n[b] (%)
Race		
White	290 (75.1)	136 (73.9)
Black or African American	10 (2.6)	11 (6.0)
American Indian or Alaska Native	1 (0.3)	0
Asian	42 (10.9)	17 (9.2)
Other[c]	43 (11.1)	20 (10.9)
Ethnicity		
Hispanic or Latino	40 (10.4)	13 (7.1)
Not Hispanic or Latino	344 (89.1)	169 (91.8)
Not reported	2 (0.5)	2 (1.1)
Comorbidities[d]		
Yes	17 (4.4)	9 (4.9)
No	369 (95.6)	175 (95.1)

Abbreviation: SD = standard deviation.

a. N = Number of participants in the specified group from the Dose 3 all-available efficacy population. This value is the denominator for the percentage calculations. Dose 3 all-available efficacy population included all randomized participants who received 3 doses of TRADENAME (3 mcg modRNA) or placebo.
b. n = Number of participants with the specified characteristic.
c. Includes multiracial and not reported.
d. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least 1 of the prespecified comorbidities based on Morbidity and Mortality Weekly Report 69(32);1081-1088.

The descriptive vaccine efficacy results after Dose 3 in participants 6 through 23 months of age are presented in Table 25.

Table 25. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 3 – Phase 2/3 – Participants 6 Through 23 Months of Age – Dose 3 All-available Efficacy Population (Blinded Follow-up Period)[105]

	TRADENAME 3 mcg/Dose N[a]=386 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=184 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy (%) (95% CI[e])
First COVID-19 occurrence from 7 days after Dose 3	1 0.030 (277)	2 0.015 (139)	75.5 (-370.1, 99.6)

Abbreviation: VE = vaccine efficacy.

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting; inability to eat/poor feeding).

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1,000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 3 to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Two-sided 95% confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

Additional evaluation of vaccine efficacy for cases confirmed at least 7 days after Dose 2 and before Dose 3 was performed. In the evaluable efficacy population in participants without prior evidence of SARS-CoV-2 infection before or during the vaccination regimen the observed vaccine efficacy from at least 7 days after Dose 2 and before Dose 3 was 16.1% (2-sided 95% CI: -24.9%, 43.1%). The vaccine efficacy in participants with or without prior evidence of SARS-CoV-2 infection before or during the vaccination regimen was similar.

Analysis of COVID-19 cases that excluded those involving coinfection with other respiratory pathogens did not meaningfully impact the estimated vaccine efficacy in this population.

One participant in the placebo group, had confirmed COVID-19 which met a single severe case criterion described in the protocol (increased heart rate [172 bpm]). None of the cases accrued met criteria for multisystem inflammatory syndrome in children (MIS-C).

Immunogenicity analyses have been performed in the immunobridging subset of 82 Study 3 participants 6 through 23 months of age without evidence of infection up to 1 month after Dose 3 based on a data cutoff date of 29 April 2022.

Table 26 presents the specific demographic characteristics in the studied evaluable immunogenicity population.

Table 26. Demographics Characteristics – Immunobridging Subset – Participants 6 Through 23 Months of Age (Study 3) and Participants 16 Through 25 Years of Age (Study 2) – Without Evidence of Infection -Evaluable Immunogenicity Population[106]

	TRADENAME 3 mcg/Dose 6 Through 23 Months of Age (N^a=82) n^b (%)	TRADENAME 30 mcg/Dose 16 Through 25 Years of Age (N^a=170) n^b (%)
Sex		
Male	51 (62.2)	79 (46.5)
Female	31 (37.8)	91 (53.5)
Age at Vaccination (years)		
Mean (SD)	15.7 (4.84)	21.2 (2.95)
Median	16.0	2.0
Min, max	(6, 23)	(16, 25)

	TRADENAME 3 mcg/Dose 6 Through 23 Months of Age (N[a]=82) n[b] (%)	TRADENAME 30 mcg/Dose 16 Through 25 Years of Age (N[a]=170) n[b] (%)
Race		
White	59 (72.0)	130 (76.5)
Black or African American	1 (1.2)	15 (8.8)
American Indian or Alaska Native	1 (1.2)	3 (1.8)
Asian	11 (13.4)	13 (7.6)
Native Hawaiian or other Pacific Islander	0	1 (0.6)
Other[c]	10 (12.2)	8 (4.7)
Ethnicity		
Hispanic or Latino	13 (15.9)	51 (30.0)
Not Hispanic or Latino	69 (84.1)	119 (70.0)

Note: Participants who had no serological or virological evidence (up to 1 month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at pre-Dose 1 and 1 month after Dose 2, SARS-CoV-2 not detected by NAAT [nasal swab] at pre-Dose 1 and pre-Dose 2, and negative NAAT [nasal swab] at any unscheduled visit up to 1 month after Dose 2 blood collection) and had no medical history of COVID-19 were included in the analysis.

a. N = Number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Includes multiracial and not reported.

SARS-CoV-2 50% neutralizing antibody titers (NT50) 1 month after the vaccination course were compared between an immunogenicity subset of Phase 2/3 participants 6 through 23 months of age from Study 3 and a randomly selected subset from Study 2 (Phase 2/3) participants 16 through 25 years of age, using a microneutralization assay against the reference strain (USA_WA1/2020). The primary immunobridging analyses compared the geometric mean titers (using a GMR) and the seroresponse (defined as achieving at least 4-fold rise in SARS-CoV-2 NT50 from before Dose 1) rates in the evaluable immunogenicity population of participants without evidence of prior SARS-CoV-2 infection up to 1 month after Dose 3 in participants 6 through 23 months of age and up to 1 month after Dose 2 in participants 16 through 25 years of age. The prespecified immunobridging criteria were met for both the GMR and the seroresponse difference (Table 27 and Table 28, respectively).

Table 27. SARS-CoV-2 GMTs (NT50) at 1 Month After Vaccination Course – Immunobridging Subset - Participants 6 Through 23 Months of Age (Study 3) 1 Month After Dose 3 and Participants 16 rough 25 Years of Age (Study 2) 1 Month After Dose 2 – Without Evidence of SARS-CoV-2 – Evaluable Immunogenicity Population[107]

	TRADENAME		
	3 mcg/Dose 6 Through 23 Months of Age (1 Month After Dose 3) n[a]=82	30 mcg/Dose 16 Through 25 Years of Age (1 Month After Dose 2) n[a]=170	GMR (95%CI) (6 Through 23 Months of Age/16 Through 25 Years of Age)[c,d]
Assay	GMT[b] (95% CI[b])	GMT[b] (95% CI[b])	
SARS-CoV-2 neutralization assay - NT50 (titer)[e]	1406.5 (1211.3, 1633.1)	1180.0 (1066.6, 1305.4)	1.19 (1.00, 1.42)

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Participants who had no serological or virological evidence [(up to 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood sample collection)] of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Dose 1, Dose 3 (Study 3) and 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3), SARS-CoV-2 not detected by NAAT [nasal swab] at Dose 1, Dose 2, and Dose 3 (Study 3) study visits, and negative NAAT [nasal swab] at any unscheduled visit up to 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood collection)] and had no medical history of COVID-19 were included in the analysis.

a. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.
b. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
c. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (6 through 23 months of age minus 16 through 25 years of age) and the corresponding CI (based on the Student t distribution).
d. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the GMR ratio is greater than 0.67 and the point estimate of the GMR is ≥0.8.
e. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

Table 28. Difference in Percentages of Participants With Seroresponse at 1 Month After Vaccination Course – Immunobridging Subset – Participants 6 Through 23 Months of Age (Study 3) 1 Month After Dose 3 and Participants 16 Through 25 Years of Age (Study 2) to 1 Month After Dose 2 Without Evidence of Infection – Evaluable Immunogenicity Population[108]

	TRADENAME		
	3 mcg/Dose 6 Through 23 Months of Age (1 Month After Dose 3) N[a]=80	30 mcg/Dose 16 Through 25 Years of Age (1 Month After Dose 2) N[a]=170	Difference in Seroresponse Rates %[d] (95% CI[e]) (6 Through 23 Months of Age Minus 16 Through 25 Years of Age)[f]
Assay	n[b] (%) (95% CI[c])	n[b] (%) (95% CI[c])	
SARS-CoV-2 neutralization assay - NT50 (titer)[g]	80 (100.0) (95.5, 100.0)	168 (98.8) (95.8, 99.9)	1.2 (-3.4, 4.2,)

Abbreviations: LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NT50 = 50% neutralizing titer 50; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Seroresponse is defined as achieving a ≥4-fold rise from baseline (before Dose 1). If the baseline measurement is below the LLOQ, a postvaccination assay result ≥4 × LLOQ is considered a seroresponse.

Note: Participants who had no serological or virological evidence [(up to 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood sample collection) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at pre-Dose 1, Dose 3 (Study 3) and 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3), SARS-CoV-2 not detected by NAAT [nasal swab] at pre-Dose 1, pre-Dose 2, and pre-Dose 3 (Study 3) study visits, and negative NAAT [nasal swab] at any unscheduled visit up to 1 month after Dose 2 (Study 2) or 1 month after Dose 3 (Study 3) blood collection)] and had no medical history of COVID-19 were included in the analysis.

a. N = Number of participants with valid and determinate assay results both before vaccination and at 1 month after Dose 2. These values are the denominators for the percentage calculations.
b. n = Number of participants with seroresponse for the given assay at the given dose/sampling time point.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Difference in proportions, expressed as a percentage (6 through 23 months of age minus 16 through 25 years of age).
e. 2-sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.
f. Immunobridging is declared if the lower bound of the 2-sided 95% CI for the difference in proportions is greater than -10.0% provided that the immunobridging criteria based on GMR were met.
g. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

Using a non-validated fluorescence focus reduction neutralization test assay against the Omicron variant of SARS-CoV-2 (BA.1), the NT50 GMT at 1 month after Dose 3 among a subset of 32 study participants without evidence of prior SARS-CoV-2 infection (127.5 [2-sided 95% CI: 90.2, 180.1]) was increased compared to the NT50 GMT before Dose 3 (16.3 [2-sided 95% CI: 12.8, 20.8]).

An additional descriptive immunogenicity analysis was performed for participants 6 through 23 months of age who received a 3-dose course of TRADENAME in Study 3 (Phase 2/3), compared with a subset of participants 18 through 50 years of age in Phase 3 Study C4591017 who had received a 2-dose primary course followed by a booster dose of TRADENAME 30 mcg. The comparator group (participants 18 through 50 years of age) in this analysis had a similar interval between TRADENAME Dose 2 and Dose 3 (median 13.0 weeks) as the participants 6 through 23 months of age (median 12.9 weeks). Among 32 participants 6 through 23 months of age without evidence of prior SARS-CoV-2 infection who received 3 doses of TRADENAME 3 mcg, Omicron neutralizing GMTs were 128.8 at 1-month post-Dose 3. Among 27 participants 18 through 50 years of age without evidence of prior SARS-CoV-2 infection who received 3 doses of TRADENAME 30 mcg, Omicron neutralizing GMTs were 164.2 at 1-month post-Dose 3.

Immunogenicity in participants 18 years of age and older – after booster dose[71]

Effectiveness of a booster dose of TRADENAME was demonstrated by evaluating noninferiority immune responses of SARS-CoV-2 NT50 1 month after a booster dose. In Study 2, an analysis of SARS-CoV-2 NT50 demonstrated non-inferior immune responses 1 month after a booster dose compared to 1 month after Dose 2 in participants at least 18 through 55 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster dose, based on prespecified noninferiority criteria for both GMR and difference in seroresponse rates. Seroresponse for a participant was defined as achieving a ≥4-fold rise from baseline (before Dose 1) in NT50 (Table 29 and Table 30).

The SARS-CoV-2 NT50 GMR of 1 month after the booster dose to 1 month after Dose 2 was 3.26 (2-sided 97.5% CI: 2.76, 3.86), which met the noninferiority criteria for GMR (lower bound of the 2-sided 97.5% CI >0.67 and point estimate of the GMR ≥0.8).

A high proportion of participants (99.5%) had seroresponse 1 month after Dose 3 compared with 95.0% 1 month after Dose 2. The difference in proportions of participants with a seroresponse 1 month after the booster dose (Dose 3) and 1 month after Dose 2 (Dose 3 minus Dose 2) was 1.5% (2-sided 97.5% CI: 1.0%, 7.9%), which met the 10% noninferiority criterion (i.e., lower bound of the 2-sided 97.5% CI >10%).

Table 29. Summary of Geometric Mean Ratio for 50% Neutralizing Titer – Comparison of 1 Month After Booster Dose to 1 Month After Dose 2 – Participants Without Evidence of Infection up to 1 Month After Booster Dose* – Booster Dose Evaluable Immunogenicity Population±,71,109,110

		TRADENAME Sampling Time Point			
		1 Month After Booster Dose	1 Month After Dose 2	1 Month After Booster Dose - 1 Month After Dose 2	Met Noninferiority Objective[d] (Y/N)
Assay	n[a]	GMT[b] (95% CI[b])	GMT[b] (95% CI[b])	GMR[c] (97.5% CI[c])	
SARS-CoV-2 neutralization assay - reference strain - NT50 (titer)[e]	212	2466.0 (2202.6, 2760.8)	755.7 (663.1, 861.2)	3.26 (2.76, 3.86)	Y

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Y/N = yes/no.

* Participants who had no serological or virological evidence (up to 1 month after receipt of a booster dose of TRADENAME) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative and SARS-CoV-2 not detected by NAAT [nasal swab]) and had a negative NAAT [nasal swab] at any unscheduled visit up to 1 month after the booster dose were included in the analysis.

± All eligible participants who had received 2 doses of TRADENAME as initially randomized, with Dose 2 received within the predefined window (within 19 to 42 days after Dose 1), received a booster dose of TRADENAME, had at least 1 valid and determinate immunogenicity result after booster dose from a blood collection within an appropriate window (within 28 to 42 days after the booster dose), and had no other important protocol deviations as determined by the clinician.

a. n = Number of participants with valid and determinate assay results at both sampling time points within specified window.

b. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.

c. GMRs and 2-sided 97.5% CIs were calculated by exponentiating the mean differences in the logarithms of the assay and the corresponding CIs (based on the Student t distribution).

d. Noninferiority is declared if the lower bound of the 2-sided 97.5% CI for the GMR is >0.67 and the point estimate of the GMR is ≥0.80.

e. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

Table 30. Percentage Difference of Participants Achieving Seroresponse – Comparison of 1 Month After Booster Dose to 1 Month After Dose 2 – Phase 3 – Participants Without Evidence of Infection up to 1 Month After Booster Dose* – Booster Dose Evaluable Immunogenicity Population±,71,110,111

Assay	N[a]	TRADENAME Sampling Time Point: 1 Month After Booster Dose n[b] % (95% CI[c])	TRADENAME Sampling Time Point: 1 Month After Dose 2 n[b] % (95% CI[c])	Difference (1 Month After Booster Dose - 1 Month After Dose 2) %[d] (97.5% CI[e])	Met Noninferiority Objective[f] (Y/N)
SARS-CoV-2 neutralization assay - reference strain - NT50 (titer)[g]	200	199 99.5 (97.2, 100.0)	190 95.0 (91.0, 97.6)	4.5 (1.0, 7.9)	Y

Abbreviations: CI = confidence interval; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Y/N = yes/no.

Note: Seroresponse is defined as achieving a ≥4-fold rise from baseline (before Dose 1). If the baseline measurement is below the LLOQ, a postvaccination assay result ≥4 × LLOQ is considered a seroresponse.

* Participants who had no serological or virological evidence (up to 1 month after receipt of booster dose) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative and SARS-CoV-2 not detected by NAAT [nasal swab]) and had a negative NAAT (nasal swab) at any unscheduled visit up to 1 month after booster dose were included in the analysis.

± All eligible participants who had received 2 doses of TRADENAME as initially randomized, with Dose 2 received within the predefined window (within 19 to 42 days after Dose 1), received a booster dose of TRADENAME, had at least 1 valid and determinate immunogenicity result after booster dose from a blood collection within an appropriate window (within 28 to 42 days after the booster dose), and had no other important protocol deviations as determined by the clinician.

a. N = Number of participants with valid and determinate assay results for the specified assay at baseline, 1 month after Dose 2 and 1 month after the booster dose within specified window. These values are the denominators for the percentage calculations.

b. n = Number of participants with seroresponse for the given assay at the given dose/sampling time point.

c. Exact 2-sided CI based on the Clopper and Pearson method.

d. Difference in proportions, expressed as a percentage (1 month after booster dose – 1 month after Dose 2).

e. Adjusted Wald 2-sided CI for the difference in proportions, expressed as a percentage.

f. Noninferiority is declared if the lower bound of the 2-sided 97.5% CI for the percentage difference is >-10%.

g. SARS-CoV-2 NT50 were determined using the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay. The assay uses a fluorescent reporter virus derived from the USA_WA1/2020 strain and virus neutralization is read on Vero cell monolayers. The sample NT50 is defined as the reciprocal serum dilution at which 50% of the virus is neutralized.

Relative vaccine efficacy in participants 16 years of age and older – after booster dose[80,112,113]

An interim efficacy analysis of Study 4, a placebo-controlled booster study, was performed in approximately 10,000 participants 16 years of age and older who were recruited from Study 2, evaluated confirmed COVID-19 cases accrued from at least 7 days after booster vaccination up to a data cut-off date of 8 February 2022 (a period when Delta and then Omicron was the predominant variant), which represents a median of 2.8 months (range 0.3 to 7.5 months) post-booster follow-up. Vaccine efficacy of the TRADENAME booster dose after the primary series relative to the placebo booster group who only received the primary series dose was

assessed. The relative vaccine efficacy information for participants 16 years of age and older is presented in Table 31.

Table 31. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination – Participants 16 Years of Age and Older Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population[80,114,115]

First COVID-19 occurrence from 7 days after booster dose in participants without evidence of prior SARS-CoV-2 infection*			
	TRADENAME N[a]=4689 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=4664 Cases n1[b] Surveillance Time[c] (n2[d])**	**Relative Vaccine Efficacy[e] % (95% CI[f])**
First COVID-19 occurrence from 7 days after booster vaccination	63 1.098 (4639)	148 0.932 (4601)	63.9 (51.1, 73.5)
First COVID-19 occurrence from 7 days after booster dose in participants with or without evidence of prior SARS-CoV-2 infection			
	TRADENAME N[a]=4997 Cases n1[b] Surveillance Time[c] (n2[d])	**Placebo N[a]=4942 Cases n1[b] Surveillance Time[c] (n2[d])**	**Relative Vaccine Efficacy[e] % (95% CI[f])**
First COVID-19 occurrence from 7 days after booster vaccination	67 1.179 (4903)	150 0.989 (4846)	62.4 (49.5, 72.2)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no serological or virological evidence (prior to 7 days after receipt of the booster vaccination) of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1, and had a negative NAAT [nasal swab] at any unscheduled visit prior to 7 days after booster vaccination) were included in the analysis.

a. N = Number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. Relative vaccine efficacy of the TRADENAME booster group relative to the placebo group (non-booster).
f. Two-sided confidence interval (CI) for relative vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time.

Immunogenicity in children 5 through <12 years of age – after booster dose[84]

Effectiveness of a booster dose of TRADENAME was based on an assessment of NT50 against the reference strain of SARS-CoV-2 (USA_WA1/2020). Analyses of NT50 1 month after the booster dose compared to before the booster dose (Dose 3) demonstrated a substantial increase in GMTs in individuals 5 through <12 years of age who had no serological or virological evidence of past SARS-CoV-2 infection up to 1 month after the booster dose. This analysis is summarized in Table 32.

Table 32. Summary of Geometric Mean Titers – NT50 – Participants Without Evidence of Infection – Phase 2/3 – Immunogenicity Set – 5 Through <12 Years of Age – Evaluable Immunogenicity Population

		TRADENAME 10 mcg/Dose					
		3-Dose Set		2-Dose Set		Total	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1 month Prevax	79	20.5 (20.5, 20.5)	67	20.5 (20.5, 20.5)	146	20.5 (20.5, 20.5)
	1 month after Dose 2	29	1659.4 (1385.1, 1988.0)	67	1110.7 (965.3, 1278.1)	96	1253.9 (1116.0, 1408.9)
	3 months Prevax	67	271.0 (229.1, 320.6)	-	-	67	271.0 (229.1, 320.6)
	1 month after Dose 3	67	2720.9 (2280.1, 3247.0)	-	-	67	2720.9 (2280.1, 3247.0)

Abbreviations: CI = confidence interval; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NT50 = 50% neutralizing titer; Prevax = before vaccination; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Three-dose immunogenicity set included the first 130 participants who received Dose 3 and completed 1-month post–Dose 3 visit prior to March 15, 2022. Among those, 30 had blood sample collection at 1-month post-Dose 2. Two-dose immunogenicity set included an extra 67 participants randomly selected from previous Dose-2 evaluable immunogenicity population and without evidence of infection up to 1-month post–Dose 2 subset used for 2-dose immunobridging analysis.
Note: Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection up to the 1-month post–Dose 2 (for 1-month post–Dose 2 time point) or 1-month post–Dose 3 (for pre–Dose 3 and 1-month post–Dose 3 time point) study blood sample collection. Having no evidence of past SARS-CoV-2 infection up to 1-month post–Dose 2 was defined as having a negative N-binding antibody (serum) result at the Dose 1 and 1-month post–Dose 2 study visits; a negative NAAT (nasal swab) result at the Dose 1 and Dose 2 study visits and any unscheduled visit prior to the 1-month post–Dose 2 blood sample collection; and no medical history of COVID-19. Having no evidence of past SARS-CoV-2 infection up to 1-month post-Dose 3 was defined as having a negative N-binding antibody (serum) result at the Dose 1, 1-month post–Dose 2 (if available), Dose 3, and 1-month post–Dose 3 study visits; a negative NAAT (nasal swab) result at the Dose 1, Dose 2, and Dose 3 study visits and any unscheduled visit prior to the 1-month post–Dose 3 blood sample collection; and no medical history of COVID-19.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given dose/sampling time point.

c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.

Immunogenicity in children 5 through <12 years of age on the Omicron variant – after booster dose[84]

The neutralizing GMTs against both the Omicron variant and reference strain were substantially increased after booster vaccination compared with after the 2-dose primary series. At 1-month post-Dose 2, the observed neutralizing GMTs for the Omicron variant and reference strain were 27.6 and 323.8, respectively. At 1-month post-Dose 3, the observed neutralizing GMTs for the Omicron variant and reference strain were 614.4 and 1702.8, respectively (see Table 33).

For the Omicron variant, neutralizing titers after booster vaccination (1-month post-Dose 3) increased 22-fold over those after the 2-dose primary series (1-month post-Dose 2). For the reference strain, the increase after the booster relative to the primary series was 5.3-fold.

Table 33. Summary of Geometric Mean Titers – Omicron-Neutralization Subset – Participants Without Evidence of Infection – Phase 2/3 – Immunogenicity Set – 5 Through <12 Years of Age – Evaluable Immunogenicity Population

		TRADENAME 10 mcg/Dose	
		Vaccine Group (as Randomized)	
Assay	Time Point[b]	n[b]	GMT[c] (95% CI[c])
SARS-COV-2 FFRNT- B.1.1.529 strain (Omicron) - NT50 (titer)	1 month after Dose 2	29	27.6 (22.1, 34.5)
	1 month after Dose 3	17	614.4 (410.7, 919.2)
SARS-CoV-2 FFRNT- reference strain - NT50 (titer)	1 month after Dose 2	29	323.8 (267.5, 392.1)
	1 month after Dose 3	17	1702.8 (1282.6, 2260.7)

Abbreviations: CI = confidence interval; FFRNT = fluorescence focus reduction neutralization test; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection up to the 1-month post–Dose 2 (for 1-month post–Dose 2 time point) or 1-month post–Dose 3 (for 1-month post–Dose 3 time point) study blood sample collection. Having no evidence of past SARS-CoV-2 infection up to 1-month post–Dose 2 was defined as having a negative N-binding antibody (serum) result at the Dose 1 and 1-month post–Dose 2 study visits; a negative NAAT (nasal swab) result at the Dose 1 and Dose 2 study visits and any unscheduled visit prior to the 1-month post–Dose 2 blood sample collection; and no medical history of COVID-19. Having no evidence of past SARS-CoV-2 infection up to 1-month post–Dose 3 was defined as having a negative N-binding antibody (serum) result at the Dose 1, 1-month post–Dose 2 (if available), Dose 3, and 1-month post–Dose 3 study visits; a negative NAAT (nasal swab) result at the Dose 1, Dose 2, and Dose 3 study visits and any unscheduled visit prior to the 1-month post–Dose 3 blood sample collection; and no medical history of COVID-19.

a. Protocol-specified timing for blood sample collection.

b. n = Number of participants with valid and determinate assay results for the specified assays at the given dose/sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.

Omicron-adapted TRADENAME

The efficacy of a booster dose of TRADENAME (Bivalent) is inferred from clinical data from the studies of a booster dose of an Omicron BA.1 adapted vaccine.

Immunogenicity in participants greater than 55 years of age – after a booster dose of TRADENAME (Bivalent, Original/Omicron BA.1) (fourth dose)

In an analysis of a subset from Study 4 (Substudy E), 610 adults greater than 55 years of age who had completed a series of 3 doses of TRADENAME received 1 of the following as a booster dose (fourth dose): TRADENAME (30 mcg) or TRADENAME (Bivalent, Original/Omicron BA.1) 15/15 mcg.[140] GMRs and seroresponse rates were evaluated at 1 month after TRADENAME (Bivalent, Original/Omicron BA.1)15/15 mcg booster vaccination.[141] TRADENAME (Bivalent, Original/Omicron BA.1) 15/15 mcg booster dose was administered 4.7 to 11.5 months (median 6.3 months) after the third dose.[140]

The primary objective of the analysis was to assess superiority with respect to level of neutralizing titer and noninferiority with respect to seroresponse rate of the anti-Omicron immune response induced by a dose of TRADENAME (Bivalent, Original/Omicron BA.1) 15/15 mcg relative to the response elicited by a dose of TRADENAME (30 mcg) given as a fourth dose in TRADENAME-experienced participants greater than 55 years of age.

Superiority of TRADENAME (Bivalent, Original/Omicron BA.1) 15/15 mcg to TRADENAME (30 mcg) was met, as the lower bound of the 2-sided 95% CI for GMR was >1 (Table 34).[142]

The difference in proportions of participants who achieved seroresponse between the Omicron BA.1 (15/15 mcg) group and TRADENAME (30 mcg) group was 14.6 (2-sided 95% CI: 4.0, 24.9). Noninferiority was met, as the lower limit of the 2-sided 95% CI for the difference in percentages of participants with seroresponse was >-5% (Table 35).[143,154]

Table 34: Substudy E - Geometric Mean Ratios for Between Vaccine Group Comparison – Participants Without Evidence of Infection Up to 1 Month after Dose 4 – Expanded Cohort – Immunogenicity Subset – Participants Greater Than 55 Years of Age – Evaluable Immunogenicity Population[144]

Assay	Vaccine Group (as randomized)	Sampling Time Point[a]	N[b]	GMT (95% CI[c])	GMR (95% CI[d])
SARS-CoV-2 neutralization assay - Omicron BA.1 - NT50 (titer)	TRADENAME (30 mcg)	1 month	163	455.8 (365.9, 567.6)	
	TRADENAME(Bivalent) BA.1 (15/15 mcg)	1 month	178	711.0 (588.3, 859.2)	1.56 (1.17, 2.08)

Abbreviations: GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Immunogenicity subset = a random sample of 230 participants in each vaccine group selected from the expanded cohort.
Note: Participants who had no serological or virological evidence (prior to the 1-month post–study vaccination blood sample collection) of past SARS-CoV-2 infection (i.e. N-binding antibody [serum] result negative at the study vaccination and the 1-month post–study vaccination visits, negative NAAT [nasal swab] result at the study vaccination visit, and any unscheduled visit prior to the 1-month post–study vaccination blood sample collection) and had no medical history of COVID-19 were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (vaccine group in the corresponding row - Comirnaty [30 mcg]) and the corresponding CI (based on the Student t distribution).

Table 35: Substudy E - Number (%) of Participants Achieving Seroresponse – Participants Without Evidence of Infection Up to 1 Month after Dose 4 – Expanded Cohort – Immunogenicity Subset – Participants Greater Than 55 Years of Age – Evaluable Immunogenicity Population[145]

Assay	Vaccine Group (as randomized)	Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	Difference %[e] (95% CI[f])
SARS-CoV-2 neutralization assay - Omicron BA.1 - NT50 (titer)	TRADENAME (30 mcg)	1 month	149	85 (57.0) (48.7, 65.1)	
	TRADENAME (Bivalent BA.1) (15/15 mcg)	1 month	169	121 (71.6) (64.2, 78.3)	14.6 (4.0, 24.9)

Abbreviations: LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Immunogenicity subset = a random sample of 230 participants in each vaccine group selected from the expanded cohort.
Note: Seroresponse is defined as achieving ≥4-fold rise from baseline (before the study vaccination). If the baseline measurement is below the LLOQ, the postvaccination measure of ≥4 × LLOQ is considered a seroresponse.
Note: Participants who had no serological or virological evidence (prior to the 1-month post–study vaccination blood sample collection) of past SARS-CoV-2 infection (i.e. N-binding antibody [serum] result negative at the study vaccination and the 1-month post–study vaccination visits, negative NAAT [nasal swab] result at the study vaccination visit, and any unscheduled visit prior to the 1-month post–study vaccination blood sample collection) and had no medical history of COVID-19 were included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. N = Number of participants with valid and determinate assay results for the specified assay at both the pre-vaccination time point and the given sampling time point. This value is the denominator for the percentage calculation.
c. n = Number of participants with seroresponse at 1 month after vaccination for the given assay.
d. Exact 2-sided CI based on the Clopper and Pearson method.
e. Difference in proportions, expressed as a percentage (vaccine group in the corresponding row - Comirnaty [30 mcg]).
f. Two-sided CI based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.

Immunogenicity in participants 18 to ≤55 years of age – after a booster dose of TRADENAME or monovalent Omicron BA.1 (fourth dose)

In Substudy D [a subset from Study 2 (Phase 3) and Study 4 (Phase 3)], 640 participants 18 to ≤55 years of age who had completed 3 doses of TRADENAME received 1 of the following as a booster (fourth dose):[146,147] TRADENAME (30 mcg) or monovalent Omicron BA.1 90 to 180 days after receiving Dose 3.[147]

In the primary immunogenicity subset of participants without prior evidence of infection up to 1 month after Dose 4, the ratio of GMTs for the monovalent Omicron BA.1 group to the TRADENAME group GMR was 1.75 (2-sided 95% CI: 1.39, 2.22) (Table 36).[148]

The lower bound of the 2-sided 95% CI for GMR was >1, which meets the prespecified simple superiority criterion. Therefore, superiority of monovalent Omicron BA.1 to TRADENAME for the Omicron variant was achieved based on the GMR at 1 month after Dose 4.[148]

The difference in proportions of participants who achieved seroresponse between the monovalent Omicron BA.1 group and TRADENAME group was 23.0% (2-sided 95% CI: 11.1, 34.3)[149] (Table 37), the noninferiority criterion (lower bound of the 2-sided 95% CI >-5)[150] was achieved.

Table 36: Substudy D – Geometric Mean Ratios for Between Vaccine Group Comparison - Cohort 2 - Primary Immunogenicity Subset - Participants Without Evidence of Infection Up to 1 Month After Dose 4 - Evaluable Immunogenicity Population[151]

		Vaccine Group (as randomized)				
		Monovalent Omicron BA.1 (30 mcg)		TRADENAME (30 mcg)		Monovalent Omicron BA.1 / TRADENAME
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT[c] (95% CI[c])	n[b]	GMT[c] (95% CI[c])	GMR[d] (95% CI)[d]
SARS-CoV-2 neutralization assay - Omicron BA.1 - NT50 (titer)	1/1 month	132	1929.2 (1631.5, 2281.1)	141	1099.6 (932.0, 1297.4)	1.75 (1.39, 2.22)

Abbreviations: GMT = geometric mean titer; GMR = geometric mean ratio; LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Primary immunogenicity subset = a random sample of 175 participants in each vaccine group selected from the full expanded set.

Note: Participants who had no serological or virological evidence (prior to the 1-month post–first study vaccination blood sample collection) of past SARS-CoV-2 infection (i.e. N-binding antibody [serum] negative at the first study vaccination and the 1-month post–first study vaccination visits, negative NAAT [nasal swab] at the first study vaccination visit, and any unscheduled visit prior to the 1-month post–first study vaccination blood sample collection) and had no medical history of COVID-19 were included in the analysis.

a. Protocol-specified timing for blood sample collection.
b. n = Number of participants with valid and determinate assay results for the specified assay at the given sampling time point.
c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (monovalent Omicron BA.1 [30 mcg] - Comirnaty [30 mcg]) and the corresponding CI (based on the Student t distribution).

Table 37: Substudy D – Difference in Percentages of Participants With Seroresponse - Cohort 2 – Primary Immunogenicity Subset - Participants Without Evidence of Infection Up to 1 Month After Dose 4 - Evaluable Immunogenicity Population[149]

		Vaccine Group (as randomized)				
		Monovalent Omicron BA.1 (30 mcg)		TRADENAME (30 mcg)		Difference
Assay	Dose/Sampling Time Point[a]	N[a]	n[b] (%) (95% CI[c])	N[a]	n[b] (%) (95% CI[c])	%[d] (95% CI[e])
SARS-CoV-2 neutralization assay - Omicron BA.1 - NT50 (titre)	1/1 month	130	81 (62.3) (53.4, 70.7)	140	55 (39.3) (31.1, 47.9)	23.0 (11.1, 34.3)

Abbreviations: LLOQ = lower limit of quantitation; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Seroresponse is defined as achieving a ≥ 4-fold rise from baseline (before the first dose of study vaccination). If the baseline measurement is below the LLOQ, the postvaccination measure of ≥4 × LLOQ is considered seroresponse.
Note: Primary immunogenicity subset = a random sample of 175 participants in each vaccine group selected from the full expanded set.
Note: Participants who had no serological or virological evidence (prior to the 1-month post–first study vaccination blood sample collection) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at the first study vaccination and the 1-month post–first study vaccination visits, negative NAAT [nasal swab] at the first study vaccination visit, and any unscheduled visit prior to the 1-month post–first study vaccination blood sample collection) and had no medical history of COVID-19 were included in the analysis.
a. N = Number of participants with valid and determinate assay results for the specified assay at both the pre-vaccination time point and the given sampling time point. This value is the denominator for the percentage calculations.
b. n = Number of participants with seroresponse for the given assay at the given sampling time point.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Difference in proportions, expressed as a percentage (monovalent Omicron BA.1 [30 mcg] - Comirnaty [30 mcg]).
e. 2-sided CI based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeat dose toxicity and reproduction and developmental toxicity.[10,11]

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients[2,3,74,116]

*[Editorial Guidance for countries: Select this text for the **PBS/Sucrose presentation, 30 micrograms/dose.**]*

TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap

(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)

1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
Cholesterol
Potassium chloride
Potassium dihydrogen phosphate
Sodium chloride
Disodium hydrogen phosphate dihydrate
Sucrose
Water for injections

*[Editorial Guidance for countries: Select this text for the **Tris/Sucrose presentation, 30 micrograms/dose.]***

TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap

Or

*[Editorial Guidance for countries: Select this text for the **Tris/Sucrose presentation, 10 micrograms/dose.]***

TRADENAME (for age 5 years to <12 years), orange cap

Or

*[Editorial Guidance for countries: Select this text for the **Tris/Sucrose presentation, 3 micrograms/dose.]***

TRADENAME (for age 6 months to <5 years), maroon cap

Or

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 15/15 micrograms/dose**.]*

TRADENAME (Bivalent) (for age 12 years and older), grey cap

Or

*[Editorial Guidance for countries: Select this text for the **Bivalent (Original/Omicron presentation, 5/5 micrograms/dose**.]*

TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap

((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
Cholesterol

Tromethamine
Tromethamine hydrochloride
Sucrose
Water for injections

6.2. Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in Sections 6.3 and 6.6.

6.3. Shelf life

*[Editorial Guidance for countries: Select this text for the **PBS/Sucrose presentation, 30 micrograms/dose**.]*

TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap

Unopened vial

15 months at -90 °C to -60 °C.[63,70,83,157]

Alternatively, unopened vials may be stored and transported at -25 °C to -15 °C for a total of 2 weeks and can be returned to -90 ºC to -60 ºC; not exceeding the printed expiry date (EXP).[39]

Once removed from the freezer, the unopened vial can be stored for up to 1 month at 2 °C to 8 °C; not exceeding the printed expiry date (EXP). Within the 1-month shelf life at 2 °C to 8 °C, up to 48 hours may be used for transportation.[29,63,117] Prior to use, the unopened vial can be stored for up to 2 hours at temperatures up to 30 °C.

Once thawed, the vaccine should not be re-frozen.

Transfers of frozen vials stored at ultra-low temperature (<-60 °C)

- Closed-lid vial trays containing 195 vials removed from ultra-low temperature frozen storage (<-60 °C) may be at temperatures up to 25 °C for up to 5 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from ultra-low temperature frozen storage (<-60 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- After vial trays are returned to frozen storage following temperature exposure up to 25 °C, they must remain in frozen storage for at least 2 hours before they can be removed again.

Transfers of frozen vials stored at -25 °C to -15 °C[40]

- Closed-lid vial trays containing 195 vials removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 1 minute.

Once a vial is removed from the vial tray, it should be thawed for use.

Diluted medicinal product

Chemical and physical in-use stability, including during transportation,[30] has been demonstrated for 6 hours at 2 ºC to 30 ºC after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

*[Editorial Guidance for countries: Select this text for the **Tris/Sucrose presentation, 30 micrograms/dose**.]*

TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap[75]

Or

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 15/15 micrograms/dose**.]*

TRADENAME (Bivalent) (for age 12 years and older), grey cap

Unopened vial

12 months when stored at -90 °C to -60 °C.[79,83]

TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap, {{TRADENAME (Bivalent) (for age 12 years and older), grey cap}} will be received frozen at -90 °C to -60 °C.[76] Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

Once removed from frozen storage, the unopened vial may be stored refrigerated at 2 °C to 8 °C for a single period of up to 10 weeks; not exceeding the printed expiry date (EXP).[79]

Upon moving the product to 2 °C to 8 °C storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out.

If the vaccine is received at 2 °C to 8 °C it should be stored at 2 °C to 8 °C. Check that the expiry date on the outer carton has been updated to reflect the refrigerated expiry date and that the original expiry date has been crossed out.

When stored frozen at -90 °C to -60 °C, the vaccine can be thawed at either 2 °C to 8 °C or at temperatures up to 30 °C.

Vaccine may be stored at temperatures between 8 ºC to 30 ºC for up to 24 hours, including any time at these temperatures following first puncture.[77]

Thawed vials can be handled in room light conditions.

Once thawed, the vaccine should not be re-frozen.

Opened vial

Chemical and physical in-use stability has been demonstrated for 12 hours at 2 ºC to 30 ºC. From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately after the first puncture. If not used immediately, in-use storage times and conditions are the responsibility of the user.[77]

*[Editorial Guidance for countries: Select this text for the **Tris/Sucrose presentation, 10 micrograms/dose**.]*

TRADENAME (for age 5 years to <12 years), orange cap[75]

Or

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 5/5 micrograms/dose**.]*

TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap

Unopened vial

12 months when stored at -90 °C to -60 °C.[79,83]

TRADENAME (for age 5 years to <12 years), orange cap, {{TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap}} will be received frozen at -90 °C to -60 °C.[76] Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

Once removed from frozen storage, the unopened vial may be stored refrigerated at 2 °C to 8 °C for a single period of up to 10 weeks; not exceeding the printed expiry date (EXP).[79]

Upon moving the product to 2 °C to 8 °C storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out.

If the vaccine is received at 2 °C to 8 °C it should be stored at 2 °C to 8 °C. Check that the expiry date on the outer carton has been updated to reflect the refrigerated expiry date and that the original expiry date has been crossed out.

When stored frozen at -90 °C to -60 °C, the vaccine can be thawed at either 2 °C to 8 °C or at temperatures up to 30 °C.

Vaccine may be stored at temperatures between 8 ºC to 30 ºC for up to 24 hours, including any time at these temperatures following dilution.[77]

Thawed vials can be handled in room light conditions.

Once thawed, the vaccine should not be re-frozen.

Diluted medicinal product

Chemical and physical in-use stability has been demonstrated for 12 hours at 2 ºC to 30 ºC, after dilution with sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.[77]

*[Editorial Guidance for countries: Select this text for the **Tris/Sucrose presentation, 3 micrograms/dose**.]*

TRADENAME (for age 6 months to <5 years), maroon cap[118]

Unopened vial

12 months when stored at -90 °C to -60 °C.

TRADENAME (for age 6 months to <5 years), maroon cap, will be received frozen at -90 °C to -60 °C.[76] Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

Once removed from frozen storage, the unopened vial may be stored refrigerated at 2 °C to 8 °C for a single period of up to 10 weeks; not exceeding the printed expiry date (EXP).

Upon moving the product to 2 °C to 8 °C storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out.

If the vaccine is received at 2 °C to 8 °C it should be stored at 2 °C to 8 °C. Check that the expiry date on the outer carton has been updated to reflect the refrigerated expiry date and that the original expiry date has been crossed out.

When stored frozen at -90 °C to -60 °C, the vaccine can be thawed at either 2 °C to 8 °C or at temperatures up to 30 °C.

Vaccine may be stored at temperatures between 8 ºC to 30 ºC for up to 24 hours, including any time at these temperatures following dilution.

Thawed vials can be handled in room light conditions.

Once thawed, the vaccine should not be re-frozen.

Diluted medicinal product[119]

Chemical and physical in-use stability has been demonstrated for 12 hours at 2 ºC to 30 ºC, after dilution with sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4. Special precautions for storage[2,25,75,101]

*[Editorial guidance for countries: Select this text for the **PBS/Sucrose presentation, 30 micrograms/dose**.]*

TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap

Store in a freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

For storage conditions after thawing and dilution of the medicinal product, see Section 6.3.

*[Editorial Guidance for countries: Select this text for the **Tris/Sucrose presentation, 30 micrograms/dose**.]*

TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap

Or

*[Editorial Guidance for countries: Select this text for the **Tris/Sucrose presentation, 10 micrograms/dose**.]*

TRADENAME (for age 5 years to <12 years), orange cap

Or

*[Editorial Guidance for countries: Select this text for the **Tris/Sucrose presentation, 3 micrograms/dose.]***

TRADENAME (for age 6 months to <5 years), maroon cap

Or

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 15/15 micrograms/dose**.]*

TRADENAME (Bivalent) (for age 12 years and older), grey cap

Or

*[Editorial Guidance for countries: Select this text for the **Bivalent (Original/Omicron presentation, 5/5 micrograms/dose**.]*

TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap

TRADENAME (Do Not Dilute) (for age 12 years and older),grey cap, TRADENAME (for age 5 years to <12 years), orange cap, TRADENAME (for age 6 months to <5 years), maroon cap, {{TRADENAME (Bivalent) (for age 12 years and older), grey cap,}} and {{TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap,}} can be stored in a refrigerator at 2 °C to 8 °C for a single period of up to 10 weeks, not exceeding the original expiry date (EXP). Alternatively, the vaccine may be stored in a freezer at -90 °C to -60 °C. The expiry date for storage at -90 °C to -60 °C is printed on the vial and outer carton after "EXP".

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt. Upon moving the product to 2 °C to 8 °C storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out.

If the vaccine is received at 2 °C to 8 °C it should be stored at 2 °C to 8 °C. Check that the expiry date has been updated to reflect the refrigerated EXP date and that the original expiry date has been crossed out.

Store in the original package in order to protect from light.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

When stored frozen at -90 °C to -60 °C, the vaccine can be thawed at either 2 °C to 8 °C or at room temperature (up to 30 °C).

Once thawed, the vaccine cannot be re-frozen.

Thawed vials can be handled in room light conditions.

6.5. Nature and contents of container

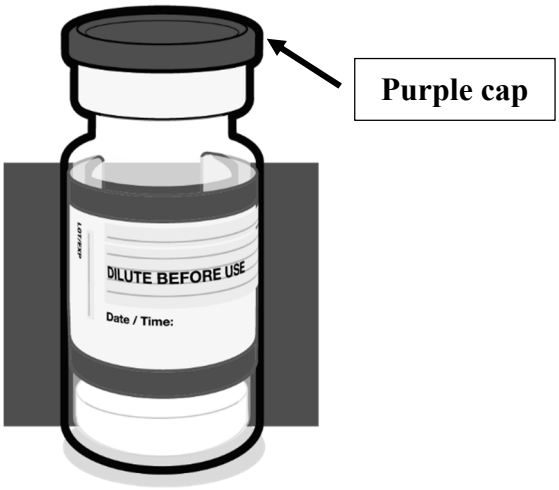
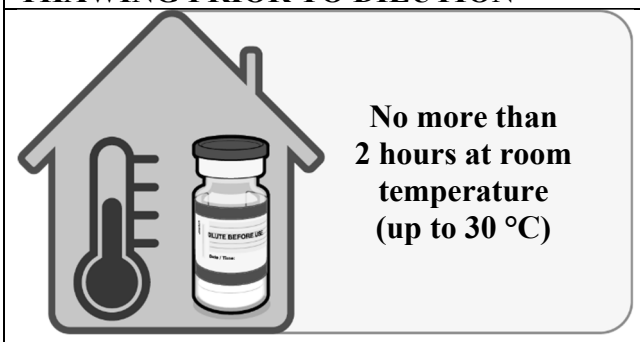
Information to be provided by local subsidiary.

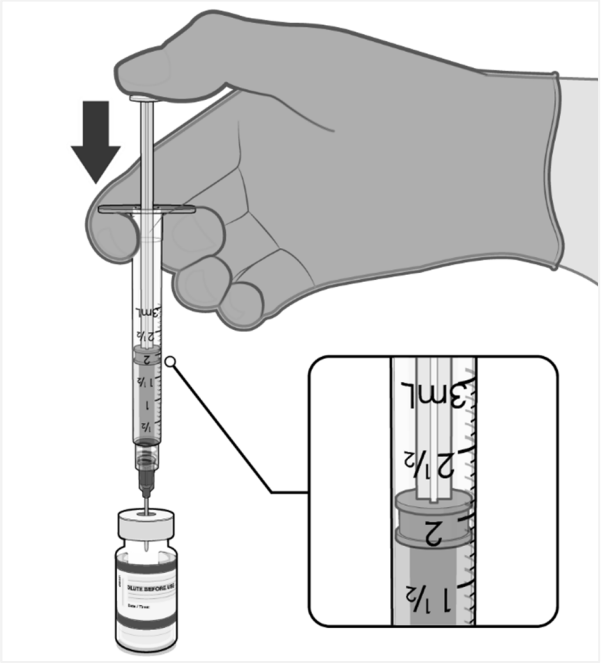
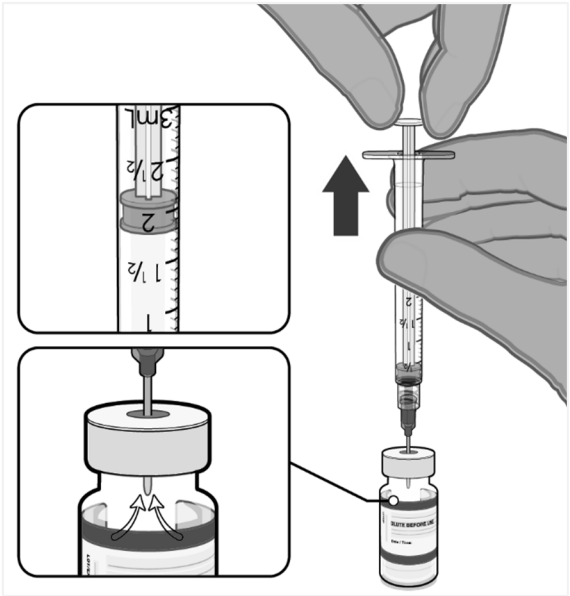
6.6. Special precautions for disposal and other handling[2,3,26,29,30,35,63,75,77,78,116,117,118,119,152,153]

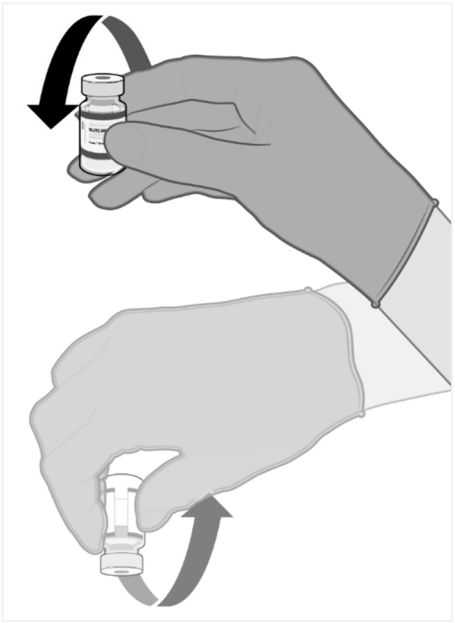
Handling instructions

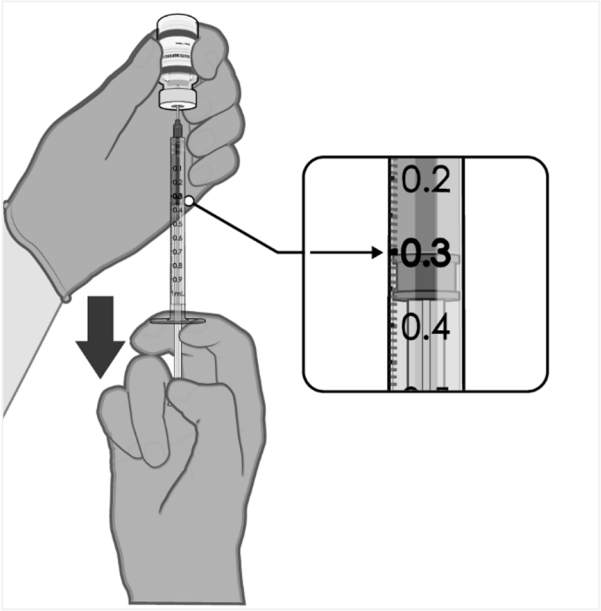
TRADENAME {{or TRADENAME (Bivalent)}} should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

*[Editorial guidance for countries: Select this text for the **PBS/Sucrose presentation, 30 micrograms/dose**.]*

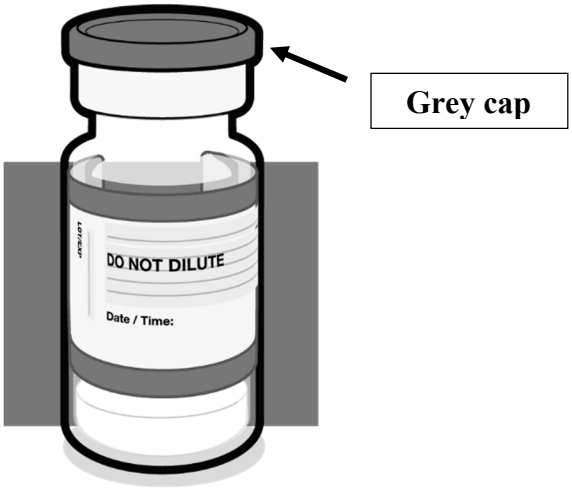
TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap	
VIAL VERIFICATION	
	• Verify that the vial has a purple plastic cap. • If the vial has a grey plastic cap, refer to the handling instructions for TRADENAME (Do Not Dilute) (for age 12 years and older), or TRADENAME (Bivalent) (for 12 years of age and older). • If the vial has an orange plastic cap, refer to the handling instructions for TRADENAME (for ages 5 years to <12 years), or TRADENAME (Bivalent) (for age 5 years to <12 years). • If the vial has a maroon plastic cap, refer to the handling instructions for TRADENAME (for age 6 months to <5 years).
THAWING PRIOR TO DILUTION	
	• The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use. • The unopened vial can be stored for up to 1 month at 2 °C to 8 °C; not exceeding the printed expiry date (EXP). Within the 1-month shelf life at 2 °C to 8 °C, up to 48 hours may be used for transportation. • Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake. • Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.

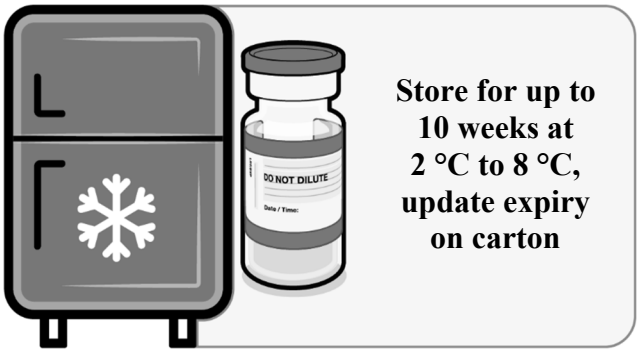
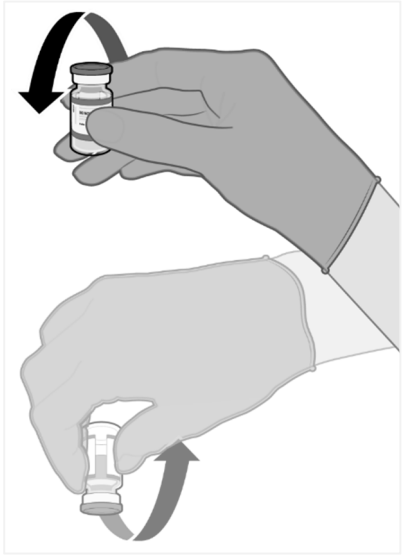
TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap	
DILUTION	
 **1.8 mL of 0.9% sodium chloride injection**	• The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.
 **Pull back plunger to 1.8 mL to remove air from vial.**	• Equalize vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.

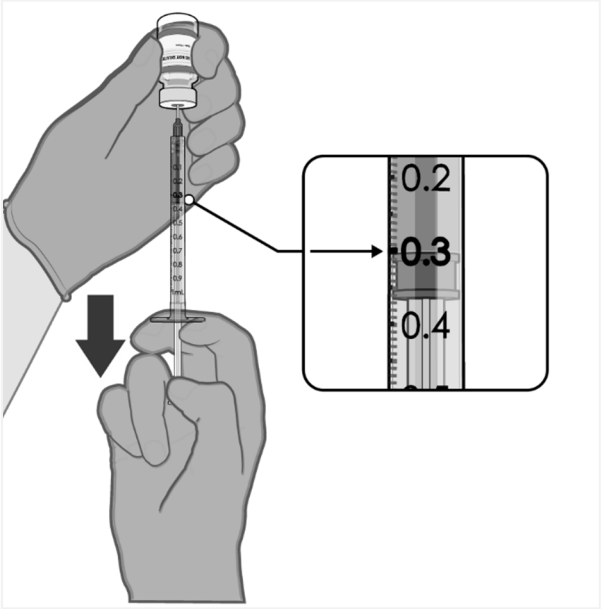
TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap	
 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as an off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discoloration are present.
 **Record appropriate date and time.** **Use within 6 hours after dilution.**	• The diluted vials should be marked with the appropriate date and time. • After dilution, store at 2 ºC to 30 ºC and use within 6 hours, including any transportation time. • Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

TRADENAME (Dilute Before Use) (for age 12 years and older), purple cap	
PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF TRADENAME	
 **0.3 mL diluted vaccine**	• After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted. • Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw 0.3 mL of TRADENAME (Dilute Before Use) (for age 12 years and older). Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microliters. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Discard any unused vaccine within 6 hours after dilution.

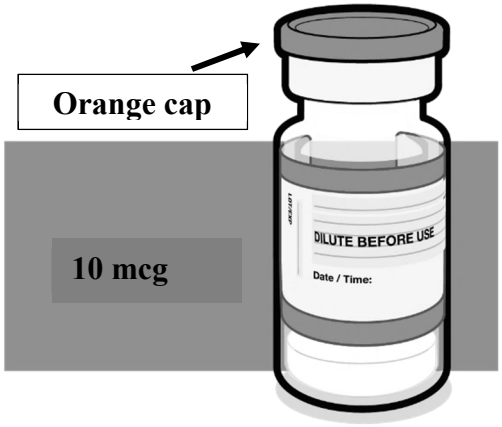
*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 30 micrograms/dose**.]*

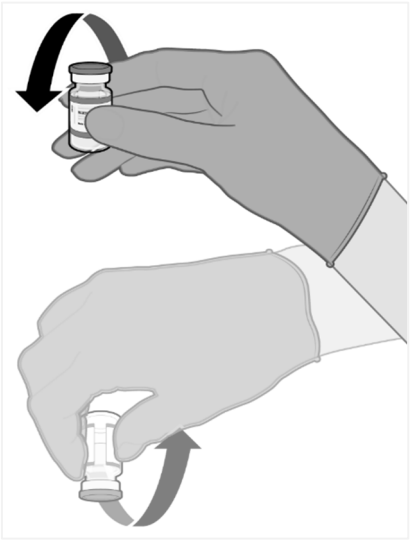
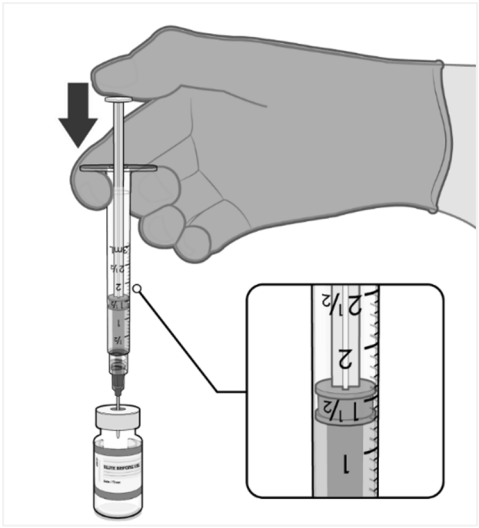
TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap	
VIAL VERIFICATION	
	• Verify that the vial has a grey plastic cap and a grey border around the label and the product name is TRADENAME 30 micrograms/dose dispersion for injection. • If the vial has a grey plastic cap and a grey border around the label, and the product name is TRADENAME (Bivalent) 15/15 micrograms per dose dispersion for injection, refer to the handling instructions for TRADENAME (Bivalent) (for 12 years of age and older). • If the vial has a purple plastic cap, refer to the handling instructions for TRADENAME (Dilute Before Use) (for age 12 years and older). • If the vial has an orange plastic cap, refer to the handling instructions for TRADENAME (for ages 5 years to <12 years), or TRADENAME (Bivalent) (for age 5 years to <12 years). • If the vial has a maroon plastic cap, refer to the handling instructions for TRADENAME (for age 6 months to <5 years).

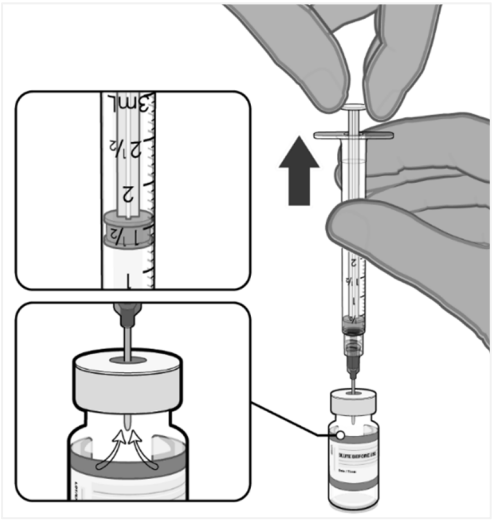
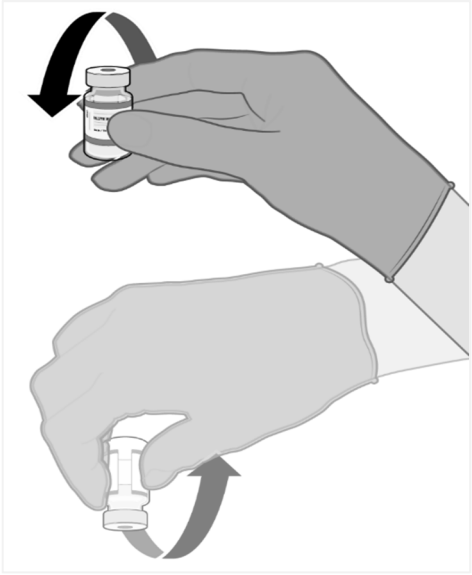
TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap	
HANDLING PRIOR TO USE	
	• If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10 vial pack may take 6 hours to thaw. Ensure vials are completely thawed prior to use. • Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton. • Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C; not exceeding the printed expiry date (EXP). • Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C for immediate use.
 **Gently × 10**	• Gently mix by inverting vials 10 times prior to use. Do not shake. • Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles. • After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discoloration are present.

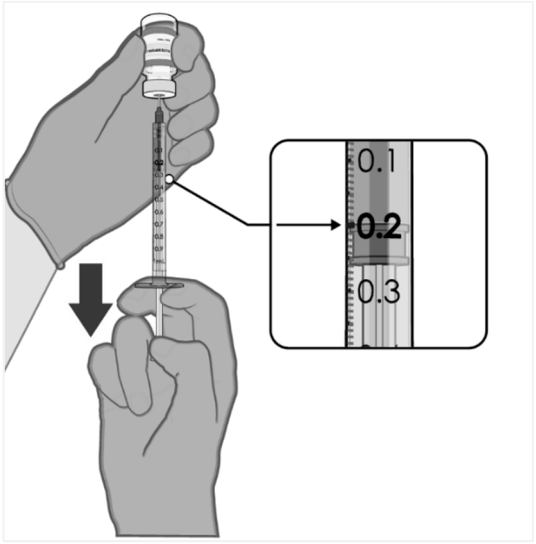
TRADENAME (Do Not Dilute) (for age 12 years and older), grey cap	
PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF TRADENAME	
 **0.3 mL vaccine**	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw 0.3 mL of TRADENAME (Do Not Dilute) (for age 12 years and older). Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Discard any unused vaccine 12 hours after first puncture. Record the appropriate date/time on the vial.

*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 10 micrograms/dose**.]*

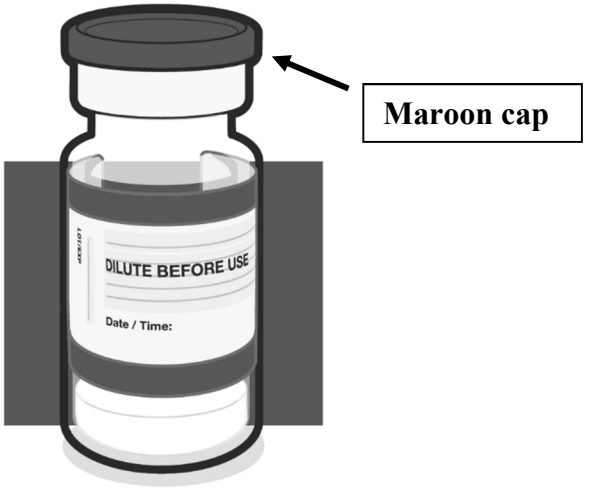
TRADENAME (for age 5 years to <12 years), orange cap	
VIAL VERIFICATION	
	• Verify that the vial has an orange plastic cap and an orange border around the label and the product name is TRADENAME 10 micrograms/dose concentrate for dispersion for injection. • If the vial has an orange plastic cap and an orange border around the label and the product name is TRADENAME (Bivalent) 5/5 micrograms per dose concentrate for dispersion for injection, please refer to the handling instructions for TRADENAME (Bivalent) (5 years to <12 years). • If the vial has a purple plastic cap, refer to the handling instructions for TRADENAME (Dilute Before Use) (for age 12 years and older). • If the vial has a grey plastic cap, refer to the handling instructions for TRADENAME (Do Not Dilute) (for age 12 years and older), or TRADENAME (Bivalent) (for age 12 years and older). • If the vial has a maroon plastic cap, refer to the handling instructions for TRADENAME (for age 6 months to <5 years).
HANDLING PRIOR TO USE	
	• If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10 vial pack may take 4 hours to thaw. Ensure vials are completely thawed prior to use. • Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C; not exceeding the printed expiry date (EXP). • Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C for immediate use.

TRADENAME (for age 5 years to <12 years), orange cap	
MIXING PRIOR TO DILUTION	
 **Gently × 10**	• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake. • Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.
DILUTION	
 **1.3 mL of 0.9% sodium chloride**	• The thawed vaccine must be diluted in its original vial with 1.3 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.

TRADENAME (for age 5 years to <12 years), orange cap	
 **Pull back plunger to 1.3 mL to remove air from vial.**	• Equalize vial pressure before removing the needle from the vial stopper by withdrawing 1.3 mL air into the empty diluent syringe.
 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discoloration are present.

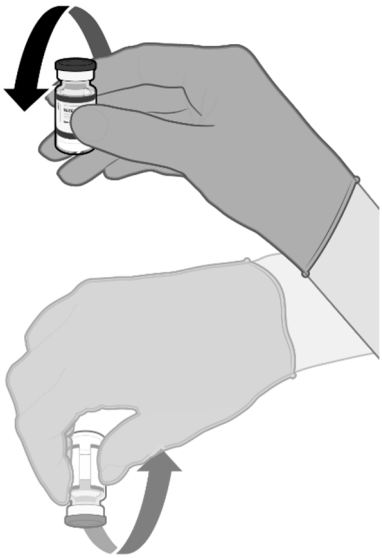
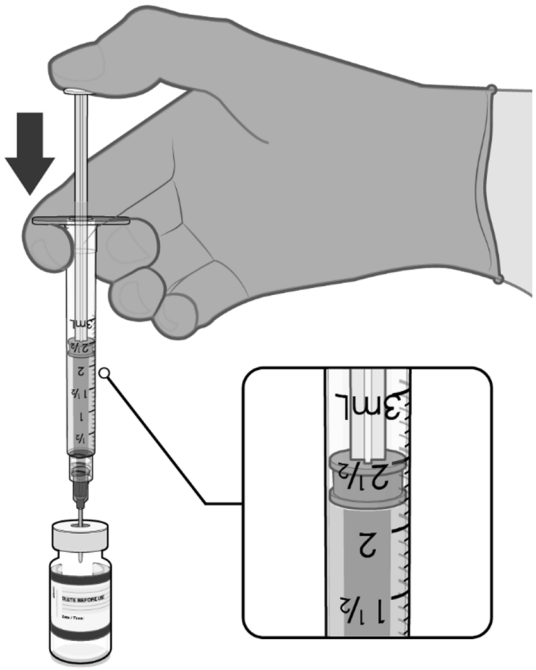
TRADENAME (for age 5 years to <12 years), orange cap	
 **Record appropriate date and time.** **Use within 12 hours after dilution.**	• The diluted vials should be marked with the appropriate date and time. • After dilution, store at 2 ºC to 30 ºC and use within 12 hours. • Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.
PREPARATION OF INDIVIDUAL 0.2 mL DOSES OF TRADENAME	
 **0.2 mL diluted vaccine**	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw 0.2 mL of TRADENAME (for age 5 to <12 years). Low dead-volume syringes and/or needles should be used in order to extract 10 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters. If standard syringes and needles are used, there may not be sufficient volume to extract ten doses from a single vial. • Each dose must contain 0.2 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. • Discard any unused vaccine within 12 hours after dilution.

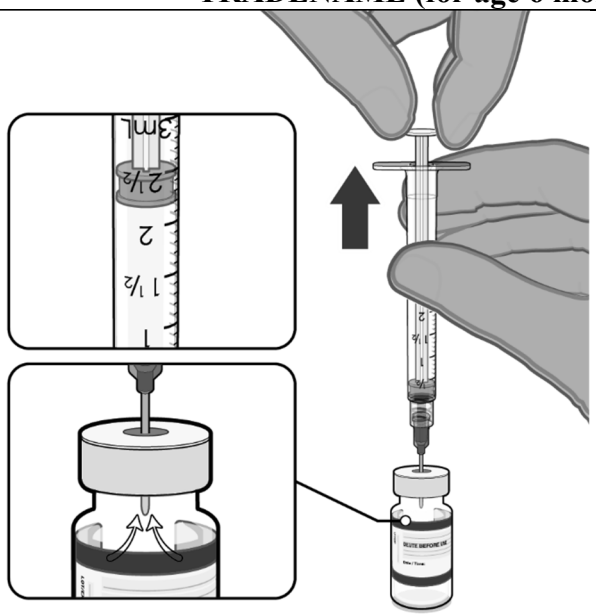
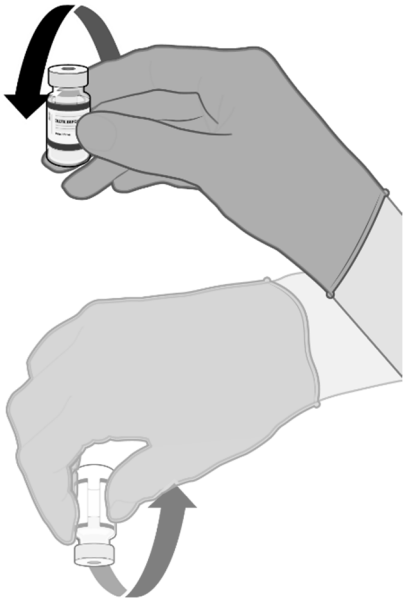
*[Editorial guidance for countries: Select this text for the **Tris/Sucrose presentation, 3 micrograms/dose**.]*

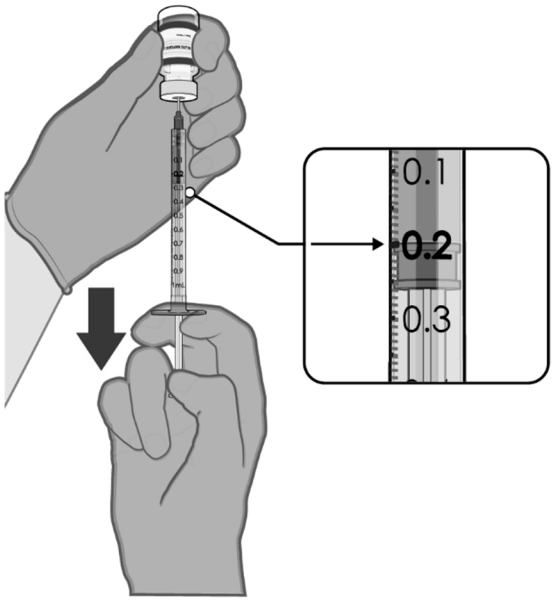
<table>
<tr><th colspan="2">TRADENAME (for age 6 months to <5 years), maroon cap</th></tr>
<tr><td colspan="2">VIAL VERIFICATION</td></tr>
<tr><td> 

3 mcg</td><td>• Verify that the vial has a maroon plastic cap.
• If the vial has a purple plastic cap, refer to the handling instructions for TRADENAME (Dilute Before Use) (for age 12 years and older).
• If the vial has a grey plastic cap, refer to the handling instructions for TRADENAME (Do Not Dilute) (for age 12 years and older), or TRADENAME (Bivalent) (for age 12 years and older).
• If the vial has an orange plastic cap, refer to the handling instructions for TRADENAME (for age 5 years to <12 years of age), TRADENAME (Bivalent) (for age 5 years to <12 years).</td></tr>
<tr><td colspan="2">HANDLING PRIOR TO USE</td></tr>
<tr><td> 

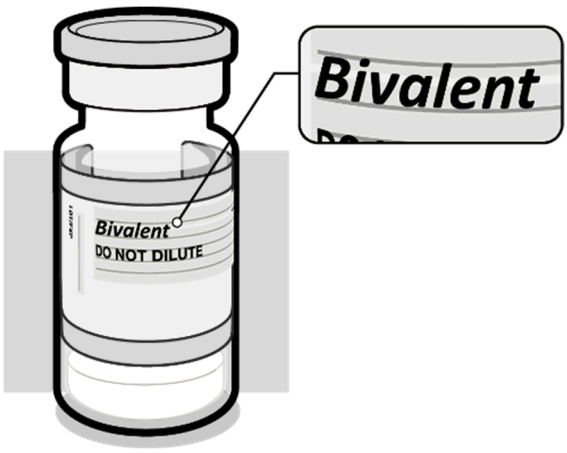
Store for up to 10 weeks at 2 °C to 8 °C</td><td>• If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10 vial pack may take 2 hours to thaw. Ensure vials are completely thawed prior to use.
• Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C; not exceeding the printed expiry date (EXP).
• Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C for immediate use.</td></tr>
</table>

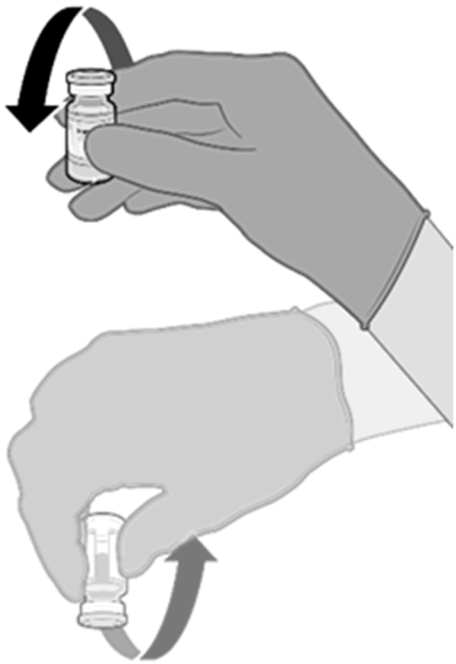
TRADENAME (for age 6 months to <5 years), maroon cap	
MIXING PRIOR TO DILUTION	
 **Gently × 10**	• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake. • Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.
DILUTION	
 **2.2 mL of 0.9% sodium chloride**	• The thawed vaccine must be diluted in its original vial with 2.2 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.

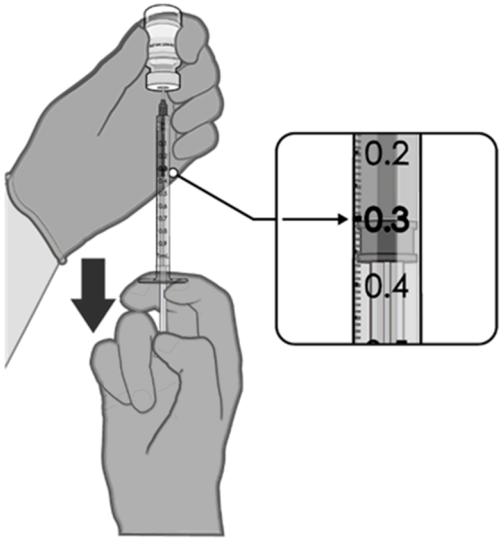
TRADENAME (for age 6 months to <5 years), maroon cap	
 **Pull back plunger to 2.2 mL to remove air from vial.**	• Equalize vial pressure before removing the needle from the vial stopper by withdrawing 2.2 mL air into the empty diluent syringe.
 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discoloration are present.

TRADENAME (for age 6 months to <5 years), maroon cap	
 **Record appropriate date and time.** **Use within 12 hours after dilution.**	• The diluted vials should be marked with the appropriate date and time. • After dilution, store at 2 ºC to 30 ºC and use within 12 hours. • Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.
PREPARATION OF INDIVIDUAL 0.2 mL DOSES OF TRADENAME	
 **0.2 mL diluted vaccine**	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw 0.2 mL of TRADENAME (for age 6 months to <5 years). Low dead-volume syringes and/or needles should be used in order to extract 10 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters. If standard syringes and needles are used, there may not be sufficient volume to extract ten doses from a single vial. • Each dose must contain 0.2 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. • Discard any unused vaccine within 12 hours after dilution.

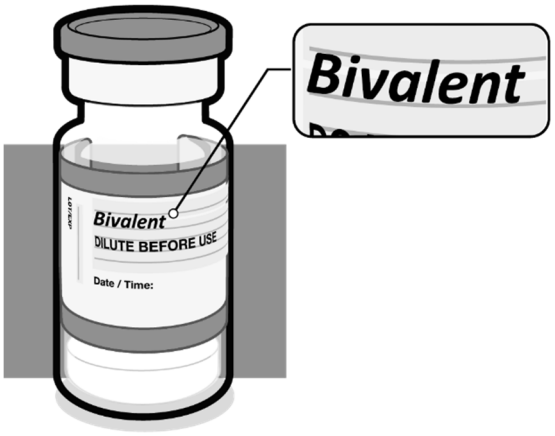
*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 15/15 micrograms/dose**]*

TRADENAME (Bivalent) (for age 12 years and older), grey cap	
VIAL VERIFICATION	
	• Verify that the vial has a grey cap and a grey border around the label and the product name is TRADENAME (Bivalent) 15/15 micrograms per dose dispersion for injection. • If the vial has a grey plastic cap and a grey border and the product name is TRADENAME 30 micrograms/dose dispersion for injection, please refer to the handling instructions for TRADENAME (Do Not Dilute) (for age 12 years and older). • If the vial has a purple plastic cap, refer to the handling instructions for TRADENAME (Dilute Before Use) (for age 12 years and older). • If the vial has an orange plastic cap, refer to the handling instructions for TRADENAME (for ages 5 years to <12 years), or TRADENAME (Bivalent) (for age 5 years to <12 years). • If the vial has a maroon plastic cap, refer to the handling instructions for TRADENAME (for age 6 months to <5 years).
HANDLING PRIOR	

 **Store in the refrigerator for up to 10 weeks prior to use.**	• If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10 vial pack may take 6 hours to thaw. Ensure vials are completely thawed prior to use. • Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton. • Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C; not exceeding the printed expiry date (EXP). • Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C. • Prior to use, the unopened vial can be stored for up to 12 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.
 **Gently × 10**	• Gently mix by inverting vials 10 times prior to use. Do not shake. • Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles. • After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF TRADENAME (Bivalent) (for age 12 years and older), grey cap	
 **Withdraw 0.3 mL dose of vaccine.**	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw 0.3 mL of TRADENAME (Bivalent) (for age 12 years and older). Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.

*[Editorial guidance for countries: Select this text for the **Bivalent (Original/Omicron) presentation, 5/5 micrograms/dose**.]*

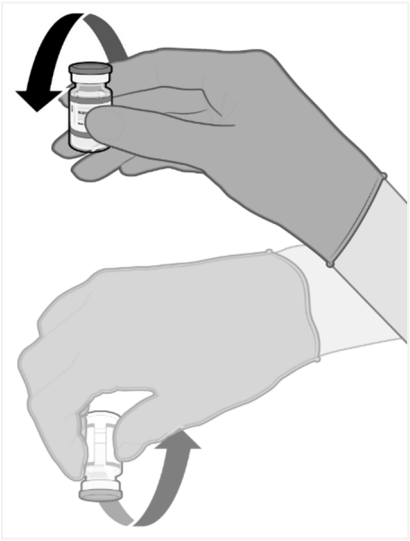
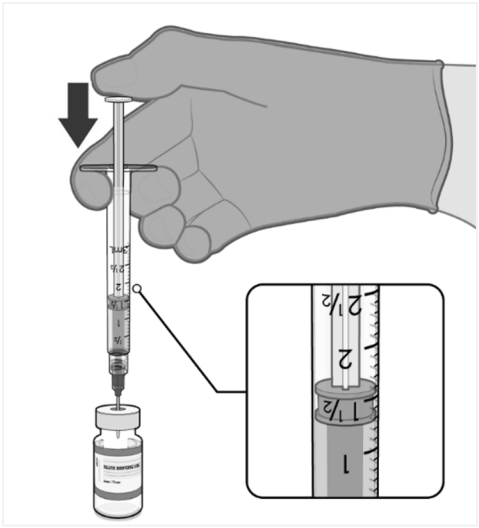
<table>
<tr><th colspan="2">TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap</th></tr>
<tr><td colspan="2">VIAL VERIFICATION</td></tr>
<tr><td> 
</td><td>

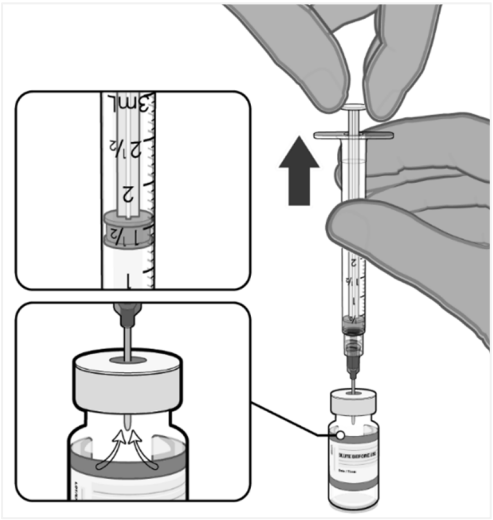
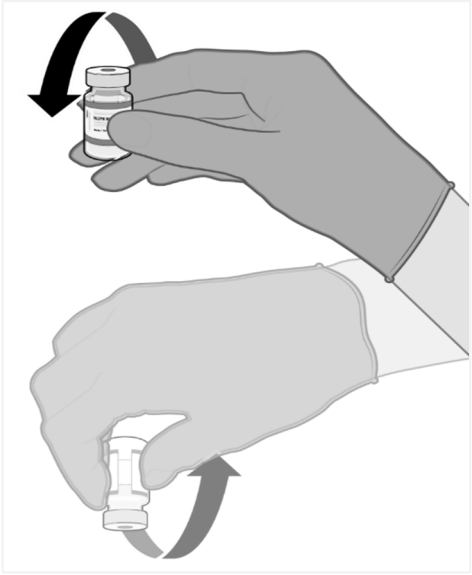
Verify that the vial has an orange plastic cap and an orange border around the label and the product name is TRADENAME (Bivalent) 5/5 micrograms per dose concentrate for dispersion for injection.
If the vial has an orange plastic cap and an orange border around the label and the product name is TRADENAME 10 micrograms/dose concentrate for dispersion for injection, please refer to the handling instructions for TRADENAME (for age 5 years to <12 years).
If the vial has a purple plastic cap, refer to the handling instructions for TRADENAME (Dilute Before Use) (for age 12 years and older).
If the vial has a grey plastic cap, refer to the handling instructions for TRADENAME (Do Not Dilute) (for age 12 years and older), or TRADENAME (Bivalent) (for age 12 years and older).
If the vial has a maroon plastic cap, refer to the handling instructions for TRADENAME (for age 6 months to <5 years).

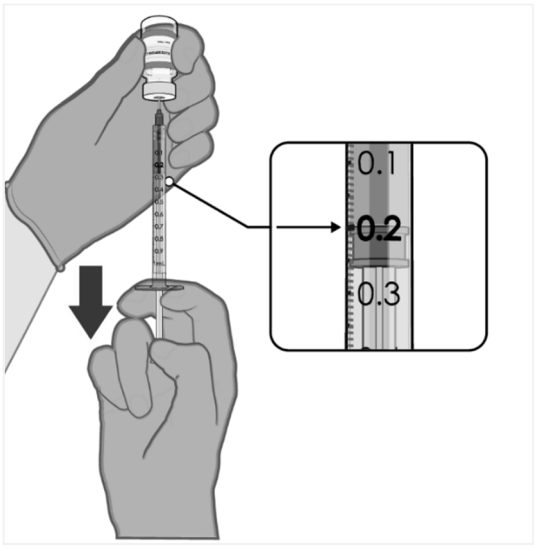
</td></tr>
<tr><td colspan="2">HANDLING PRIOR TO USE</td></tr>
<tr><td> 
</td><td>

If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10 vial pack may take 4 hours to thaw. Ensure vials are completely thawed prior to use.
Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C; not exceeding the printed expiry date (EXP).
Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C for immediate use.

</td></tr>
</table>

TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap	
MIXING PRIOR TO DILUTION	
 **Gently × 10**	• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake. • Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.
DILUTION	
 **1.3 mL of 0.9% sodium chloride**	• The thawed vaccine must be diluted in its original vial with 1.3 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.

TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap	
 **Pull back plunger to 1.3 mL to remove air from vial.**	• Equalize vial pressure before removing the needle from the vial stopper by withdrawing 1.3 mL air into the empty diluent syringe.
 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discoloration are present.

TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap	
 **Record appropriate date and time.** **Use within 12 hours after dilution.**	• The diluted vials should be marked with the appropriate date and time. • After dilution, store at 2 ºC to 30 ºC and use within 12 hours. • Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.
PREPARATION OF INDIVIDUAL 0.2 mL DOSES OF TRADENAME (Bivalent) (for age 5 years to <12 years), orange cap	
 **0.2 mL diluted vaccine**	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw 0.2 mL of TRADENAME (Bivalent) (for age 5 years to <12 years). Low dead-volume syringes and/or needles should be used in order to extract 10 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters. If standard syringes and needles are used, there may not be sufficient volume to extract ten doses from a single vial. • Each dose must contain 0.2 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. • Discard any unused vaccine within 12 hours after dilution.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. REFERENCES

1. BB-IND19736 Section 3.2.S.1.1
2. BB-IND19736 Section 3.2.P.2
3. BB-IND19736 Section 3.2.P.1
4. Global Emergency Use Authorization Application, Section 1.3 Intended Use
5. Global Emergency Use Authorization Application, Section 1.2 Description of Product
6. Vaccine Efficacy – First COVID-19 Occurrence ≥7 Days After Dose 2 – Subjects Without Evidence of Infection Before Vaccination, by Subgroup – Evaluable Efficacy (7 Days) Population
7. Global Emergency Use Authorization Application, Section 7.3.1 Geriatric use
8. ~~Module 5.3.5.1 Table 5: Demographic Characteristics – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population~~ Reference no longer applicable; removed in CDS version 4
9. Ezeanolue E, Harriman K, Hunter P, Kroger A, Pellegrini C. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)
10. Module 4.2.3 Study 20256434 (RN9391R58), Section 4.2.3.5 Final Report - A Combined Fertility and Developmental Study of BNT162b1, BNT162b2 and BNT162b3 by the Intramuscular Route in the Wistar Rat
11. Module 4.2.3.5 Study 20256434 (RN9391R58) Summary for BNT162b2 DART
12. Global Emergency Use Authorization Application, Section 6.2.1.2
13. Module 5.3.5.1 Study 20256434 (RN9391R58), Table Title: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population
14. Module 5.3.5.1 Study 20256434 (RN9391R58), Table Title: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population
15. Module 2.7.4 Summary of Clinical Safety, Section 2.7.4.5 Overall Conclusions
16. Module 2.5 Clinical Overview, COVID-19 Vaccine, 2021, CO for CDS (anaphylaxis & hypersensitivity)
17. Global Emergency Use Authorization, Section 6.2.4.1.1.3.1 Overview of Adverse Events
18. Module 2.7.4 Summary of Clinical Safety, Section 2.7.4.4.5
19. Global Emergency Use Authorization Application, Section 1.2.2 RNA-Lipid Nanoparticle Formulation
20. Global Emergency Use Authorization, Section 6.2.2.1.1.3 Study BNT162-01 Immunogenicity Conclusions in Phase 1
21. Global Emergency Use Authorization, Section 6.2.1.1 Phase 1 First-in-Human BNT162-01

22. Module 5.3.5.1 Study C4591001, Table Title: Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 Evaluable Efficacy (7 Days) Population
23. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
24. Baseline Charlson Comorbidities – ~38,000 Subjects for Phase 2/3 Analysis – Safety Population
25. BB-IND19736, Section 3.2.P.8
26. BB-IND19736, Section 3.2.P.5.2
27. Global Emergency Use Authorization, Table 5: Demographic Characteristics – Phase 2 – Dose 2 Evaluable Immunogenicity Population
28. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
29. BB-IND19736, Section 3.2.P.3.5
30. BB-IND19736, Section 3.2.P.2.6
31. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by Baseline SARS-CoV-2 Status -- ~38000 Subjects for Phase 2/3 Analysis – Safety Population
32. Global Emergency Use Application, Table 35 Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
33. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
34. Vaccine Efficacy - First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup - Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy
35. Module 3.2.P Dosage and Administration Instructions for BNT162 (PF-07302048) Vaccine, 0.5 mg/mL
36. Module 5.3.5.1 C4591001 Clinical Study Report, Section 11.1.2.3.2.1.3 Table 40
37. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition After Dose 1 – Dose 1 All-Available Efficacy Population
38. Module 2.5, Clinical Overview to Support Inclusion of Pain in Extremity, Diarrhea, and Vomiting as Adverse Drug Reactions in Section 4.8 of the Core Data Sheet, February 2021
39. Module 3.2.P.8.1 Stability Summary and Conclusion
40. IND Section 3.2.P.2.3 Storage Shipping and Distribution

41. Module 2.7.4 Summary of Clinical Safety, MAA Type II Variation (12-15 Years) Table 6: Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age – Safety Population
42. Table: Follow-up Time After Dose 2 – Subjects 12 Through 15 Years of Age – Safety Population
43. Table: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population
44. Table: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population
45. Table: Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population
46. Table: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
47. Table: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
48. Table: Summary of Geometric Mean Ratio – NT50 – Comparison of Subjects 12 Through 15 Years of Age to Subjects 16 Through 25 Years of Age (Immunogenicity Subset) – Subjects Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population
49. Module 2.7.4 Summary of Clinical Safety, COVID-19 Vaccine – MAA Type II Variation (12-15 Years) April 2021
50. Interim Report – 6 Month Update: A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-COV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals [hereafter Interim Report – 6 Month Update] (13 March 2021), Supplemental Table 14.198 Demographic Characteristics, by Age Groups – Phase 2/3 Subjects ≥16 Years of Age – Safety Population
51. Interim Report – 6 Month Update (13 March 2021), Supplemental table 14.84 – Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV Positive Subjects ≥16 Years of Age – Safety Population
52. Final Analysis Interim Report: A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-COV-2 RNA Vaccine Candidates Against COVID-19 in Healthy

Individuals (04 November 2020), Section 10.3.3 Phase 2/3, Table 8 Vaccine Administration Timing – ~38000 Subjects for Phase 2/3 Analysis – All Randomized Subjects

53. Interim Report – 6 Month Update (13 March 2021), Table 19. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
54. Interim Report – 6 Month Update (13 March 2021), Supplemental Table 14.59. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup– Blinded Placebo-Controlled Follow-up Period–Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
55. Interim Report – 6 Month Update (13 March 2021), Table 20. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
56. Interim Report – 6 Month Update (13 March 2021), Table 21. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
57. Interim Report – 6 Month Update (13 March 2021), Table 25. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
58. Interim Report – 6 Month Update (13 March 2021), Table 26. Vaccine Efficacy – First Severe COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population
59. Interim Report – 6 Month Update (13 March 2021), Supplemental Table 14.61. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population
60. Interim Report – 6 Month Update (13 March 2021), Table 28. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population
61. EUA Amendment for Pfizer-BioNTech COVID-19 Vaccine, 6-Month Follow-Up Data from Participants 16 Years of Age and Older (13 March 2021), Section 6.2.1.2.1.2 Efficacy
62. Interim Report – 6 Month Update (13 March 2021), Table 4. Analysis Populations
63. Module 3.2.P.8.1 Stability Summary and Conclusion, August 2021
64. Adverse Drug Reaction Frequency Justification Document, COVID-19 Vaccine (BNT162B2), October 2022
65. Interim Report – 6 Month Update (13 March 2021), Supplemental Table 14.72 – Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset)

– Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

66. Interim Report – 6 Month Update (13 March 2021), Supplemental Table 14.79 – Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population
67. 2.5 Clinical Overview to Support Inclusion of Vaccine Stress-Related Reactions in Section 4.4 of the Core Data Sheet, May 2021
68. EUA Amendment for Pfizer-BioNTech COVID-19 Vaccine, 6-Month Follow-Up Data from Participants 16 Years of Age and Older (13 March 2021), Section 6.2.2.1.1 Study Populations – BNT162-01 Phase 1 Participants
69. 2.5 Clinical Overview to Support Inclusion of Myocarditis & Pericarditis in Section 4.4 (Special Warnings and Precautions for use) of the Core Data Sheet, July 2021
70. Module 3.2.P.8.3 Stability Data, August 2021
71. Interim Report – BNT162b2 Booster (Dose 3): A Phase 1/2/3, Placebo Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals
72. Module 3.2.P.2.2 Drug Product – Tris-Sucrose, September 2021
73. Interim Report – Children 5 to <12 Years of Age: A Phase 1, Open-Label Dose-Finding Study to Evaluate Safety, Tolerability, and Immunogenicity and Phase 2/3 Placebo-Controlled, Observer-Blinded Safety, Tolerability, and Immunogenicity Study of a SARS-CoV-2 RNA Vaccine Candidate against COVID-19 in Healthy Children and Young Adults
74. Module 3.2.P.1 Description and Composition of the Drug Product – Tris-Sucrose, September 2021
75. Module 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose, September 2021
76. Module 3.2.P.3.5 Shipping Validation – Tris-Sucrose, September 2021
77. Module 3.2.P.2.6 Compatibility – Tris-Sucrose, September 2021
78. Module 3.2.P.2.3 Manufacturing Process Development – Process Development and Characterization – Tris/Sucrose, September 2021
79. Module 3.2.P.8.1 Stability Summary and Conclusions – Tris-Sucrose, November 2021
80. 2.5 Clinical Overview for Adult Booster Efficacy MAA – Study C4591031, November 2021
81. Interim Clinical Study Report, Protocol C4591001 – Interim Report – Adolescent 6-Month Update: A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 mRNA Vaccine Candidates Against COVID-19 in Healthy Individuals
82. Clinical Information Amendment – COVID-19 Vaccine C4591007 (5 to <12 Years) Efficacy Data in Phase 2/3 Study C4591007, October 2021

83. Module 3.2.P.8.3 Stability Data, August 2021
84. 2.5 Clinical Overview – Pediatric (5-12 Years) Booster MAA Extension – April 2022
85. Module 3.2.P.2.2 Drug Product – Tris-Sucrose, May 2022
86. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022
87. 2.5 Clinical Overview – BNT162b2 30 mcg Adult Booster (Dose 3) sBLA_MAA – May 2022 - 2.5.1.2.4 Proposed Indication
88. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 - 2.5.1.2.3.2.2 Phase 1/2/3 Study C4591007
89. 2.5 Clinical Overview – To Support Inclusion of Myocarditis and Pericarditis as Adverse Drug Reactions in Section 4.8 of the Core Data Sheet – July 2022
90. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 – Table 41. Disposition of All Randomized Participants Prior to Unblinding – Phase 2/3 – 2 to <5 Years of Age, Table 40. Follow-Up Time After Dose 2 or Dose 3 – Phase 2/3 – 2 to <5 Years of Age – Safety Population
91. Module 5 Table: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population
92. Module 5 Table: Systemic Events, by Maximum Severity, Within 7 days After Each Dose – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population
93. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 - Table 50. Disposition of All Randomized Participants Prior to Unblinding – Phase 2/3 – 6 Months to <2 Years of Age
94. Module 5 Table: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population
95. Module 5 Table: Systemic Events, by Maximum Severity, Within 7 days After Each Dose – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population
96. Interim Clinical Study Report – C4591001 – 19 May 2022 - Table 12. Follow-up Time After Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (30 μg)
97. 2.5 Clinical Overview – BNT162b2 30 mcg Adult Booster (Dose 3)_sBLA_MAA – May 2022 - 2.5.4.4.2.1.2 Duration of Follow-Up – C4591031 – 6 Months Post-Dose 3
98. Interim Full Clinical Study Report – C4591031 Substudy A - 6 Month Analysis – 07 June 2022 – Table 10. Follow-Up Time After Booster Vaccination – Safety Population
99. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 - Table 28. Demographic Characteristics – Phase 2/3 – 2 to <5 Years of Age – Dose 3 All-Available Efficacy Population

100. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 - Table 29. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 3 – Blinded Follow-Up Period – Phase 2/3 – 2 to <5 Years of Age – Dose 3 All-Available Efficacy Population
101. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 – Table 7. Demographic Characteristics – Immunobridging Subset – Participants Without Evidence of Infection – Study C4591007 Phase 2/3 2 to <5 Years of Age and Study C4591001 Phase 2/3 16 Through 25 Years of Age – Evaluable Immunogenicity Population
102. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 - Table 8. Summary of Geometric Mean Ratios – NT50 – Participants Without Evidence of Infection – Immunobridging Subset – Study C4591007 Phase 2/3 2 to <5 Years of Age (1 Month After Dose 3) and Study C4591001 Phase 2/3 16 Through 25 Years of Age (1 Month After Dose 2) – Evaluable Immunogenicity Population
103. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 - Table 9. Difference in Percentages of Participants With Seroresponse – Participants Without Evidence of Infection – Immunobridging Subset – Comparison of Study C4591007 Phase 2/3 2 to <5 Years of Age (1 Month After Dose 3) and Study C4591001 Phase 2/3 16 Through 25 Years of Age (1 Month After Dose 2) – Evaluable Immunogenicity Population
104. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 - Table 34. Demographic Characteristics – Phase 2/3 – 6 Months to <2 Years of Age – Dose 3 All-Available Efficacy Population
105. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 - Table 35. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 3 – Blinded Follow-Up Period – Phase 2/3 – 6 Months to <2 Years of Age – Dose 3 All-Available Efficacy Population
106. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 – Table 17. Demographic Characteristics – Immunobridging Subset – Participants Without Evidence of Infection – Study C4591007 Phase 2/3 6 Months to <2 Years of Age and Study C4591001 Phase 2/3 16 Through 25 Years of Age – Evaluable Immunogenicity Population
107. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 – Table 18. Summary of Geometric Mean Ratios – NT50 – Participants Without Evidence of Infection – Immunobridging Subset – Study C4591007 Phase 2/3 6 Months to <2 Years of Age (1 Month After Dose 3) and Study C4591001 Phase 2/3 16 Through 25 Years of Age (1 Month After Dose 2) – Evaluable Immunogenicity Population
108. 2.5 Clinical Overview – Pediatric (6m-5y) Three-Dose Series MAA Extension - June 2022 – Table 19. Difference in Percentages of Participants With Seroresponse – Participants Without Evidence of Infection – Immunobridging Subset – Comparison of Study C4591007 Phase 2/3 6 Months to <2 Years of Age (1 Month After Dose 3) and Study C4591001 Phase 2/3 16 Through 25 Years of Age (1 Month After Dose 2) – Evaluable Immunogenicity Population
109. Module 5.3.5.1. Table: Geometric Mean Ratio – Comparison of 1 Month After Booster Dose to 1 Month After Dose 2 – Phase 3 – BNT162b2 – Experienced Subjects Without

Evidence of Infection up to 1 Month After Booster Dose Who Were Rerandomized to Receive 1 Booster Dose (30 ug) – Dose 3 Booster Evaluable Immunogenicity Population

110. Interim Clinical Study Report – C4591001 – 19 May 2022 – Table 4 Analysis Populations
111. Module 5.3.5.1. Table: Percentage Difference of Subjects Achieving Seroresponse – Comparison of 1 Month After Booster Dose to 1 Month After Dose 2 – Phase 3 – BNT162b2 – Experienced Subjects Without Evidence of Infection up to 1 Month After Booster Dose Who Were Rerandomized to Receive 1 Booster Dose (30 ug) – Dose 3 Booster Evaluable Immunogenicity Population
112. 2.5 Clinical Overview – BNT162b2 30 mcg Adult Booster (Dose 3) sBLA_MAA – May 2022 – 2.5.4.4.2.5 Efficacy Conclusions – C4591031 – 6 Months Post-Dose 3
113. 2.5 Clinical Overview – BNT162b2 30 mcg Adult Booster (Dose 3) sBLA_MAA – May 2022 – 2.5.4.4.2.1.2 Duration of Follow-Up - C4591031 - 6 Month Post-Dose 3, Table 14. Follow-Up Time After Booster Vaccination – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population
114. 2.5 Clinical Overview – BNT162b2 30 mcg Adult Booster (Dose 3) sBLA_MAA – May 2022 – 2.5.4.4.2.2 Confirmed COVID-19 Cases – C4591031 – 6 Months Post-Dose 3, Table 16. Vaccine Efficacy - First COVID-19 Occurrence From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population
115. 2.5 Clinical Overview – BNT162b2 30 mcg Adult Booster (Dose 3) sBLA_MAA – May 2022 – 2.5.4.4.2.2 Confirmed COVID-19 Cases – C4591031 – 6 Months Post-Dose 3, Table 17. Vaccine Efficacy - First COVID-19 Occurrence From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population
116. Module 3.2.P.1 Description and Composition of the Drug Product – Tris-Sucrose – May 2022
117. Module 3.2.P.3.5 Process Validation and/or Evaluation – Shipping Validation – June 2022
118. Module 3.2.P.8.1 Stability Summary and Conclusion – Tris-Sucrose – May 2022
119. Module 3.2.P.2.6 Compatibility – Tris-Sucrose – May 2022
120. Module 3.2.S.1.1 Nomenclature, Omicron BA.4/BA.5 – July 2022
121. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – 2.5.6.3 Benefit-Risk Conclusions
122. Interim Full Clinical Study Report – Protocol C4591031 Substudy D: Substudy D Interim Report – Cohort 2 – 1-Month Analysis: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2 – Section 3.1 Overview of Study Design - 10 June 2022
123. Interim Full Clinical Study Report – Protocol C4591031 Substudy D: Substudy D Interim Report – Cohort 2 – 1-Month Analysis: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2 – Section 4.1 Disposition of Participants – Cohort 2 - 10 June 2022

124. Interim Full Clinical Study Report – Protocol C4591031 Substudy D – Section 4.7 Duration of Follow-UP - 10 June 2022
125. Interim Full Clinical Study Report – Protocol C4591031 Substudy D: Substudy D Interim Report – Cohort 2 – 1-Month Analysis: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2 – Section 5.2.1. Local Reactions - 10 June 2022
126. Interim Full Clinical Study Report – Protocol C4591031 Substudy D: Substudy D Interim Report – Cohort 2 – 1-Month Analysis: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2 – Section 5.2.2. Systemic Events - 10 June 2022
127. Interim Full Clinical Study Report – Protocol C4591031 Substudy E – Table 7. Demographic Characteristics – Expanded Cohort – Participants >55 Years of Age – Safety Population - 16 July 2022
128. Interim Full Clinical Study Report – Protocol C4591031 Substudy E – Table 5. Follow-up Time After Study Vaccination – Expanded Cohort – Participants >55 Years of Age – Safety Population - 16 July 2022
129. Interim Full Clinical Study Report – Protocol C4591031 Substudy E – Section 5.1.2.3.1.2 Adverse Events from Study Vaccination to Data Cutoff Date - 16 July 2022
130. Interim Full Clinical Study Report – Protocol C4591031 Substudy E – Table 21. Number (%) of Participants Reporting at Least 1 Adverse Event From the Study Vaccination Through 1 Month After the Study Vaccination, by System Organ Class and Preferred Term — Expanded Cohort — Participants >55 Years of Age — Safety Population – 16 July 2022
131. Interim Full Clinical Study Report – Protocol C4591031 Substudy E – Supplemental Table 14.38 Systemic Events, by Maximum Severity, Within 7 Days After the Study Vaccination – Expanded Cohort – Participants >55 Years of Age – Safety Population - 16 July 2022
132. Interim Full Clinical Study Report – Protocol C4591031 Substudy E – Supplemental Table 14.26 Local Reactions, by Maximum Severity, Within 7 Days After the Study Vaccination – Expanded Cohort – Participants >55 Years of Age – Safety Population - 16 July 2022
133. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – Section 2.5.1.2.3.2.1. Study C4591031 Substudy E
134. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – Section 2.5.5.2.1.1. Safety Population Characteristics – C4591031 Substudy E (Expanded Cohort)
135. Module 5.3.5.1 – Table – Demographic Characteristics – Expanded Cohort – Participants >55 Years of Age – Safety Population
136. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – 2.5.5.2.1.3.1. Overview of Adverse Events
137. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – 2.5.5.2.1.3.1.1. Adverse Events by System Organ Class and Preferred Term, Adverse Events from Study Vaccination to Data Cutoff Date

138. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – 2.5.5.2.1.2. Reactogenicity – C4591031 Substudy E (Expanded Cohort)
139. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – 2.5.5.2.1.8. Safety Conclusions – C4591031 Substudy E
140. Interim Full Clinical Study Report – Protocol C4591031 Substudy E – Table 7. Demographic Characteristics – Expanded Cohort – Participants >55 Years of Age – Safety Population - 16 July 2022
141. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – 2.5.1.1.1.1. Immunogenicity Endpoints and Analysis Methods – C4591031 Substudy E, Immunogenicity Analysis Methods - C4591031 Substudy E
142. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – 2.5.4.2.1.2.1.1. GMR of Omicron BA.1 Neutralizing Titres
143. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – Table 4. Difference in Percentages of Participants With Seroresponse – Participants Without Evidence of Infection up to 1 Month After the Study Vaccination – Expanded Cohort – Immunogenicity Subset – Participants >55 Years of Age – Evaluable Immunogenicity Population
144. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – Table 2. Geometric Mean Ratios For Between Vaccine Group Comparison – Participants Without Evidence of Infection up to 1 Month After the Study Vaccination – Expanded Cohort – Immunogenicity Subset – Participants >55 Years of Age – Evaluable Immunogenicity Population
145. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – Table 4. Difference in Percentages of Participants With Seroresponse – Participants Without Evidence of Infection up to 1 Month After the Study Vaccination – Expanded Cohort – Immunogenicity Subset – Participants >55 Years of Age – Evaluable Immunogenicity Population
146. Interim Full Clinical Study Report – Protocol C4591031 Substudy D: Substudy D Interim Report – Cohort 2 – 1-Month Analysis: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2 – Table 4. Disposition of All Randomized Participants - Cohort 2 - 10 June 2022
147. Interim Full Clinical Study Report – Protocol C4591031 Substudy D: Substudy D Interim Report – Cohort 2 – 1-Month Analysis: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2 – Section 3.1. Overview of Study Design - 10 June 2022
148. Interim Full Clinical Study Report – Protocol C4591031 Substudy D: Substudy D Interim Report – Cohort 2 – 1-Month Analysis: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2 – Section 5.1.1.1. Superiority Analysis - GMR of Omicron-Neutralizing Titers in BNT162b2 OMI Dose 4 Recipients Compared to BNT162b2 Dose 4 Recipients - 10 June 2022

149. Interim Full Clinical Study Report – Protocol C4591031 Substudy D: Substudy D Interim Report – Cohort 2 – 1-Month Analysis: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2 – Table 11 - 10 June 2022
150. Interim Full Clinical Study Report – Protocol C4591031 Substudy D: Substudy D Interim Report – Cohort 2 – 1-Month Analysis: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2 – Section 5.4.1. Immunogenicity, Descriptive Immunogenicity Analyses – Full Expanded Set - 10 June 2022
151. Interim Full Clinical Study Report – Protocol C4591031 Substudy D: Substudy D Interim Report – Cohort 2 – 1-Month Analysis: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2 – Table 10 - 10 June 2022
152. Module 3.2.P.1 Description and composition of the drug product – July 2022
153. Module 3.2.P.2.3 Process development and characterization – July 2022
154. 2.5 Clinical Overview – BNT162b2– Omicron Modified Vaccine (C4591031 SSE)_MAA_July 2022 – 2.5.4.2.1.2.1.2. Seroresponse Rate to Omicron BA.1 Strain
155. 2.5 Clinical Overview – To Support Inclusion of Dizziness as Adverse Drug Reactions in Section 4.8 of the Core Data Sheet – October 2022
156. 2.5 Clinical Overview – Omicron BA.4-BA.5 COVID-19 Vaccine: Peds 5 to 11 years of Age – September 2022
157. 3.2.P.8.1 Stability Summary and Conclusion, September 2022

Appendix A: Adverse Drug Reactions (ADRs) and Numeric Frequencies Listed in Order of Decreasing Frequency Within Each System Organ Class (SOC)

Table A-1. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 16 Years of Age and Older (13 March 2021 Data Cut-off Date)[64]

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy	83/21926 (0.4%)[a]
Immune system disorders	Anaphylaxis[d]	Not known
	Hypersensitivity reactions	
	Rash[d]	54/21926 (0.2%)[a]
	Pruritus[d]	23/21926 (0.1%)[a]
	Urticaria[d]	15/21926 (0.1%)[a]
	Angioedema[d]	3/21926 (0.01%)[a]
Metabolism and nutrition disorders	Decreased appetite	39/21926 (0.2%)[a]
Nervous system disorders	Headache	2814/4924 (57.1%)[b]
	Dizziness[d]	78/21926 (0.4%)[a]
	Lethargy	25/21926 (0.1%)[a]
Cardiac disorders	Myocarditis[d]	N/A[e]
	Pericarditis[d]	N/A[e]
Gastrointestinal disorders	Diarrhea[d]	758/4924 (15.4%)[b]
	Vomiting[d]	110/4924 (2.2%)[b]
	Nausea	274/21926 (1.2%)[a]
Skin and subcutaneous tissue disorders	Hyperhidrosis	31/21926 (0.1%)[a]
	Night sweats	17/21926 (0.1%)[a]
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	1980/4924 (40.2%)[b]
	Arthralgia (joint pain)	1232/4924 (25.0%)[b]
	Pain in extremity (arm)[d]	185/21926 (0.8%)[a]
General disorders and administration site conditions	Injection site pain	4153/4924 (84.3%)[c]
	Fatigue	3185/4924 (64.7%)[b]
	Chills	1707/4924 (34.7%)[b]
	Pyrexia	749/4924 (15.2%)[b]
	Injection site swelling	546/4924 (11.1%)[c]
	Injection site redness	486/4924 (9.9%)[c]
	Malaise	130/21926 (0.6%)[a]
	Asthenia	76/21926 (0.3%)[a]

a. Source: Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population (Study C4591001, Cut-off date: 13March2021).
b. Source: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population (Study C4591001, Cut-off date: 13March2021).
c. Source: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population (Study C4591001, Cut-off date: 13March2021).
d. These adverse reactions were identified in the post-authorization period.
e. Due to the cross-over design of clinical trials, the actual incidence of myocarditis and pericarditis cannot be reliably estimated however, based on published literature presented in the Clinical Overview to support inclusion of myocarditis and pericarditis as adverse drug reactions in Section 4.8 of the CDS, the CIOMS frequency category for myocarditis and pericarditis is "very rare."[89]

Table A-2. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 12 Through 15 Years of Age (13 March 2021 Data Cut-off Date)[64]

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy	9/1131 (0.8%)[a]
Immune system disorders	Anaphylaxis[d]	Not known
	Hypersensitivity reactions	
	Rash[d]	2/1131 (0.2%)[a]
	Urticaria[d]	2/1131 (0.2%)[a]
	Pruritus[d,e]	
	Angioedema[d,e]	
Metabolism and nutrition disorders	Decreased appetite[e]	
Nervous system disorders	Headache	854/1131 (75.5%)[b]
	Dizziness[d]	2/1131 (0.2%)[a]
	Lethargy[e]	
Cardiac disorders	Myocarditis[d]	N/A[f]
	Pericarditis[d]	N/A[f]
Gastrointestinal disorders	Diarrhea[d]	141/1131 (12.5%)[b]
	Vomiting[d]	59/1131 (5.2%)[b]
	Nausea	5/1131 (0.4%)[a]
Skin and subcutaneous tissue disorders	Hyperhidrosis[e]	
	Night sweats[e]	
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	477/1131 (42.2%)[b]
	Arthralgia (joint pain) (new)	229/1131 (20.2%)[b]
	Pain in extremity (arm)[d]	1/1131 (0.1%)[a]
General disorders and administration site conditions	Injection site pain	1023/1131 (90.5%)[c]
	Fatigue	876/1131 (77.5%)[b]
	Chills	557/1131 (49.2%)[b]
	Pyrexia	275/1131 (24.3%)[b]
	Injection site swelling	104/1131 (9.2%)[c]
	Injection site redness	97/1131 (8.6%)[c]
	Malaise[e]	
	Asthenia[e]	

a. Source: Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) –Safety Population (Study C4591001, Cut-off date: 13March2021).
b. Source: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population (Study C4591001, Cut-off date: 13March2021).
c. Source: Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population (Study C4591001, Cut-off date: 13March2021).
d. These adverse reactions were identified in the post-authorization period.
e. The following reactions were not reported in the 12 through 15 year old age group in Study C4591001: angioedema, pruritus, malaise, lethargy, asthenia, decreased appetite, hyperhidrosis, and night sweats but are still considered adverse reactions for this age group.
f. Due to the cross-over design of clinical trials, the actual incidence of myocarditis and pericarditis cannot be reliably estimated however, based on published literature presented in the Clinical Overview to support

inclusion of myocarditis and pericarditis as adverse drug reactions in Section 4.8 of the CDS, the CIOMS frequency category for myocarditis and pericarditis is “very rare.”[89]

Table A-3. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency within each System Organ Class: Individuals 5 Through <12 Years of Age (06 September 2021 Data Cut-off Date)[64]

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy	13/1518 (0.9%)[a]
Immune system disorders	Anaphylaxis[d]	Not known
	Hypersensitivity reactions	
	Rash[d]	5/1518 (0.3%)[a]
	Urticaria[d]	3/1518 (0.2%)[a]
	Pruritus[d]	1/1518 (0.1%)[a]
	Angioedema[d,e]	
Metabolism and nutrition disorders	Decreased appetite	1/1518 (0.1%)[a]
Nervous system disorders	Headache	579/1517 (38.2%)[b]
	Dizziness[d]	1/1518 (0.1%)[a]
	Lethargy[e]	
Cardiac disorders	Myocarditis[d,e]	N/A[f]
	Pericarditis[d,e]	N/A[f]
Gastrointestinal disorders	Diarrhea[d]	146/1517 (9.6%)[b]
	Vomiting[d]	60/1517 (4.0%)[b]
	Nausea	6/1518 (0.4%)[a]
Skin and subcutaneous tissue disorders	Hyperhidrosis[e]	
	Night sweats[e]	
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	266/1517 (17.5%)[b]
	Arthralgia (joint pain) (new)	115/1517 (7.6%)[b]
	Pain in extremity (arm)[d]	3/1518 (0.2%)[a]
General disorders and administration site conditions	Injection site pain	1279/1517 (84.3%)[c]
	Fatigue	785/1517 (51.7%)[b]
	Injection site redness	401/1517 (26.4%)[c]
	Injection site swelling	309/1517 (20.4%)[c]
	Chills	188/1517 (12.4%)[b]
	Pyrexia	126/1517 (8.3%)[b]
	Malaise	2/1518 (0.1%)[a]
	Asthenia[e]	

a. Source: Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Phase 2/3 – 5 to <12 Years of Age – Safety Population (Study C4591007, Cut-off date: 06Sep2021).
b. Source: Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 2/3 – 5 to <12 Years of Age – Safety Population (Study C4591007, Cut-off date: 06Sep2021).
c. Source = Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 2/3 – 5 to <12 Years of Age – Safety Population (Study C4591007, Cut-off date: 06Sep2021).
d. These adverse reactions were identified in the post-authorization period.
e. At the time of the data cut-off date, the following reactions were not reported in participants 5 through <12 years of age in Study C4591007: **Error! Reference source not found.**angioedema, lethargy, myocarditis, pericarditis, asthenia, hyperhidrosis, and night sweats but are still considered adverse reactions for this age group.
f. Due to the cross-over design of clinical trials, the actual incidence of myocarditis and pericarditis cannot be reliably estimated however, based on published literature presented in the Clinical Overview to support inclusion of myocarditis and pericarditis as adverse drug reactions in Section 4.8 of the CDS, the CIOMS frequency category for myocarditis and pericarditis is "very rare."[89]

Table A-4. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 2 to <5 Years of Age (29 April 2022 Data Cut-off Date)[64]

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy	1/1835 (0.1%)[a]
Immune system disorders	Anaphylaxis[d]	Not known
	Hypersensitivity reactions	
	Rash[d,e]	6/1835 (0.3%)[a]
	Urticaria[d]	6/1835 (0.3%)[a]
	Pruritis[d,f]	
	Angioedema[d,f]	
Metabolism and nutrition disorders	Decreased appetite	1/1835 (0.1%)[a]
Nervous system disorders	Headache	159/1826 (8.7%)[b]
	Dizziness[d,f]	
	Lethargy[f]	
Cardiac disorders	Myocarditis[d,f]	N/A[g]
	Pericarditis[d,f]	N/A[g]
Gastrointestinal disorders	Diarrhea[d]	248/1826 (13.6%)[b]
	Vomiting[d]	117/1826 (6.4%)[b]
	Nausea	2/1835 (0.1%)[a]
Skin and subcutaneous tissue disorders	Hyperhidrosis[f]	
	Night sweats[f]	
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	92/1826 (5.0%)[b]
	Arthralgia (joint pain) (new)	44/1826 (2.4%)[b]
	Pain in extremity (arm)[d]	3/1835 (0.2%)[a]
General disorders and administration site conditions	Injection site pain	858/1826 (47.0%)[c]
	Fatigue	818/1826 (44.8%)[b]
	Injection site redness	346/1833 (18.9%)[c]
	Pyrexia	192/1832 (10.5%)[b]
	Injection site swelling	154/1833 (8.4%)[c]
	Chills	104/1826 (5.7%)[b]
	Asthenia	1/1835 (0.1%)[a]
	Malaise[f]	

a. Source: Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 3, by System Organ Class and Preferred Term – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population (Study C4591007, Cutoff date: 29Apr2022)
b. Source = Systemic Events, by Maximum Severity, Within 7 Days After Each Dose –Phase 2/3 – Blinded Placebo Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population (Study C4591007, Cutoff date: 06Sep2021)
c. Source = Local Reactions, by Maximum Severity, Within 7 Days After Each Dose –Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population (Study C4591007, Cutoff date: 29Apr2022)
d. These adverse reactions were identified in the post-authorization period.
e. The frequency of rash was calculated as follows: Rash (n=4), Rash erythematous (n=1), Rash maculo-papular (n=1) (4+1+1=6/1835=0.3%).
f. At the time of the data-lock the following reactions were not reported in participants 2 to <5 Years of Age in Study C4591007: pruritus, angioedema, dizziness, lethargy, myocarditis, pericarditis, hyperhidrosis, night sweats, and malaise but are still considered adverse reactions for this age group.
g. Due to the cross-over design of clinical trials, the actual incidence of myocarditis and pericarditis cannot be reliably estimated however, based on published literature presented in the Clinical Overview to support inclusion of myocarditis and pericarditis as adverse drug reactions in Section 4.8 of the CDS, the CIOMS frequency category for myocarditis and pericarditis is “very rare.”[89]

Table A-5. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 6 Months to <2 Years of Age (29 April 2022 Data Cut-off Date)[64]

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy	2/1178 (0.2%)[a]
Immune system disorders	Anaphylaxis[d]	Not known
	Hypersensitivity reactions	
	Rash[d,e]	13/1178 (1.1%)[a]
	Urticaria[d]	8/1178 (0.7%)[a]
	Pruritis[d,f]	
	Angioedema[d,f]	
Metabolism and nutrition disorders	Decreased appetite	451/1169 (38.6%)[b]
Psychiatric disorders	Irritability	800/1169 (68.4%)[b]
Nervous system disorders	Headache	2/1178 (0.2%)[a]
	Lethargy	1/1178 (0.1%)[a]
	Dizziness[d,f]	
Cardiac disorders	Myocarditis[d,f]	N/A[g]
	Pericarditis[d,f]	N/A[g]
Gastrointestinal disorders	Vomiting[d]	47/1178 (4.0%)[a]
	Diarrhea[d]	39/1178 (3.3%)[a]
	Nausea[f]	
Skin and subcutaneous tissue disorders	Hyperhidrosis[f]	
	Night sweats[f]	
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)[f]	
	Arthralgia (joint pain) (new)[f]	
	Pain in extremity (arm)[d,f]	
General disorders and administration site conditions	Injection site tenderness	309/1169 (26.4%)[c]
	Injection site redness	210/1177 (17.8%)[c]
	Pyrexia	169/1177 (14.4%)[b]
	Injection site swelling	86/1177 (7.3%)[c]
	Fatigue	8/1178 (0.7%)[a]
	Chills	1/1178 (0.1%)[a]
	Malaise[f]	
	Asthenia[f]	

a. Source: Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 3, by System Organ Class and Preferred Term – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 months to <2 Years of Age – Safety Population (Study C4591007, Cutoff date: 29Apr2022)
b. Source = Systemic Events, by Maximum Severity, Within 7 Days After Each Dose –Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 months to <2 Years of Age – Safety Population (Study C4591007, Cutoff date: 29Apr2022)
c. Source = Local Reactions, by Maximum Severity, Within 7 Days After Each Dose –Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 months to <2 Years of Age – Safety Population (Study C4591007, Cutoff date: 29Apr2022)
d. These adverse reactions were identified in the post-authorization period.
e. The frequency of rash was calculated as follows: Rash (n=8), Rash macular (n=1), Rash maculo-papular (n=2); Rash papular (n=1); Rash erythematous (n=1) (8+1+2+1+1=13/1178=1.1%)
f. At the time of the data cut-off date, the following reactions were not reported in participants 6 months to <2 Years of Age in Study C4591007: pruritus, angioedema, dizziness, myocarditis, pericarditis, nausea, hyperhidrosis, night sweats, myalgia, arthralgia, pain in extremity, malaise, and asthenia but are still considered adverse reactions for this age group.
g. Due to the cross-over design of clinical trials, the actual incidence of myocarditis and pericarditis cannot be reliably estimated however, based on published literature presented in the Clinical Overview to support inclusion of myocarditis and pericarditis as adverse drug reactions in Section 4.8 of the CDS, the CIOMS frequency category for myocarditis and pericarditis is “very rare.”[89]

Table A-6. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: BNT162b2-Experienced Subjects (18 to 55 Years of Age) Who Were Rerandomized to Receive 1 Booster (Dose 3) of BNT162b2 (30 µg) – Booster Safety Population (17 June 2021 Data Cut-off Date)[*,64]

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy	16/306 (5.2%)[a,b]
Immune system disorders	Anaphylaxis[e]	Not known
	Hypersensitivity reactions	
	Rash[e]	1/306 (0.3%)[b]
	Pruritus[e,f]	
	Urticaria[e,f]	
	Angioedema[e,f]	
Metabolism and nutrition disorders	Decreased appetite	1/306 (0.3%)[b]
Nervous system disorders	Headache	140/289 (48.4%)[c]
	Dizziness[e]	1/306 (0.3%)[b]
	Lethargy[f]	
Cardiac disorders	Myocarditis[e]	N/A[g]
	Pericarditis[e]	N/A[g]
Gastrointestinal disorders	Diarrhea[e]	25/289 (8.7%)[c]
	Vomiting[e]	5/289 (1.7%)[c]
	Nausea	2/306 (0.7%)[b]
Skin and subcutaneous tissue disorders	Hyperhidrosis[f]	
	Night sweats[f]	
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	113/289 (39.1%)[c]
	Arthralgia (joint pain) (new)	73/289 (25.3%)[c]
	Pain in extremity (arm)[e]	1/306 (0.3%)[b]
General disorders and administration site conditions	Injection site pain	240/289 (83.0%)[d]
	Fatigue	184/289 (63.7%)[c]
	Chills	84/289 (29.1%)[c]
	Pyrexia	25/289 (8.7%)[c]
	Injection site swelling	23/289 (8.0%)[d]
	Injection site redness	17/289 (5.9%)[d]
	Malaise[f]	
	Asthenia[f]	

* The booster dose (a third dose) of BNT162b2 30 µg was administered to participants 18 to 55 years of age.

a. A higher frequency of lymphadenopathy (5.2% vs. 0.4%) was observed in participants receiving a booster dose (third dose) compared to participants receiving 2 doses.

b. Source: Number (%) of Subjects Reporting at Least 1 Adverse Event From Booster Dose to 1 Month After Booster Dose, by System Organ Class and Preferred Term – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (30 µg) – Booster Safety Population (Study C4591001, Cut-off date: 17June2021).

c. Source = Systemic Events, by Maximum Severity, Within 7 Days After Booster Dose Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (30 µg) – Booster Safety Population (Study C4591001, Cut-off date: 17June2021).

d. Source = Local Reactions, by Maximum Severity, Within 7 Days After Booster Dose – Phase 3 – BNT162b2-Experienced Subjects Who Were Rerandomized to Receive 1 Booster Dose of BNT162b2 (30 µg) –Booster Safety Population (Study C4591001, Cut-off date: 17June2021).

e. These adverse reactions were identified in the post-authorization period.

f. The following reactions were **not** reported in the booster safety population in Study C4591001: angioedema, pruritus, urticaria, malaise, lethargy, asthenia, hyperhidrosis, and night sweats but are still considered adverse reactions.

g. Due to the cross-over design of clinical trials, the actual incidence of myocarditis and pericarditis cannot be reliably estimated however, based on published literature presented in the Clinical Overview to support inclusion of myocarditis and pericarditis as adverse drug reactions in Section 4.8 of the CDS, the CIOMS frequency category for myocarditis and pericarditis is “very rare.”[89]

Table A-7. Adverse Drug Reaction Table of Non-reactogenicity Reactions[a] with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: BNT162b2-Experienced Subjects (≥16 Years of Age) Who Received 1 Booster (Dose 3) of BNT162b2 (30 µg) in Study C4591031 Substudy A (SSA) – Booster Safety Population (5 October 2021 Data Cut-off Date)[64,80]

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy[b]	141/5055 (2.8%)[c]
Immune system disorders	Anaphylaxis[d]	Not known
	Hypersensitivity reactions	
	Rash[d]	3/5055 (0.1%)[c]
	Pruritus[d]	3/5055 (0.1%)[c]
	Urticaria[d]	2/5055 (0.04%)[c]
	Angioedema[d,e]	
Metabolism and nutrition disorders	Decreased appetite	9/5055 (0.2%)[c]
Nervous system disorders		9/5055 (0.2%)[c]
	Lethargy	12/5055 (0.2%)[c]
	Headache[a]	
Cardiac disorders	Myocarditis[d]	N/A[f]
	Pericarditis[d]	N/A[f]
Gastrointestinal disorders	Diarrhea[a,d]	
	Vomiting[a,d]	
	Nausea	48/5055 (0.9%)[c]
Skin and subcutaneous tissue disorders	Night sweats	5/5055 (0.1%)[c]
	Hyperhidrosis	4/5055 (0.1%)[c]
Musculoskeletal and connective tissue disorders	Pain in extremity (arm)[d]	54/5055 (1.1%)[c]
	Arthralgia (joint pain) (new)[a]	
	Myalgia (muscle pain)[a]	
General disorders and administration site conditions	Malaise	35/5055 (0.7%)[c]
	Asthenia	8/5055 (0.2%)[c]
	Injection site pain[a]	
	Fatigue[a]	
	Chills[a]	
	Pyrexia[a,g]	
	Injection site swelling[a]	
	Injection site redness[a]	

a. Please see Table A-6 for the booster (Dose 3) frequencies of the reactogenicity adverse reactions which were determined from the booster safety population of Study C4591001 who utilized e-diaries: headache, diarrhea, vomiting, myalgia (muscle pain), arthralgia (joint pain) (new), injection site pain, fatigue, chills, pyrexia, injection site swelling, injection site redness.
b. A higher frequency of lymphadenopathy (2.8% vs. 0.4%) was observed in participants receiving a booster dose (in Study C4591031) compared to participants receiving 2 doses. The frequency of lymphadenopathy was calculated as follows: Lymphadenopathy (n=135), Lymph node pain (n=4), Lymphadenitis (n=2) (135+4+2=141/5055=2.8%).
c. Source: Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 1 Month After Booster Vaccination, by System Organ Class and Preferred Term – Blinded Follow-up Period – Safety Population (Study C4591031 SSA, Cut-off date: 05October2021).
d. These adverse reactions were identified in the post-authorization period.
e. The following reaction was not reported in Study C4591031: angioedema but it is still considered an adverse reactions.
f. Due to the cross-over design of clinical trials, the actual incidence of myocarditis and pericarditis cannot be reliably estimated however, based on published literature presented in the Clinical Overview to support inclusion of myocarditis and pericarditis as adverse drug reactions in Section 4.8 of the CDS, the CIOMS frequency category for myocarditis and pericarditis is "very rare."[89]

g. The preferred term pyrexia is a cluster term also covering ‘body temperature increased’.

Table A-8. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 18 to 55 years old Who Received a Booster (Dose 4) of BNT162b2 30 µg in Study C4591031 Substudy D (SSD) — Safety Population (11 March 2022 Data Cut-off Date)[64]

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy	3/325 (0.9%)[a]
Immune system disorders	Anaphylaxis[b]	Not known
	Hypersensitivity reactions	
	Rash[b,c]	
	Pruritus[b,c]	
	Urticaria[b,c]	
	Angioedema[b,c]	
Metabolism and nutrition disorders	Decreased appetite[c]	
Nervous system disorders	Headache	138/306 (45.1%)[d]
	Dizziness[b]	1/325 (0.3%)[a]
	Lethargy[c]	
Cardiac disorders	Myocarditis[b]	N/A[e]
	Pericarditis[b]	N/A[e]
Gastrointestinal disorders	Diarrhea[b]	36/306 (11.8%)[d]
	Vomiting[b]	5/306 (1.6%)[d]
	Nausea[c]	
Skin and subcutaneous tissue disorders	Hyperhidrosis[c]	
	Night sweats[c]	
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	87/306 (28.4%)[d]
	Arthralgia (joint pain) (new)	46/306 (15.0%)[d]
	Pain in extremity (arm)[b,c]	
General disorders and administration site conditions	Injection site pain	240/306 (78.4%)[f]
	Fatigue	185/306 (60.5%)[d]
	Chills	80/306 (26.1%)[d]
	Injection site swelling	27/306 (8.8%)[f]
	Pyrexia	22/306 (7.2%)[d]
	Injection site redness	13/306 (4.2%)[f]
	Malaise[c]	
	Asthenia[c]	

a. Source: Number (%) of Participants Reporting at Least 1 Adverse Event From First Study Vaccination Through 1 Month After First Study Vaccination, by System Organ Class and Preferred Term - Cohort 2 - Safety Population (Study C4591031 SSD, Cutoff date: 11 March 2022)
b. These adverse reactions were identified in the post-authorization period.
c. At the time of the data cut-off date, the following reactions were not reported in the safety population in Study C4591031 SSD: rash, pruritus, urticaria, angioedema, decreased appetite, lethargy, nausea, hyperhidrosis, night sweats, pain in extremity, malaise, and asthenia but are still considered adverse reactions.
d Source = Systemic Events, by Maximum Severity, Within 7 Days After First Study Vaccination - Cohort 2 - Safety Population (Study C4591031 SSD, Cutoff date: 11 March 2022)
e. Due to the cross-over design of clinical trials, the actual incidence of myocarditis and pericarditis cannot be reliably estimated however, based on published literature presented in the Clinical Overview to support inclusion of myocarditis and pericarditis as adverse drug reactions in Section 4.8 of the CDS, the CIOMS frequency category for myocarditis and pericarditis is "very rare."[89]
f. Source = Local Reactions, by Maximum Severity, Within 7 Days After First Study Vaccination - Cohort 2 - Safety Population (Study C4591031 SSD, Cutoff date: 11 March 2022)

Table A-9. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals >55 years old Who Received a Booster (Dose 4) of BNT162b2 30 µg in Study C4591031 Substudy E (SSE) – Expanded Cohort – Safety Population (16 May 2022 Data Cut-off Date)[64]

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy	1/305 (0.3%)[a]
Immune system disorders	Anaphylaxis[b]	Not known
	Hypersensitivity reactions	
	Rash[b,c]	
	Pruritus[b,c]	
	Urticaria[b,c]	
	Angioedema[b,c]	
Metabolism and nutrition disorders	Decreased appetite[c]	
Nervous system disorders	Headache	79/298 (26.5%)[d]
	Dizziness[b]	1/305 (0.3%)[a]
	Lethargy[c]	
Cardiac disorders	Myocarditis[b]	N/A[e]
	Pericarditis[b]	N/A[e]
Gastrointestinal disorders	Diarrhea[b]	13/298 (4.4%)[d]
	Vomiting[b]	4/298 (1.3%)[d]
	Nausea	1/305 (0.3%)[a]
Skin and subcutaneous tissue disorders	Hyperhidrosis[c]	
	Night sweats[c]	
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	59/298 (19.8%)[d]
	Arthralgia (joint pain) (new)	27/298 (9.1%)[d]
	Pain in extremity (arm)[b]	1/305 (0.3%)[a]
General disorders and administration site conditions	Injection site pain	179/298 (60.1%)[f]
	Fatigue	135/298 (45.3%)[d]
	Chills	49/298 (16.4%)[d]
	Injection site redness	19/298 (6.4%)[f]
	Injection site swelling	18/298 (6.0%)[f]
	Pyrexia	11/298 (3.7%)[d]
	Malaise[c]	
	Asthenia[c]	

a. Source: Number (%) of Participants Reporting at Least 1 Adverse Event From the Study Vaccination Through 1 Month After the Study Vaccination, by System Organ Class and Preferred Term — Expanded Cohort — Participants >55 Years of Age — Safety Population (Study C4591031 SSE, Cutoff date: 16 May 2022)
b. These adverse reactions were identified in the post-authorization period.
c. At the time of the data cut-off date, the following reactions were not reported in the safety population in Study C4591031 SSE: rash, pruritus, urticaria, angioedema, decreased appetite, lethargy, hyperhidrosis, night sweats, malaise and asthenia but are still considered ADRs.
d. Source = Systemic Events, by Maximum Severity, Within 7 Days After the Study Vaccination – Expanded Cohort – Participants >55 Years of Age – Safety Population (Study C4591031 SSE, Cutoff date: 16 May 2022)
e. Due to the cross-over design of clinical trials, the actual incidence of myocarditis and pericarditis cannot be reliably estimated however, based on published literature presented in the Clinical Overview to support inclusion of myocarditis and pericarditis as adverse drug reactions in Section 4.8 of the CDS, the CIOMS frequency category for myocarditis and pericarditis is "very rare."[89]
f. Source = Local Reactions, by Maximum Severity, Within 7 Days After the Study Vaccination – Expanded Cohort – Participants >55 Years of Age – Safety Population (Study C4591031 SSE, Cutoff date: 16 May 2022)

Table A-10. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 18 to 55 years old Who Received a Booster (Dose 4) of Monovalent BNT162b2 OMI BA.1 (30 ug) in Study C4591031 Substudy D (SSD) – Safety Population (11 March 2022 Data Cut-off Date)[64]

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy[a]	2/315 (0.6%)[b]
Immune system disorders	Anaphylaxis[c]	Not known
	Hypersensitivity reactions	
	Rash[c,d]	
	Pruritus[c,d]	
	Urticaria[c,d]	
	Angioedema[c,d]	
Metabolism and nutrition disorders	Decreased appetite[d]	
Nervous system disorders	Headache	140/294 (47.6%)[e]
	Dizziness[c]	1/315 (0.3%)[b]
	Lethargy[d]	
Cardiac disorders	Myocarditis[c]	N/A[f]
	Pericarditis[c]	N/A[f]
Gastrointestinal disorders	Diarrhea[c]	25/294 (8.5%)[e]
	Vomiting[c]	8/294 (2.7%)[e]
	Nausea[d]	
Skin and subcutaneous tissue disorders	Night sweats	1/315 (0.3%)[b]
	Hyperhidrosis[d]	
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	99/294 (33.7%)[e]
	Arthralgia (joint pain) (new)	69/294 (23.5%)[e]
	Pain in extremity (arm)[c,d]	
General disorders and administration site conditions	Injection site pain	229/294 (77.9%)[g]
	Fatigue	189/294 (64.3%)[e]
	Chills	93/294 (31.6%)[e]
	Pyrexia	25/294 (8.5%)[e]
	Injection site swelling	25/294 (8.5%)[g]
	Injection site redness	21/294 (7.1%)[g]
	Malaise[d]	
	Asthenia[d]	

a. The frequency of lymphadenopathy was calculated as follows: Lymphadenopathy (n=1), axillary pain (n=1) (1+1=2/315=0.6%)
b. Source: Number (%) of Participants Reporting at Least 1 Adverse Event From First Study Vaccination Through 1 Month After First Study Vaccination, by System Organ Class and Preferred Term - Cohort 2 - Safety Population (Study C4591031 SSD, Cutoff date: 11 March 2022)
c. These adverse reactions were identified in the post-authorization period.
d. At the time of the data cut-off date, the following reactions were not reported in the safety population in Study C4591031 SSD: rash, pruritus, urticaria, angioedema, decreased appetite, lethargy, nausea, hyperhidrosis, pain in extremity, malaise, and asthenia but are still considered ADRs.
e. Source = Systemic Events, by Maximum Severity, Within 7 Days After First Study Vaccination - Cohort 2 - Safety Population (Study C4591031 SSD, Cutoff date: 11 March 2022)
f. Due to the cross-over design of clinical trials, the actual incidence of myocarditis and pericarditis cannot be reliably estimated however, based on published literature presented in the Clinical Overview to support inclusion of myocarditis and pericarditis as adverse drug reactions in Section 4.8 of the CDS, the CIOMS frequency category for myocarditis and pericarditis is "very rare."[89]
g. Source = Local Reactions, by Maximum Severity, Within 7 Days After First Study Vaccination - Cohort 2 – Safety Population (Study C4591031 SSD, Cutoff date: 11 March 2022)

Table A-11. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals >55 years old Who Received a Booster (Dose 4) of Bivalent BNT162b2 (15 µg) + BNT162b2 OMI BA.1 (15 µg) in Study C4591031 Substudy E (SSE) – Expanded Cohort – Safety Population (16 May 2022 Data Cut-off Date)[64]

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy	1/305 (0.3%)[a]
Immune system disorders	Anaphylaxis[b]	Not known
	Hypersensitivity reactions	
	Rash[b,c]	
	Pruritus[b,c]	
	Urticaria[b,c]	
	Angioedema[b,c]	
Metabolism and nutrition disorders	Decreased appetite[c]	
Nervous system disorders	Headache	101/301 (33.6%)[d]
	Dizziness[b]	3/305 (1.0%)[a]
	Lethargy[c]	
Cardiac disorders	Myocarditis[b]	N/A[e]
	Pericarditis[b]	N/A[e]
Gastrointestinal disorders	Diarrhea[b]	27/301 (9.0%)[d]
	Vomiting[b]	5/301 (1.7%)[d]
	Nausea	1/305 (0.3%)[a]
Skin and subcutaneous tissue disorders	Hyperhidrosis[c]	
	Night sweats[c]	
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	67/301 (22.3%)[d]
	Arthralgia (joint pain) (new)	34/301 (11.3%)[d]
	Pain in extremity (arm)[b,c]	
General disorders and administration site conditions	Injection site pain	175/301 (58.1%)[f]
	Fatigue	148/301 (49.2%)[d]
	Chills	39/301 (13.0%)[d]
	Injection site redness	21/301 (7.0%)[f]
	Injection site swelling	20/301 (6.6%)[f]
	Pyrexia	15/301 (5.0%)[d]
	Malaise	1/305 (0.3%)[a]
	Asthenia[c]	

a. Source: Number (%) of Participants Reporting at Least 1 Adverse Event From the Study Vaccination Through 1 Month After the Study Vaccination, by System Organ Class and Preferred Term — Expanded Cohort — Participants >55 Years of Age — Safety Population (Study C4591031 SSE, Cutoff date: 16May2022)
b. These adverse reactions were identified in the post-authorization period.
c. At the time of the data cut-off date, the following reactions were not reported in the safety population in Study C4591031 SSE: rash, pruritus, urticaria, angioedema, decreased appetite, lethargy, hyperhidrosis, night sweats, pain in extremity and asthenia but are still considered adverse reactions.
d. Source = Systemic Events, by Maximum Severity, Within 7 Days After the Study Vaccination – Expanded Cohort – Participants >55 Years of Age – Safety Population (Study C4591031 SSE, Cutoff date: 16May2022)
e. Due to the cross-over design of clinical trials, the actual incidence of myocarditis and pericarditis cannot be reliably estimated however, based on published literature presented in the Clinical Overview to support inclusion of myocarditis and pericarditis as adverse drug reactions in Section 4.8 of the CDS, the CIOMS frequency category for myocarditis and pericarditis is "very rare."[89]
f. Source = Local Reactions, by Maximum Severity, Within 7 Days After the Study Vaccination – Expanded Cohort – Participants >55 Years of Age – Safety Population (Study C4591031 SSE, Cutoff date: 16May2022)

Table A-12. Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 5 Through <12 Years of Age Who Received a Booster Dose (Dose 3) of BNT162b2 (22 March 2022 Data Cut-off Date)[*,64,84]

System Organ Class	ADR Term	Frequency n/N (%)
Blood and lymphatic system disorders	Lymphadenopathy[a]	10/401 (2.5%)[b]
Immune system disorders	Anaphylaxis[e]	Not known
	Hypersensitivity reactions	
	Rash[e]	1/401 (0.2%)[b]
	Urticaria[e,f]	
	Pruritus[e,f]	
	Angioedema[e,f]	
Metabolism and nutrition disorders	Decreased appetite[f]	
Nervous system disorders	Headache	126/371 (34.0%)[c]
	Dizziness[e]	1/401 (0.2%)[b]
	Lethargy[f]	
Cardiac Disorders	Myocarditis[e,f]	N/A[g]
	Pericarditis[e,f]	N/A[g]
Gastrointestinal disorders	Diarrhea[e]	18/371 (4.9%)[c]
	Vomiting[e]	9/371 (2.4%)[c]
	Nausea[f]	
Skin and subcutaneous tissue disorders	Hyperhidrosis[f]	
	Night sweats[f]	
Musculoskeletal and connective tissue disorders	Myalgia (muscle pain)	68/371 (18.3%)[c]
	Arthralgia (joint pain) (new)	25/371 (6.7%)[c]
	Pain in extremity (arm)[e,f]	
General disorders and administration site conditions	Injection site pain	274/371 (73.9%)[d]
	Fatigue	169/371 (45.6%)[c]
	Injection site swelling	61/371 (16.4%)[d]
	Injection site redness	58/371 (15.6%)[d]
	Chills	39/371 (10.5%)[c]
	Pyrexia	25/371 (6.7%)[c]
	Malaise[f]	
	Asthenia[f]	

* Dose 3 (a booster dose) of BNT162b2 10 µg was administered to participants 5 through <12 years of age in Study C4591007.

a. A higher frequency of lymphadenopathy was observed in participants 5 through <12 years of age in Study C4591007 (2.5% vs. 0.9%) receiving a booster dose compared to participants receiving 2 doses. The frequency of lymphadenopathy was calculated as follows: lymphadenopathy (n = 8), lymph node palpable (n = 1), axillary mass (n = 1) (8+1+1 = 10/401 = 2.5%).

b. Source: Number (%) of Participants Reporting at Least 1 Adverse Event From Dose 3 to 1 Month After Dose 3, by System Organ Class and Preferred Term – Phase 2/3 – Participants Who Received Dose 3 of BNT162b2 – 5 to <12 Years of Age – Safety Population (Study C4591007, Cut-off date: 22 March 2022).

c. Source = Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 2/3 – Participants Who Received Dose 3 of BNT162b2 – 5 to <12 Years of Age – Safety Population (Study C4591007, Cut-off date: 22 March 2022).

d. Source = Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 2/3 – Participants Who Received Dose 3 of BNT162b2 – 5 to <12 Years of Age – Safety Population (Study C4591007, Cut-off date: 22 March 2022).

e. These adverse reactions were identified in the post-authorization period.

f. At the time of the data cut-off date, the following reactions were **not** reported in participants 5 through <12 Years of Age in Study C4591007 after Dose 3: urticaria, pruritus, angioedema, decreased appetite, lethargy, myocarditis, pericarditis, nausea, night sweats, hyperhidrosis, pain in extremity (arm), malaise, asthenia but are still considered adverse reactions.

g. Due to the cross-over design of clinical trials, the actual incidence of myocarditis and pericarditis cannot be reliably estimated however, based on published literature presented in the Clinical Overview to support inclusion of myocarditis and pericarditis as adverse drug reactions in Section 4.8 of the CDS, the CIOMS frequency category for myocarditis and pericarditis is "very rare."[89]

Appendix B: Adverse Drug Reactions (ADRs) by System Organ Class and Council for International Organizations of Medical Science (CIOMS) Frequency Category Listed in Order of Decreasing Medical Seriousness or Clinical Importance Within Each Frequency Category and SOC

Table B-1. ADRs by SOC and CIOMS Frequency Category* Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and SOC: Individuals 16 Years of Age and Older (13 March 2021 Data Cut-off Date)[64]

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders			Urticaria[a,b]; Pruritus[a,b]; Rash[a,b]	Angioedema[a,b]		Anaphylaxis[a]
Metabolism and Nutrition disorders			Decreased appetite			
Nervous system disorders	Headache		Dizziness[a]; Lethargy			
Cardiac disorders					Myocarditis[a]; Pericarditis[a]	
Gastrointestinal disorders	Diarrhea[a]	Vomiting[a]; Nausea				
Skin and subcutaneous Tissue disorders			Hyperhidrosis; Night sweats			
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia		Pain in extremity (arm)[a]			
General disorders and administration site conditions	Pyrexia; Injection site pain; Fatigue; Chills; Injection site swelling	Injection site redness	Asthenia; Malaise			

* CIOMS frequency categories are based on clinical trial C4591001 crude incidence and was reported to only one significant figure.

a. These adverse reactions were identified in the post-authorization period.

b. The following events are categorized as hypersensitivity reactions: urticaria, pruritus, rash, and angioedema.

Table B-2. ADRs by SOC and CIOMS Frequency Category* Listed in order of Decreasing Medical Seriousness Within Each Frequency Category and SOC: Individuals 12 Through 15 Years of Age (13 March 2021 Data Cut-off Date)[64]

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders			Urticaria[a,b]; Rash[a,b]			Anaphylaxis[a]
Nervous system disorders	Headache		Dizziness[a]			
Cardiac disorders					Myocarditis[a]; Pericarditis[a]	
Gastrointestinal disorders	Diarrhea[a]	Vomiting[a]	Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia		Pain in extremity (arm)[a]			
General disorders and administration site conditions	Pyrexia; Injection site pain; Fatigue; Chills	Injection site swelling; Injection site redness				

* CIOMS frequency categories are based on clinical trial C4591001 crude incidence and was reported to only one significant figure.

a. These adverse reactions were identified in the post-authorization period. The following events were not reported in the 12 through 15 years of age group in Study C4591001: angioedema, pruritus, malaise, lethargy, asthenia, decreased appetite, hyperhidrosis, and night sweats but are still considered adverse reactions for this age group.

b. The following events are categorized as hypersensitivity reactions: urticaria and rash.

Table B-3. ADRs by System Organ Class and CIOMS Frequency Category* Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Individuals 5 Through <12 Years of Age (06 September 2021 Data Cut-off Date)[64]

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders			Urticaria[a,b]; Pruritus[a,b]; Rash[a,b]			Anaphylaxis[a]
Metabolism and nutrition disorders			Decreased appetite			
Nervous system disorders	Headache		Dizziness[a]			
Gastrointestinal disorders		Diarrhea[a]; Vomiting[a]	Nausea			
Musculoskeletal and connective tissue disorders	Myalgia	Arthralgia	Pain in extremity (arm)[a]			
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Injection site swelling; Injection site redness	Pyrexia	Malaise			

* CIOMS frequency categories are based on clinical trial C4591007 crude incidence and was reported to only one significant figure.

a. These adverse reactions were identified in the post-authorization period. At the time of the data cut-off date, the following reactions were not reported in participants 5 through <12 years of age in Study C4591007: angioedema, lethargy, myocarditis, pericarditis, asthenia, hyperhidrosis, and night sweats but are still considered adverse reactions for this age group.

b. The following events are categorized as hypersensitivity reactions: urticaria, pruritus, and rash.

Table B-4. ADRs by System Organ Class and CIOMS Frequency Category* Listed in order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Individuals 2 to <5 Years of Age (29 April 2022 Data Cut-off Date)[64]

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders			Rash[a,b]; Urticaria[a,b]			Anaphylaxis[a]
Metabolism and nutrition disorders			Decreased appetite			
Nervous system disorders		Headache				
Gastrointestinal disorders	Diarrhea[a]	Vomiting[a]	Nausea			
Musculoskeletal and connective tissue disorders		Arthralgia; Myalgia	Pain in extremity (arm)[a]			
General disorders and administration site conditions	Pyrexia; Injection site pain; Fatigue; Injection site redness	Chills; Injection site swelling	Asthenia			

* CIOMS frequency categories are based on clinical trial C4591007 crude incidence and was reported to only one significant figure.

a. These adverse reactions were identified in the post-authorization period. At the time of the data cut-off date, the following reactions were not reported in participants 2 to <5 Years of Age in Study C4591007: pruritus, angioedema, dizziness, lethargy, myocarditis, pericarditis, hyperhidrosis, night sweats, and malaise but are still considered adverse reactions for this age group.

b. The following events are categorized as hypersensitivity reactions: rash and urticaria.

Table B-5. ADRs by System Organ Class and CIOMS Frequency Category* Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Individuals 6 Months to <2 Years of Age (29 April 2022 Data Cut-off Date)[64]

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders		Rash[a,b]	Urticaria[a,b]			Anaphylaxis[a]
Metabolism and nutrition disorders	Decreased appetite					
Psychiatric disorders	Irritability					
Nervous system disorders			Headache Lethargy			
Gastrointestinal disorders		Diarrhea[a]; Vomiting[a]				
General disorders and administration site conditions	Pyrexia; Injection site tenderness; Injection site redness	Injection site swelling	Fatigue; Chills			

* CIOMS frequency categories are based on clinical trial C4591007 crude incidence and was reported to only one significant figure.

a. These adverse reactions were identified in the post-authorization period. At the time of the data cut-off date, the following reactions were not reported in participants 6 months to <2 Years of Age in Study C4591007: pruritus, angioedema, dizziness, myocarditis, pericarditis, nausea, hyperhidrosis, night sweats, myalgia, arthralgia, pain in extremity, malaise, and asthenia but are still considered adverse reactions for this age group.

b. The following events are categorized as hypersensitivity reactions: rash and urticaria.

Table B-6. ADRs by SOC and CIOMS Frequency Category* Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and SOC: BNT162b2-Experienced Individuals (18 to 55 Years of Age) Who Were Rerandomized to Receive 1 Booster (Dose 3) of BNT162b2 (30 µg) – Booster Safety Population (17 June 2021 Data Cut-off Date)†,[64]

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders		Lymphadenopathy				
Immune system disorders			Rash[a]			Anaphylaxis[a]
Metabolism and nutrition disorders			Decreased appetite			
Nervous system disorders	Headache		Dizziness[a]			
Cardiac disorders					Myocarditis[a]; Pericarditis[a]	
Gastrointestinal disorders		Diarrhea[a]; Vomiting[a]	Nausea			
Skin and subcutaneous tissue disorders						
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia		Pain in extremity (arm)[a]			
General disorders and administration site conditions	Injection site pain; Fatigue; Chills	Pyrexia; Injection site swelling; Injection site redness				

* CIOMS frequency categories are based on clinical trial C4591001 crude incidence and was reported to only one significant figure.

† The booster dose (a third dose) of BNT162b2 30 µg was administered to participants 18 to 55 years of age.

a. These adverse reactions were identified in the post-authorization period. The following events were not reported in the booster safety population in Study C4591001: angioedema, pruritus, urticaria, malaise, lethargy, asthenia, hyperhidrosis, and night sweats but are still considered adverse reactions for this age group.

b. The following event is categorized as a hypersensitivity reaction: rash.

Table B-7. Non-reactogenicity* ADRs by System Organ Class and CIOMS Frequency Category† Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Study C4591031 Substudy A (SSA), Individuals ≥16 Years of Age who Received 1 Booster (Dose 3) of BNT162b2 (30 µg) in Study C4591031 SSA (5 October 2021 Data Cut-off Date)[64]

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders		Lymphadenopathy				
Immune system disorders			Pruritus[a,b]; Rash[a,b]	Urticaria[a,b]		Anaphylaxis[a]
Metabolism and nutrition disorders			Decreased appetite			
Nervous system disorders			Dizziness[a]; Lethargy			
Cardiac disorders					Myocarditis[a]; Pericarditis[a]	
Gastrointestinal disorders			Nausea			
Skin and subcutaneous tissue disorders			Hyperhidrosis; Night sweats			
Musculoskeletal and connective tissue disorders		Pain in extremity (arm)[a]				
General disorders and administration site conditions			Asthenia; Malaise			

* Refer to Table A-6 and Table B-6 for the booster (Dose 3) frequencies and CIOMS Frequency Categories for the reactogenicity adverse reactions which were determined from the booster safety population of Study C4591001 who utilized e-diaries: headache, diarrhea, vomiting, myalgia (muscle pain), arthralgia (joint pain) (new), injection site pain, fatigue, chills, pyrexia, injection site swelling, injection site redness.

† CIOMS frequency categories are based on clinical trial C4591031 crude incidence and was reported to only one significant figure.

The preferred term pyrexia is a cluster term also covering 'body temperature increased'.

a. These adverse reactions were identified in the post-authorization period. The following non-reactogenicity reaction was not reported in Study C4591031: angioedema but it is still considered an ADR.

b. The following events are categorized as hypersensitivity reactions: urticaria, pruritus, and rash.

Table B-8. ADRs by System Organ Class and CIOMS Frequency Category* Listed in order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 18 to 55 years old Who Received a Booster (Dose 4) of BNT162b2 30 µg in Study C4591031 Substudy D (SSD) — Safety Population (11 March 2022 Data Cut-off Date)[64]

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders						Anaphylaxis[a]
Nervous system disorders	Headache		Dizziness[a]			
Cardiac disorders					Myocarditis[a]; Pericarditis[a]	
Gastrointestinal disorders	Diarrhea[a]	Vomiting[a]				
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia					
General disorders and administration site conditions	Injection site pain; Fatigue; Chills	Pyrexia; Injection site swelling; Injection site redness				

* CIOMS frequency categories are based on clinical trial C4591031 SSD crude incidence and was reported to only one significant figure.

a. These adverse reactions were identified in the post-authorization period. At the time of the data cut-off date, the following reactions were not reported in the safety population in Study C4591031 SSD: rash, pruritus, urticaria, angioedema, decreased appetite, lethargy, nausea, hyperhidrosis, night sweats, pain in extremity, malaise, and asthenia but are still considered adverse reactions.

Table B-9. ADRs by System Organ Class and CIOMS Frequency Category* Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Individuals >55 years old Who Received a Booster (Dose 4) of BNT162b2 30 µg in Study C4591031 Substudy E (SSE) – Expanded Cohort – Safety Population (16 May 2022 Data Cut-off Date)[64]

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders						Anaphylaxis[a]
Nervous system disorders	Headache		Dizziness[a]			
Cardiac disorders					Myocarditis[a]; Pericarditis[a]	
Gastrointestinal disorders		Diarrhea[a]; Vomiting[a]	Nausea			
Musculoskeletal and connective tissue disorders	Myalgia	Arthralgia	Pain in extremity[a]			
General disorders and administration site conditions	Injection site pain; Fatigue; Chills	Pyrexia; Injection site swelling; Injection site redness				

* CIOMS frequency categories are based on clinical trial C4591031 SSE crude incidence and was reported to only one significant figure.

a. These adverse reactions were identified in the post-authorization period. At the time of the data cut-off date, the following reactions were not reported in the safety population in Study C4591031 SSE: rash, pruritus, urticaria, angioedema, decreased appetite, lethargy, hyperhidrosis, night sweats, malaise and asthenia but are still considered adverse reactions.

Table B-10. ADRs by System Organ Class and CIOMS Frequency Category* Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Adverse Drug Reaction Table with Preferred Terms Listed by Decreasing Frequency Within Each System Organ Class: Individuals 18 to 55 Years Old Who Received a Booster (Dose 4) of Monovalent BNT162b2 OMI BA.1 (30 µg) in Study C4591031 Substudy D (SSD) — Safety Population (11 March 2022 Data Cut-off Date)[64]

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders						Anaphylaxis[a]
Nervous system disorders	Headache		Dizziness[a]			
Cardiac disorders					Myocarditis[a,b]; Pericarditis[a,b]	
Gastrointestinal disorders		Diarrhea[a]; Vomiting[a]				
Skin and subcutaneous tissue disorders			Night sweats			
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia					
General disorders and administration site conditions	Injection site pain; Fatigue; Chills	Pyrexia; Injection site swelling; Injection site redness				

* CIOMS frequency categories are based on clinical trial C4591031 SSD crude incidence and was reported to only one significant figure.

a. These adverse reactions were identified in the post-authorization period. At the time of the data cut-off date, the following reactions were not reported in the safety population in Study C4591031 SSD: rash, pruritus, urticaria, angioedema, decreased appetite, lethargy, nausea, hyperhidrosis, pain in extremity, malaise, and asthenia but are still considered adverse reactions.

Table B-11. ADRs by System Organ Class and CIOMS Frequency Category* Listed in order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Individuals >55 years old Who Received a Booster (Dose 4) of Bivalent BNT162b2 (15 µg) + BNT162b2 OMI BA.1 (15 µg) in Study C4591031 Substudy E (SSE) – Expanded Cohort – Safety Population (16 May 2022 Data Cut-off Date)[64]

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders			Lymphadenopathy			
Immune system disorders						Anaphylaxis[a]
Nervous system disorders	Headache	Dizziness[a]				
Cardiac disorders					Myocarditis[a,b]; Pericarditis[a,b]	
Gastrointestinal disorders		Diarrhea[a]; Vomiting[a]	Nausea			
Musculoskeletal and connective tissue disorders	Arthralgia; Myalgia					
General disorders and administration site conditions	Injection site pain; Fatigue; Chills	Pyrexia; Injection site swelling; Injection site redness	Malaise			

* CIOMS frequency categories are based on clinical trial C4591031 SSE crude incidence and was reported to only one significant figure.

a. These adverse reactions were identified in the post-authorization period. At the time of the data cut-off date, the following reactions were not reported in the safety population in Study C4591031 SSE: rash, pruritus, urticaria, angioedema, decreased appetite, lethargy, hyperhidrosis, night sweats, pain in extremity and asthenia but are still considered adverse reactions.

Table B-12. ADRs by System Organ Class and CIOMS Frequency Category* Listed in Order of Decreasing Medical Seriousness Within Each Frequency Category and System Organ Class: Individuals 5 Through <12 Years of Age Who Received Dose 3 (22 March 2022 Data Cut-off Date)[†,64,84]

System Organ Class	Very Common ≥1/10 (≥10%)	Common ≥1/100 to <1/10 (≥1% to <10%)	Uncommon ≥1/1,000 to <1/100 (≥0.1% to <1%)	Rare ≥1/10,000 to <1/1,000 (≥0.01% to <0.1%)	Very Rare <1/10,000 (<0.01%)	Frequency not known (cannot be estimated from the available data)
Blood and lymphatic system disorders		Lymphadenopathy				
Immune system disorders			Rash[a,b]			Anaphylaxis[a]
Metabolism and nutrition disorders						
Nervous system disorders	Headache		Dizziness[a]			
Gastrointestinal disorders		Diarrhea[a]; Vomiting[a]				
Musculoskeletal and connective tissue disorders	Myalgia	Arthralgia				
General disorders and administration site conditions	Injection site pain; Fatigue; Chills; Injection site swelling; Injection site redness	Pyrexia				

* CIOMS frequency categories are based on clinical trial C4591007 crude incidence and was reported to only one significant figure.

† Dose 3 (a booster dose) of BNT162b2 10 µg was administered to participants 5 through <12 years of age in Study C4591007.

a. These adverse reactions were identified in the post-authorization period. At the time of the data cut-off date, the following reactions were **not** reported in participants 5 through <12 years of age in Study C4591007 after Dose 3: urticaria, pruritus, angioedema, decreased appetite, lethargy, myocarditis, pericarditis, nausea, night sweats, hyperhidrosis, pain in extremity (arm), malaise, and asthenia but are still considered adverse reactions in this age group.

b. The following event is categorized as a hypersensitivity reaction: rash.

Appendix C. HIV-Positive Participants 16 Years of Age and Older – Reactogenicity Frequency in the Safety Population Subset

Table C-1. Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants 16 Years of Age and Older – Reactogenicity Subset of the Safety Population*,65

	TRADENAME Dose 1 N[a]=54 n[b] (%)	Placebo Dose 1 N[a]=56 n[b] (%)	TRADENAME Dose 2 N[a]=60 n[b] (%)	Placebo Dose 2 N[a]=62 n[b] (%)
Redness[c]				
Any (>2.0 cm)	2 (3.7)	3 (5.4)	4 (6.7)	1 (1.6)
Mild	2 (3.7)	1 (1.8)	3 (5.0)	1 (1.6)
Moderate	0	0	1 (1.7)	0
Severe	0	2 (3.6)	0	0
Swelling[c]				
Any (>2.0 cm)	3 (5.6)	1 (1.8)	5 (8.3)	0
Mild	2 (3.7)	0	2 (3.3)	0
Moderate	1 (1.9)	0	3 (5.0)	0
Severe	0	1 (1.8)	0	0
Pain at the injection site[d]				
Any	34 (63.0)	9 (16.1)	32 (53.3)	5 (8.1)
Mild	26 (48.1)	8 (14.3)	22 (36.7)	5 (8.1)
Moderate	8 (14.8)	1 (1.8)	9 (15.0)	0
Severe	0	0	1 (1.7)	0

Notes: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
No Grade 4 solicited local reactions were reported in HIV-Positive participants 16 years of age and older.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. The N for each reaction was the same, therefore, this information was included in the column header.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

Table C-2. Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants 16 Years of Age and Older – Reactogenicity Subset of the Safety Population*,66

	TRADENAME Dose 1 N[a]=54 n[b] (%)	Placebo Dose 1 N[a]=56 n[b] (%)	TRADENAME Dose 2 N[a]=60 n[b] (%)	Placebo Dose 2 N[a]=62 n[b] (%)
Fever				
≥38.0°C	1 (1.9)	4 (7.1)	9 (15.0)	5 (8.1)
≥38.0°C to 38.4°C	1 (1.9)	2 (3.6)	4 (6.7)	5 (8.1)
>38.4°C to 38.9°C	0	0	4 (6.7)	0
>38.9°C to 40.0°C	0	2 (3.6)	1 (1.7)	0
>40.0°C	0	0	0	0
Fatigue[c]				
Any	22 (40.7)	15 (26.8)	24 (40.0)	12 (19.4)
Mild	15 (27.8)	9 (16.1)	12 (20.0)	5 (8.1)
Moderate	7 (13.0)	5 (8.9)	9 (15.0)	7 (11.3)
Severe	0	1 (1.8)	3 (5.0)	0
Headache[c]				
Any	11 (20.4)	18 (32.1)	18 (30.0)	12 (19.4)
Mild	7 (13.0)	10 (17.9)	8 (13.3)	8 (12.9)
Moderate	4 (7.4)	7 (12.5)	8 (13.3)	4 (6.5)
Severe	0	1 (1.8)	2 (3.3)	0
Chills[c]				
Any	6 (11.1)	5 (8.9)	14 (23.3)	4 (6.5)
Mild	5 (9.3)	4 (7.1)	5 (8.3)	3 (4.8)
Moderate	1 (1.9)	1 (1.8)	8 (13.3)	1 (1.6)
Severe	0	0	1 (1.7)	0
Vomiting[d]				
Any	1 (1.9)	3 (5.4)	2 (3.3)	2 (3.2)
Mild	1 (1.9)	1 (1.8)	1 (1.7)	1 (1.6)
Moderate	0	0	1 (1.7)	1 (1.6)
Severe	0	2 (3.6)	0	0
Diarrhea[e]				
Any	5 (9.3)	8 (14.3)	4 (6.7)	9 (14.5)
Mild	5 (9.3)	6 (10.7)	1 (1.7)	6 (9.7)
Moderate	0	1 (1.8)	2 (3.3)	3 (4.8)
Severe	0	1 (1.8)	1 (1.7)	0
New or worsened muscle pain[c]				
Any	9 (16.7)	10 (17.9)	10 (16.7)	5 (8.1)
Mild	7 (13.0)	7 (12.5)	5 (8.3)	1 (1.6)
Moderate	2 (3.7)	3 (5.4)	5 (8.3)	4 (6.5)
Severe	0	0	0	0

Table C-2. Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – HIV-Positive Participants 16 Years of Age and Older – Reactogenicity Subset of the Safety Population*,66

	TRADENAME Dose 1 N[a]=54 n[b] (%)	Placebo Dose 1 N[a]=56 n[b] (%)	TRADENAME Dose 2 N[a]=60 n[b] (%)	Placebo Dose 2 N[a]=62 n[b] (%)
New or worsened joint pain[c]				
Any	5 (9.3)	7 (12.5)	10 (16.7)	5 (8.1)
Mild	5 (9.3)	4 (7.1)	4 (6.7)	1 (1.6)
Moderate	0	3 (5.4)	6 (10.0)	4 (6.5)
Severe	0	0	0	0
Use of antipyretic or pain medication[f]	7 (13.0)	8 (14.3)	16 (26.7)	7 (11.3)

Notes: Reactions and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.
No Grade 4 solicited systemic reactions were reported in HIV-positive participants 16 years of age and older.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. The N for each event or use of antipyretic or pain medication was the same, therefore, this information was included in the column header.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

f. Severity was not collected for use of antipyretic or pain medication.

APPENDIX 2.1 - Cumulative Summary Tabulation of Serious Adverse Events from Clinical Trials

BNT162B2-ALL

Reporting Period: Through 18-DEC-2022
Total Number of Cases: 2,629
Total Number of Adverse Events (PT): 3,460
MedDRA Version: v.25.1J

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
Blood and lymphatic system disorders	Anaemia	10	3		
	Anaemia macrocytic	1			
	Blood loss anaemia	1			
	Coagulopathy	1	1		
	Febrile neutropenia	2			
	Haemoconcentration	1			
	Haemorrhagic diathesis	1			
	Immune thrombocytopenia		2		
	Iron deficiency anaemia	2			
	Lymphadenitis		1		
	Lymphadenopathy	1			
	Microcytic anaemia		1		
	Neutropenia		1		
	Normocytic anaemia		1		

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Pancytopenia	1			
	Red blood cell abnormality		1		
	Sickle cell anaemia with crisis	1	1		
	Splenic vein thrombosis	1			
	Thrombocytopenia	1	2		
	Thrombocytopenia neonatal		1		
Sub Total:		**24**	**15**		
Cardiac disorders	Accelerated idioventricular rhythm	1			
	Acute coronary syndrome	7	5		
	Acute left ventricular failure	2	2		
	Acute myocardial infarction	22	20	1	
	Angina pectoris	3	4		
	Angina unstable	6	3		
	Aortic valve incompetence			2	
	Arteriosclerosis coronary artery		1		
	Arteriospasm coronary	1	1		
	Atrial fibrillation	29	21	1	
	Atrial flutter	3			
	Atrioventricular block	1			

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Atrioventricular block complete		1		
	Atrioventricular block first degree	1			
	Bradycardia		2		
	Bradycardia foetal		1		
	Cardiac arrest	6	10	1	
	Cardiac disorder	1			
	Cardiac failure	2	1		
	Cardiac failure acute	1		1	
	Cardiac failure chronic			1	
	Cardiac failure congestive	15	7		
	Cardiomyopathy		1		
	Cardiopulmonary failure	1			
	Cardio-respiratory arrest	4	5		
	Cardiovascular disorder	1			
	Chronic left ventricular failure	1			
	Conduction disorder	1			
	Congestive cardiomyopathy	1			
	Coronary artery disease	13	9	3	

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Coronary artery dissection		1		
	Coronary artery insufficiency		1		
	Coronary artery occlusion	1	4		
	Hypertensive heart disease		2		
	Ischaemic cardiomyopathy	1	1		
	Junctional ectopic tachycardia		1		
	Left ventricular failure		1		
	Mitral valve incompetence	4			
	Mitral valve prolapse			1	
	Myocardial infarction	18	16	1	
	Myocardial ischaemia	1	1		
	Myocarditis	1			
	Myopericarditis	2			
	Nodal arrhythmia		1		
	Nonreassuring foetal heart rate pattern		2		
	Palpitations	2			
	Pericardial haemorrhage		1		
	Pericarditis	2	1		

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Postural orthostatic tachycardia syndrome	1			
	Prinzmetal angina	1			
	Sinus node dysfunction	1			
	Supraventricular extrasystoles	1			
	Supraventricular tachycardia	6			
	Tachyarrhythmia		1		
	Tachycardia	2	1		
	Ventricular arrhythmia	2			
	Ventricular extrasystoles	1	1		
	Ventricular fibrillation	1	1		
	Ventricular tachycardia	5	1		
Sub Total:		**176**	**132**	**12**	
Congenital, familial and genetic disorders	Ankyloglossia congenital		2		
	Atrial septal defect	2	3		
	BRCA1 gene mutation	1			
	Congenital bladder neck obstruction			1	
	Congenital rubella syndrome		1		

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Treatment Grouping:
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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Congenital skin dimples			1	
	Congenital ureteropelvic junction obstruction			1	
	Craniosynostosis			1	
	DiGeorge's syndrome		1		
	Heart disease congenital		1		
	Hydrocele		1		
	Hypertrophic cardiomyopathy	2			
	Microcephaly		1		
	Mucopolysaccharidosis		1		
	Newborn persistent pulmonary hypertension		1		
	Patent ductus arteriosus		1		
	Pectus excavatum	1			
	Phimosis	1			
	Polydactyly		1		
	Sex chromosome abnormality		1		
	Sickle cell disease		1		
	Syndactyly		1		
	Syringomyelia		1		

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Treatment Grouping:
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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Thanatophoric dwarfism			1	
	Trisomy 21		2		
	Ventricular septal defect			1	
Sub Total:		**7**	**20**	**6**	
Ear and labyrinth disorders	Deafness neurosensory	3			
	Sudden hearing loss	1			
	Vertigo	4	3		
Sub Total:		**8**	**3**		
Endocrine disorders	Addison's disease	1			
	Goitre	1	2		
Sub Total:		**2**	**2**		
Eye disorders	Blindness unilateral		1		
	Choroidal neovascularisation		1		
	Diplopia	2	1		
	Eye haemorrhage	1		1	
	Eyelid ptosis	1			
	Optic ischaemic neuropathy	1			
	Papilloedema		1		
	Retinal artery occlusion		1		
	Retinal detachment	2			
	Retinal tear	1			

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Treatment Grouping:
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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Retinal vein thrombosis		1		
	Visual impairment		2		
Sub Total:		**8**	**8**	**1**	
Gastrointestinal disorders	Abdominal adhesions	1	1		
	Abdominal compartment syndrome	1			
	Abdominal discomfort	1			
	Abdominal hernia	1	1		
	Abdominal hernia obstructive	1			
	Abdominal migraine		1		
	Abdominal pain	3	4		
	Abdominal pain upper	1	2		
	Abdominal wall haematoma		1		
	Acute abdomen			1	
	Allergic colitis		1		
	Allergic gastroenteritis		1		
	Anal fistula	1		1	
	Colitis	5	3		
	Colitis ischaemic	2	1		
	Colitis ulcerative	2	1		
	Constipation	4	4		

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Treatment Grouping:
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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Dental caries	1			
	Dental cyst	1			
	Diaphragmatic hernia	1			
	Diarrhoea	1	2		
	Diverticular perforation		2		
	Diverticulum intestinal			1	
	Duodenal obstruction		1		
	Duodenal perforation		1		
	Duodenal ulcer	1			
	Duodenal ulcer perforation	1			
	Dysphagia	2	1		
	Enterocolitis		1		
	Eosinophilic oesophagitis	1			
	Food poisoning	1			
	Gastric fistula		1		
	Gastric ulcer	2			
	Gastric ulcer haemorrhage	2			
	Gastritis	1	2		
	Gastritis erosive	1			
	Gastrointestinal haemorrhage	4	4		
	Gastrointestinal mucosa hyperaemia		1		

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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Gastrointestinal necrosis		1		
	Gastrointestinal pain	1			
	Gastrointestinal perforation	1			
	Gastrooesophageal reflux disease	3			
	Haemorrhoidal haemorrhage		1		
	Haemorrhoids		1		
	Hiatus hernia	1	2	1	
	Ileus	1	1		
	Impaired gastric emptying		1		
	Incarcerated inguinal hernia		1		
	Infantile vomiting		1		
	Inguinal hernia	3		1	
	Intestinal ischaemia	1			
	Intestinal mass			1	
	Intestinal obstruction	11	2		
	Intestinal perforation		2	1	
	Intestinal strangulation		1		
	Intestinal ulcer perforation	1			
	Intra-abdominal fluid collection	2			

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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Intra-abdominal haematoma	1			
	Intussusception	1			
	Large intestine perforation	1	2		
	Lower gastrointestinal haemorrhage	3	2		
	Meconium plug syndrome		1		
	Mesenteric panniculitis	1			
	Mesenteric vein thrombosis	1			
	Nausea	3	1		
	Neonatal intestinal perforation		1		
	Obstructive pancreatitis		2		
	Oesophageal food impaction		1		
	Oesophageal stenosis	1			
	Oesophageal varices haemorrhage		1		
	Pancreatic cyst		1		
	Pancreatic pseudocyst		1		
	Pancreatitis	5	6		
	Pancreatitis acute	2	9	1	

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Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Pancreatitis necrotising	2			
	Peptic ulcer	1			
	Pneumoperitoneum		1		
	Rectal haemorrhage	1	1		
	Rectal perforation	1			
	Retroperitoneal haematoma		1		
	Salivary gland calculus			1	
	Small intestinal obstruction	5	16	1	
	Splenic artery aneurysm		1		
	Umbilical hernia		1		
	Upper gastrointestinal haemorrhage	4		1	
	Volvulus	1	1		
	Vomiting	5			
Sub Total:		**107**	**101**	**11**	
General disorders and administration site conditions	Asthenia	1	1		
	Chest discomfort	1			
	Chest pain	9	7	1	
	Condition aggravated	49	33	6	1
	Cyst	1			
	Death	11	6	2	

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	Disease progression		2		
	Disease recurrence	6	2		
	Drowning	1			
	Drug ineffective	1			
	Drug withdrawal syndrome	2	1		
	Electrocution	1			
	Fatigue	1			
	Gait disturbance	2			
	Hypothermia		1		
	Impaired healing		1		
	Influenza like illness	1	1		
	Multi-organ disorder	1			
	Multiple organ dysfunction syndrome			2	
	Non-cardiac chest pain	3	8		
	Oedema	1			
	Oedema peripheral	2			
	Organ failure		1		
	Pain	1	2		
	Procedural failure	1			
	Pyrexia	6	1		
	Shoulder injury related to vaccine administration	1			

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Treatment Grouping:
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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
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	Sudden cardiac death	1			
	Sudden death	2			
	Treatment noncompliance	1			
	Vascular stent occlusion		1		
Sub Total:		**107**	**68**	**11**	**1**
Hepatobiliary disorders	Acute hepatic failure		1		
	Alcoholic liver disease	1			
	Autoimmune hepatitis	2			
	Bile duct stenosis	2			
	Bile duct stone	6	2		
	Biliary colic	4	2		
	Biliary dyskinesia	1			
	Biliary fistula		1		
	Biliary obstruction	1			
	Cholangitis	3			
	Cholecystitis	6	2	1	
	Cholecystitis acute	9	9		
	Cholecystitis chronic	1	1		
	Cholelithiasis	16	8		
	Cholelithiasis obstructive	1			
	Cholestasis of pregnancy	1			

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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
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	Hepatic cirrhosis	1			
	Hepatitis acute	2			
	Hepatocellular injury		1		
	Hyperbilirubinaemia neonatal	2	1	1	
	Ischaemic hepatitis	1			
	Jaundice cholestatic	1			
	Liver injury	1			
	Portal vein thrombosis	2			
	Portosplenomesenteric venous thrombosis	1			
Sub Total:		**65**	**28**	**2**	
Immune system disorders	Anaphylactic reaction	4	3		
	Anaphylactic shock		1		
	Anaphylactoid reaction	1			
	Drug hypersensitivity		1		
	Food allergy	1	1		
	Haemophagocytic lymphohistiocytosis	1			
	Hypersensitivity		1		
	Kidney transplant rejection	2			
Sub Total:		**9**	**7**		
Infections and infestations	Abdominal abscess	3	3	1	
	Abdominal infection	2			

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Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

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	Abdominal sepsis	1	1		
	Abdominal wall abscess	1			
	Abscess		1		
	Abscess limb	2	1	1	
	Abscess oral	1	1		
	Acquired immunodeficiency syndrome	1	1		
	Adenovirus infection	2	4		
	Anal abscess		3		
	Appendicitis	24	31	4	
	Appendicitis perforated	5	5		
	Arteriosclerotic gangrene	1			
	Arthritis bacterial	1	2	1	
	Asymptomatic bacteriuria	1			
	Atypical pneumonia	1			
	Bacteraemia		1		
	Bacterial disease carrier	1			
	Bacterial sepsis		1		
	Brain abscess		1		
	Bronchiolitis	5	9	1	
	Bronchitis	3	2		

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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Campylobacter gastroenteritis	1	1		
	Cat scratch disease		1		
	Cellulitis	9	8	1	
	Cholangitis infective	1			
	Cholecystitis infective	1			
	Clostridium difficile colitis	3	2		
	Clostridium difficile infection	2			
	Colonic abscess		2		
	Complicated appendicitis	3	3		
	COVID-19	4	16	3	
	COVID-19 pneumonia	4	7		
	Croup infectious		1		
	Device related infection	2	2		
	Diabetic foot infection		1		
	Diverticulitis	13	6	1	
	Douglas' abscess	1			
	Emphysematous cholecystitis		1		
	Empyema		1		
	Endocarditis		1		
	Endometritis		1		

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Treatment Grouping:
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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
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SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Enterovirus infection		1		
	Epstein-Barr virus infection	1			
	Escherichia infection		1		
	Escherichia urinary tract infection		1		
	Exanthema subitum	1	1		
	Extradural abscess		1		
	Focal peritonitis	3	2		
	Gangrene	2	1		
	Gastroenteritis	12	10	1	
	Gastroenteritis adenovirus		2		
	Gastroenteritis bacterial			1	
	Gastroenteritis norovirus		1		
	Gastroenteritis rotavirus		4		
	Gastroenteritis viral		5		
	Groin abscess	1			
	HCoV-NL63 infection		1		
	Herpes zoster	2			
	Herpes zoster oticus		1		
	HIV infection	1			
	Human bocavirus infection		1		
	Infected skin ulcer			1	

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Infection		1		
	Infectious pleural effusion	1	1		
	Influenza		1		
	Intervertebral discitis	1			
	Kidney infection	3			
	Labyrinthitis	1			
	Large intestine infection		1		
	Liver abscess	2	2		
	Localised infection		2		
	Lower respiratory tract infection	1	3		
	Lower respiratory tract infection viral	2	1		
	Lung abscess	1			
	Lyme disease		1		
	Mastoiditis	2	1		
	Measles		1		
	Meningitis	1			
	Meningitis bacterial	2	3		
	Meningitis cryptococcal	1			
	Meningitis viral	1			
	Metapneumovirus infection		2		
	Neonatal pneumonia		3		
	Norovirus infection	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Osteomyelitis	4	2		
	Otitis media		1		
	Otitis media acute		1		
	Parainfluenzae virus infection		1		
	Pelvic abscess	2	1		
	Pelvic inflammatory disease	1			
	Penile abscess	1			
	Penile infection	1			
	Peritoneal abscess		1		
	Peritonitis	4	3		
	Peritonsillar abscess	1	2		
	Pharyngeal abscess		1		
	Pharyngitis		1		
	Pharyngitis streptococcal			1	
	Pneumococcal sepsis		1		
	Pneumocystis jirovecii pneumonia		1		
	Pneumonia	35	29	1	
	Pneumonia aspiration	3	3		
	Pneumonia bacterial	2	1	1	
	Pneumonia klebsiella		1		
	Pneumonia pneumococcal	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Pneumonia respiratory syncytial viral		2	1	
	Postoperative abscess		1		
	Postoperative wound infection	2	3		
	Post procedural infection	2	1	1	
	Pulmonary tuberculosis	3			
	Pyelonephritis	2	7		
	Pyelonephritis acute	2	2		
	Renal abscess		1		
	Respiratory syncytial virus bronchiolitis	1	10		
	Respiratory syncytial virus infection	6	3		
	Respiratory tract infection	1	1		1
	Respiratory tract infection viral		1		
	Rhinovirus infection	2	4		
	Salmonellosis		1		
	Sepsis	15	8	1	
	Sepsis neonatal		3		
	Septic arthritis staphylococcal	1			
	Septic endocarditis	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Septic shock	8	2		
	Shigella sepsis		1		
	Sinusitis		1		
	Skin candida		1		
	Skin infection	1			
	Soft tissue infection	1			
	Staphylococcal bacteraemia		1		
	Staphylococcal infection	2	2		
	Staphylococcal sepsis	1	1		
	Streptococcal bacteraemia	1			
	Subacute endocarditis			1	
	Subcutaneous abscess		2		
	Subdiaphragmatic abscess	1			
	Suspected COVID-19		1		
	Tinea pedis		1		
	Tonsillitis		1		
	Tooth infection		1		
	Toxic shock syndrome	2			
	Upper respiratory tract infection		3		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Urinary tract infection	16	11	2	
	Urosepsis	3	4		
	Vascular device infection	1			
	Viral infection		1		
	Wound infection	2			
Sub Total:		**274**	**309**	**25**	**1**
Injury, poisoning and procedural complications	Abdominal injury	1			
	Accidental overdose	1	1		
	Acetabulum fracture		1		
	Alcohol poisoning		1		
	Anastomotic stenosis	1			
	Animal bite	2			
	Ankle fracture	7	3		
	Arterial injury	1			
	Arthropod bite	1			
	Brain contusion	1	1		
	Burns second degree	1	2		
	Burns third degree	1			
	Cervical vertebral fracture	4	2		
	Chest injury	1			
	Clavicle fracture		2		
	Colon injury		1		
	Concussion	2	3		

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Treatment Grouping:
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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Craniocerebral injury	3	4		
	Delayed recovery from anaesthesia			1	
	Epiphyseal fracture	1	1		
	Exposure during pregnancy	1			
	Exposure via breast milk	1			
	Eyelid injury	1			
	Facial bones fracture	4	2		
	Fall	8	3		
	Femur fracture	4	4		
	Fibula fracture	2			
	Flail chest		1		
	Foot fracture	4	1	1	
	Forearm fracture		1		
	Foreign body		1		
	Foreign body in gastrointestinal tract	1			
	Foreign body ingestion		1		
	Fractured sacrum	1	2		
	Fractured skull depressed	1			
	Gastrointestinal anastomotic complication	1			
	Gun shot wound	4	1		

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Treatment Grouping:
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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Hand fracture	1	1		
	Head injury	2	2		
	Hip fracture	2	3	1	
	Humerus fracture	4	2	1	
	Infusion related reaction	1			
	Injury	2	2		
	Injury to brachial plexus due to birth trauma		1		
	Intestinal anastomosis complication	1			
	Jaw fracture	1			
	Joint dislocation	2			
	Lacrimal structure injury	1			
	Ligament rupture	2	2		
	Ligament sprain	1			
	Limb injury	1			
	Lower limb fracture	2	2	1	
	Lumbar vertebral fracture	1	1		
	Maternal exposure before pregnancy	11	2	2	
	Maternal exposure during pregnancy	9	105	9	
	Maternal exposure timing unspecified		1		

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Treatment Grouping:
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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Meniscus injury		2		
	Multiple injuries	1	1		
	Muscle contusion	1			
	Muscle rupture	3			
	Muscle strain		1		
	Neck injury	1			
	Overdose	4	3		
	Patella fracture		1		
	Pelvic fracture	2	3		
	Pneumocephalus	1			
	Postoperative ileus	2	1		
	Post procedural complication	1			
	Post procedural haematoma		1		
	Post-traumatic pain		1		
	Procedural dizziness	1			
	Procedural haemorrhage		1		
	Procedural pain	3			
	Radius fracture	1		1	
	Rib fracture	7	2		
	Road traffic accident	5	10		
	Scapula fracture	2			
	Seroma	1			
	Skeletal injury	1			

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Treatment Grouping:
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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Skin laceration	1	1		
	Skull fracture	1			
	Spinal column injury	1	1		
	Spinal cord injury	1			
	Spinal cord injury cervical		1		
	Spinal fracture	2			
	Splenic rupture		1		
	Stoma complication	1			
	Subdural haematoma	4	3		
	Suture related complication	1			
	Tendon injury		1		
	Tendon rupture	2			
	Thermal burn	4	1		
	Thoracic vertebral fracture	3	1		
	Tibia fracture	5	2		
	Toxicity to various agents	1	3		
	Traumatic haemothorax	1	1		
	Traumatic intracranial haemorrhage		2		
	Traumatic liver injury	1	1		
	Traumatic renal injury	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Ulna fracture	2	1		
	Upper limb fracture	6	2		
	Urethral injury		1		
	Urinary tract procedural complication			1	
	Venous injury		1		
	Wrist fracture	2	3		
Sub Total:		**182**	**217**	**18**	
Investigations	Blood glucose abnormal		1		
	Blood glucose increased		1		
	Blood lactic acid	1			
	Blood pressure increased		1		
	Cardiac murmur		1		
	Foetal heart rate abnormal		1		
	Hepatic enzyme increased	2	1		
	Ultrasound foetal abnormal		1		
Sub Total:		**3**	**7**		
Metabolism and nutrition disorders	Dehydration	5	4	1	
	Diabetes mellitus		1		
	Diabetes mellitus inadequate control	1	1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Diabetic ketoacidosis	6	3		
	Feeding intolerance		1		
	Fluid retention		2		
	Gout	1			
	Hyperglycaemia	3	1	1	
	Hyperkalaemia	1			
	Hypernatraemia			1	
	Hypervolaemia		1		
	Hypocalcaemia			1	
	Hypoglycaemia	1	5		
	Hypoglycaemia neonatal	1		1	
	Hypokalaemia	3	4		
	Hyponatraemia	6	2		
	Lactic acidosis	1			
	Malnutrition		1		
	Metabolic acidosis		1		
	Obesity	2	1		
	Type 1 diabetes mellitus		1		
	Type 2 diabetes mellitus	2	3		
Sub Total:		**33**	**32**	**5**	
Musculoskeletal and connective tissue disorders	Arthralgia	3	2		
	Arthritis	3	1	1	

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Back pain	9	2		
	Cervical spinal stenosis			1	
	Compartment syndrome		1		
	Connective tissue disorder		1		
	Costochondritis	1		1	
	Intervertebral disc compression		1		
	Intervertebral disc degeneration	2	1	2	
	Intervertebral disc protrusion	6	5		1
	Kyphosis	1			
	Lumbar spinal stenosis	4		1	
	Muscular weakness	1	3		
	Musculoskeletal chest pain	2	1		
	Myalgia	1			
	Myositis	1			
	Neck pain		1		
	Osteoarthritis	26	11	4	
	Osteochondritis		1		
	Osteochondrosis		2		
	Osteonecrosis		1		
	Pain in extremity	1	1		

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Treatment Grouping:
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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Pathological fracture	2			
	Psoriatic arthropathy			1	
	Rhabdomyolysis	1			
	Rheumatoid arthritis	1			
	Rotator cuff syndrome		1		
	Spinal deformity	1			
	Spinal osteoarthritis	1		1	
	Spinal stenosis	4			
	Spondylolisthesis	1	3	1	
	Synovial cyst	1			
	Synovitis	1			
	Thoracic spinal stenosis	1		1	
Sub Total:		**75**	**39**	**14**	**1**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	1			
	Acute leukaemia		1		
	Acute lymphocytic leukaemia		1		
	Acute myeloid leukaemia	3	1		
	Adenocarcinoma	1			
	Adenocarcinoma gastric		1		
	Adenocarcinoma of colon	8	3		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Adenocarcinoma pancreas	4	3		
	Adrenal gland cancer		1		
	Adrenal neoplasm	1			
	Adrenocortical carcinoma	1			
	Anal cancer	1			
	Angiosarcoma	1			
	Basal cell carcinoma	1	1	2	
	B-cell lymphoma	1	1		
	B-cell small lymphocytic lymphoma stage IV		1		
	Benign hydatidiform mole		1		
	Biliary cancer metastatic		1		
	Biliary neoplasm	1			
	Bladder cancer	3	3	1	
	Bladder cancer recurrent	2			
	Bladder transitional cell carcinoma	3			
	Bone neoplasm	1			
	Borderline serous tumour of ovary	2			
	Brain neoplasm	4	1		
	Brain neoplasm malignant	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Breast cancer	13	7	3	
	Breast cancer female	1			
	Breast cancer in situ		1		
	Breast cancer metastatic	3	1		
	Breast cancer stage I	2	3		
	Breast cancer stage II	1			
	Bronchioloalveolar carcinoma	1			
	Carcinoid tumour	1			
	Carcinoid tumour pulmonary	1			
	Cervix carcinoma	1			
	Chordoma	1			
	Chronic myeloid leukaemia		1		
	Clear cell renal cell carcinoma	1	1	1	
	Colon cancer	2			
	Colon cancer stage III	1			
	Colorectal adenoma	3	1		
	Cutaneous T-cell lymphoma	1			
	Ductal adenocarcinoma of pancreas	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Endometrial adenocarcinoma	3		1	
	Endometrial cancer	1	1		
	Follicular lymphoma	3	1		
	Gallbladder cancer stage II		1		
	Gastric cancer	1			
	Gastrointestinal stromal tumour	1			
	Glioblastoma	2	1		
	Hepatic adenoma	1			
	Hepatic cancer	2	1		
	Hepatic cancer metastatic		1		
	Hormone receptor positive breast cancer	1	2		
	Hypergammaglobulinaemia benign monoclonal	1			
	Intraductal proliferative breast lesion	4	2		
	Invasive breast carcinoma	2			
	Invasive ductal breast carcinoma	9	6		
	Invasive lobular breast carcinoma	2	1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Large intestine benign neoplasm		1		
	Laryngeal papilloma	1			
	Laryngeal squamous cell carcinoma	1			
	Leukaemia	2	2		
	Leydig cell tumour of the testis		1		
	Lipoma		1		
	Liposarcoma recurrent	1			
	Lung adenocarcinoma	4		2	
	Lung cancer metastatic	1	2		
	Lung carcinoma cell type unspecified stage II		1		
	Lung neoplasm malignant	4			
	Lymphocytic leukaemia		1		
	Malignant melanoma	3	5	1	
	Malignant melanoma in situ			1	
	Malignant melanoma stage II			1	
	Mantle cell lymphoma	1			
	Meningioma		1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Mesothelioma		1		
	Metastases to bone		1		
	Metastases to central nervous system		1		
	Metastases to liver		1		
	Metastases to lung		1		
	Metastases to lymph nodes	1	1	1	
	Metastatic gastric cancer	1			
	Metastatic malignant melanoma	1			
	Metastatic renal cell carcinoma	1			
	Metastatic squamous cell carcinoma		2		
	Mucinous breast carcinoma	1			
	Mucoepidermoid carcinoma of salivary gland	1			
	Myeloproliferative neoplasm	1			
	Neoplasm malignant	1			
	Neoplasm progression	1	1		
	Neoplasm recurrence	1	1		
	Nervous system neoplasm		1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Neuroendocrine carcinoma	1			
	Neuroendocrine tumour			1	
	Non-Hodgkin's lymphoma recurrent			1	
	Non-small cell lung cancer stage III	1			
	Non-small cell lung cancer stage IV		1		
	Ocular melanoma	1			
	Oesophageal adenocarcinoma	1			
	Oesophageal carcinoma	1			
	Oropharyngeal cancer		1		
	Oropharyngeal cancer recurrent			1	
	Oropharyngeal squamous cell carcinoma		2		
	Ovarian adenoma	1			
	Ovarian cancer	3	1		
	Ovarian cancer stage I	1			
	Ovarian neoplasm	1			
	Pancreatic carcinoma	4	2	1	

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Pancreatic carcinoma metastatic	1	2		
	Pancreatic neoplasm	1			
	Pancreatic neuroendocrine tumour	1	1		
	Papillary renal cell carcinoma		1		
	Papillary serous endometrial carcinoma			1	
	Papillary thyroid cancer	1	1	2	
	Parathyroid tumour benign			1	
	Penis carcinoma metastatic		1		
	Pituitary tumour benign	1	2	1	
	Plasma cell myeloma		1		
	Pleural mesothelioma malignant	1			
	Polycythaemia vera			1	
	Prostate cancer	26	9		
	Prostate cancer metastatic	3			
	Prostate cancer stage II	1			
	Rectal cancer	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Rectal cancer metastatic	1			
	Renal cancer	1			
	Renal cancer recurrent		1		
	Renal cell carcinoma		1		
	Renal neoplasm	1			
	Rhabdomyosarcoma	1	1		
	Salivary gland cancer stage IV	1			
	Sarcoma metastatic	1			
	Sebaceous carcinoma		1		
	Seminoma		1		
	Small cell carcinoma	1			
	Squamous cell carcinoma	3			
	Squamous cell carcinoma of the cervix	1			
	Squamous cell carcinoma of the vagina	1			
	Teratoma			1	
	Testicular germ cell cancer		1		
	Testis cancer	1	1		
	Throat cancer	1			
	Thyroid cancer	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Tongue cancer metastatic	1			
	Tonsil cancer	1	1		
	Transitional cell carcinoma	5		1	
	Transitional cell carcinoma recurrent	1			
	Triple negative breast cancer		1		
	Uterine cancer		2		
	Uterine leiomyoma	4	5	1	
	Uterine leiomyosarcoma		1		
	Vascular neoplasm	1			
Sub Total:		**215**	**120**	**27**	
Nervous system disorders	Alcoholic seizure		1		
	Amnesia		1		
	Amyotrophic lateral sclerosis	1		1	
	Anticholinergic syndrome	1			
	Aphasia	2			
	Ataxia		1		
	Autonomic nervous system imbalance	1			
	Basal ganglia haemorrhage			1	
	Bell's palsy	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Brachial plexopathy	1			
	Brain stem infarction	1			
	Carotid artery aneurysm	1			
	Carotid artery stenosis	1			
	Carpal tunnel syndrome		1		
	Cerebellar infarction	1			
	Cerebral haemorrhage	1	1		
	Cerebral infarction		1		
	Cerebral venous sinus thrombosis	1			
	Cerebral venous thrombosis	1	1		
	Cerebrospinal fistula		1		
	Cerebrovascular accident	32	11	1	
	Cervical radiculopathy	1			
	Cervicogenic headache		1		
	Coma neonatal		1		
	Dementia Alzheimer's type		1	1	
	Dizziness	1	3		
	Dural arteriovenous fistula	2			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Dyskinesia	1			
	Embolic stroke	1			
	Encephalopathy	2			
	Encephalopathy neonatal		1		
	Epilepsy	2	2		
	Febrile convulsion	1	3		
	Generalised tonic-clonic seizure	1			
	Guillain-Barre syndrome			1	
	Haemorrhage intracranial	2			
	Haemorrhagic stroke	1	2		
	Headache	1			
	Hemiplegic migraine		1		
	Hepatic encephalopathy	2			
	Hypoaesthesia		1		
	Hypoxic-ischaemic encephalopathy		1		
	Idiopathic intracranial hypertension	1	2		
	Intracranial aneurysm	1	2		
	Intracranial hypotension	1			
	Intracranial pressure increased	1	1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Intraventricular haemorrhage	1	1		
	Ischaemic stroke	8	6		
	Loss of consciousness	1			
	Lumbar radiculopathy		1		
	Migraine	2	1		
	Multifocal motor neuropathy	1			
	Multiple sclerosis relapse		1		
	Myasthenia gravis	2			
	Myelin oligodendrocyte glycoprotein antibody-associated disease	1			
	Myelitis transverse	1			
	Narcolepsy		1		
	Neonatal seizure		1		
	Nervous system disorder	1	1		
	Neuritis		1		
	Neuropathy peripheral	1	1		
	Optic neuritis	2	1		
	Paraesthesia	1	1		
	Peripheral nerve lesion	2			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Polyneuropathy	1			
	Presyncope	3			
	Psychogenic seizure	1			
	Reversible cerebral vasoconstriction syndrome	1			
	Sedation	1			
	Seizure	12	1		
	Serotonin syndrome	1			
	Somnolence	1			
	Spinal claudication	1			
	Spinal cord compression	1	1	1	
	Spinal cord haematoma	1			
	Status epilepticus		1		
	Status migrainosus	1			
	Subarachnoid haemorrhage	1	4	1	
	Superior sagittal sinus thrombosis		1		
	Syncope	19	10	1	
	Tethered cord syndrome		1		
	Toxic encephalopathy	2	2		
	Toxic leukoencephalopathy		1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Transient global amnesia		1		
	Transient ischaemic attack	9	6		
	Uraemic encephalopathy		1		
	VIth nerve paralysis		1		
Sub Total:		**148**	**89**	**8**	
Pregnancy, puerperium and perinatal conditions	Abortion complete	1			
	Abortion incomplete	1		1	
	Abortion missed	4			
	Abortion spontaneous	18	14	4	
	Abortion spontaneous incomplete		1		
	Anembryonic gestation	1			
	Arrested labour		1		
	Breech delivery		1		
	Caput succedaneum		1		
	Cephalo-pelvic disproportion		6		
	Ectopic pregnancy	2			
	Failed induction of labour		1		
	Failed trial of labour		1		
	Foetal death		2		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Foetal distress syndrome	1	7		
	Foetal growth restriction	1	1		
	Foetal hypokinesia		3		
	Gestational hypertension	1	2		
	Haemorrhage in pregnancy		1		
	Hyperemesis gravidarum	1			
	Jaundice neonatal	1	9	1	
	Low birth weight baby	1			
	Meconium in amniotic fluid		1		
	Meconium stain		1		
	Oligohydramnios	1			
	Omphalorrhexis		1		
	Placental insufficiency		1		
	Placenta praevia	1			
	Postpartum haemorrhage	1	3		
	Pre-eclampsia	2	6		
	Premature baby		1	1	
	Premature delivery	1	1	1	
	Premature labour	2			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Premature rupture of membranes	1			
	Premature separation of placenta	1	4		
	Preterm premature rupture of membranes		1		
	Prolonged rupture of membranes		1		
	Retained placenta or membranes		1		
	Retained products of conception		1		
	Small for dates baby		1		
	Threatened labour	1			
	Weight decrease neonatal			1	
Sub Total:		**44**	**75**	**9**	
Psychiatric disorders	Acute psychosis	2			
	Affective disorder		1		
	Alcohol abuse	2	1	1	
	Alcoholism		2		
	Alcohol withdrawal syndrome	1	2		
	Anorexia nervosa	1			
	Anxiety	4			
	Bipolar disorder	2	3		
	Bipolar I disorder	5			

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Bipolar II disorder		1		
	Completed suicide	8	3		
	Conversion disorder		2		
	Depression	10	8	2	
	Depression suicidal	1	1	1	
	Disorientation	1			
	Disruptive mood dysregulation disorder	1			
	Drug abuse	2	1		
	Drug dependence		2		
	Hallucination	1			
	Major depression	6	3		
	Mania	1			
	Mental disorder	2	1		
	Mental status changes	1			
	Obsessive-compulsive disorder	1			
	Panic attack		2		
	Post-traumatic stress disorder		1		
	Psychotic behaviour	1			
	Psychotic disorder	3	2		
	Suicidal behaviour	1			
	Suicidal ideation	18	8	2	
	Suicide attempt	6	2	1	

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
Sub Total:		**81**	**46**	**7**	
Renal and urinary disorders	Acute kidney injury	15	8		
	Bladder prolapse	1			
	End stage renal disease	1	1		
	Glomerulonephritis	1			
	Hydronephrosis	1		1	
	Hydroureter	1			
	Nephrolithiasis	4	17		
	Oliguria	1			
	Renal colic	3	1		
	Renal cyst		1		
	Renal failure	2			
	Renal failure neonatal		1		
	Renal infarct		1		
	Renal pain	1			
	Renal tubular necrosis		1		
	Renal vein thrombosis	1			
	Subcapsular renal haematoma		1		
	Ureterolithiasis	1	3		
	Urinary retention	6			
	Urinary tract obstruction	1	1		

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Vesicoureteric reflux		1		
Sub Total:		**40**	**37**	**1**	
Reproductive system and breast disorders	Abnormal uterine bleeding	1			
	Adenomyosis	1	2		
	Adnexal torsion	1	1	1	
	Adnexa uteri cyst	1			
	Balanoposthitis	1			
	Benign prostatic hyperplasia	3	1	2	
	Breast hyperplasia		1	1	
	Endometrial thickening		1		
	Endometriosis	2	2		
	Heavy menstrual bleeding	3			
	Infertility	1			
	Ovarian cyst		3		
	Ovarian mass		1		
	Pelvic fluid collection	1			
	Pelvic organ prolapse	1			
	Prostatitis	2	1		
	Prostatomegaly	1	1		
	Rectocele			1	
	Shortened cervix	1			
	Testicular appendage torsion		1		

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Testicular necrosis	1			
	Uterine disorder		2		
	Uterine prolapse		1		
	Vaginal haemorrhage		1		
	Vaginal prolapse			1	
Sub Total:		**21**	**19**	**6**	
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1			
	Acute respiratory distress syndrome	3			
	Acute respiratory failure	11	7		
	Asthma	5	7		
	Asthmatic crisis		2		1
	Atelectasis	1			
	Bronchial hyperreactivity	1	1		
	Bronchopleural fistula	1			
	Bronchospasm	2	1		
	Chronic obstructive pulmonary disease	10	9		
	Diaphragmatic paralysis	1			
	Dyspnoea	6	6		
	Dyspnoea exertional	1	2		
	Hypoxia	4	3		

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Interstitial lung disease	1	2		
	Meconium aspiration syndrome		2		
	Nasal septum deviation	1	1		
	Negative pressure pulmonary oedema		1		
	Neonatal hypoxia		1		
	Neonatal pneumothorax		1		
	Neonatal respiratory distress		3		
	Neonatal respiratory distress syndrome	1	1		
	Neonatal respiratory failure		2		
	Neonatal tachypnoea		1	1	
	Pleural effusion	4		1	
	Pleurisy	1			
	Pneumomediastinum		1		
	Pneumonitis	1	1		
	Pneumothorax	3	1		
	Pneumothorax spontaneous	1			
	Pulmonary embolism	25	16	4	
	Pulmonary fibrosis	1			
	Pulmonary mass	1	1		

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Pulmonary sarcoidosis	1			
	Pulmonary vein stenosis	1			
	Respiratory arrest	1	1		
	Respiratory distress		1		
	Respiratory failure	2	4		
	Sleep apnoea syndrome		2		
	Wheezing		1		
Sub Total:		**92**	**82**	**6**	**1**
Skin and subcutaneous tissue disorders	Angioedema	1			
	Dermal cyst	1			
	Dermatomyositis	1			
	Diabetic foot	1			
	Mucocutaneous rash	1			
	Pemphigoid	1			
	Pruritus		1		
	Pustular psoriasis		1		
	Skin lesion	1	1		
	Subcutaneous emphysema	1			
	Vitiligo	1			
Sub Total:		**9**	**3**		
Social circumstances	Miscarriage of partner	1	1		
	Victim of crime	1			

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
Sub Total:		**2**	**1**		
Vascular disorders	Accelerated hypertension		1		
	Aneurysm	1			
	Aortic aneurysm	1	1	1	
	Aortic dissection	1	1		
	Aortic rupture	1	1		
	Aortic stenosis	1		2	
	Arteriosclerosis	1	3		
	Cyanosis		1	1	
	Deep vein thrombosis	12	8	2	
	Embolism	1			
	Haematoma	1			
	Hypertension	5	6		
	Hypertensive crisis		2		
	Hypertensive emergency	3	1		
	Hypertensive urgency	2	3		
	Hypoperfusion		1		
	Hypotension	3	2		
	Hypovolaemic shock	1			
	Iliac artery dissection		1		
	Infarction	1			
	Internal haemorrhage		1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Kawasaki's disease	1	1		
	Neonatal hypotension		1		
	Neurogenic shock	1			
	Orthostatic hypotension	1	2		
	Penetrating aortic ulcer	1			
	Peripheral arterial occlusive disease	1			
	Peripheral artery occlusion	1			
	Peripheral artery stenosis		1		
	Peripheral artery thrombosis	2			
	Shock		1		
	Shock haemorrhagic	1	1		
	Subgaleal haemorrhage		1		
	Thrombosis	2			
	Venous thrombosis limb	1	1		
Sub Total:		**47**	**42**	**6**	
Total Number of Cases:		**1,373**	**1,121**	**133**	**2**
Total Number of Events:		**1,779**	**1,502**	**175**	**4**

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

APPENDIX 2.1.1 - Cumulative Summary Tabulation of Serious Adverse Events from Clinical Trials

BNT162B2-ALL

Reporting Period: Through 18-DEC-2022
Total Number of Cases: 95
Total Number of Adverse Events (PT): 118
MedDRA Version: v.25.1J

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	PLACEBO	COMPARATOR
Cardiac disorders	Angina pectoris	1		
	Arrhythmia	1		
	Atrial fibrillation	2		
	Congestive cardiomyopathy	1		
	Myocardial infarction	2		
	Myocardial ischaemia	1		
	Myocarditis	1		
	Supraventricular tachycardia	1		
Sub Total:		**10**		
Congenital, familial and genetic disorders	Thyroglossal cyst		1	
Sub Total:			**1**	
Endocrine disorders	Goitre	1		
	Hyperthyroidism	1		1
	Thyroid mass			1
Sub Total:		**2**		**2**

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	PLACEBO	COMPARATOR
Gastrointestinal disorders	Diverticulum intestinal haemorrhagic	1		
	Inguinal hernia	2		
	Umbilical hernia	1		
Sub Total:		**4**		
General disorders and administration site conditions	Chest pain	1		
	Condition aggravated	1		
	Disease progression	1		
	Pelvic mass			1
	Pyrexia	1		
Sub Total:		**4**		**1**
Hepatobiliary disorders	Cholecystitis acute	2		
	Cholelithiasis	2		
	Drug-induced liver injury		1	
	Hepatitis acute	1		
Sub Total:		**5**	**1**	
Infections and infestations	Appendicitis	1	1	
	Chronic sinusitis	1		
	COVID-19			2
	Cystitis	1		
	Diverticulitis	1		
	Hepatitis E	1		
	Pneumonia	1	1	

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	PLACEBO	COMPARATOR
	Urinary tract infection	4		
Sub Total:		**10**	**2**	**2**
Injury, poisoning and procedural complications	Ankle fracture	1		
	Craniocerebral injury	1		
	Extradural haematoma	1		
	Femur fracture	1		
	Foot fracture	1		
	Head injury		1	
	Humerus fracture			1
	Joint dislocation			1
	Limb traumatic amputation	1		
	Lower limb fracture	2		
	Meniscus injury	1		
	Rib fracture	1	1	
	Shunt blood flow excessive	1		
	Skull fracture	1		
	Spinal compression fracture	1		
	Spinal fracture		1	
	Stab wound	1		
	Subdural haematoma	2		
	VIIth nerve injury	1		

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	PLACEBO	COMPARATOR
Sub Total:		**17**	**3**	**2**
Metabolism and nutrition disorders	Diabetic complication	1		
	Diabetic ketoacidosis	1		
	Type 2 diabetes mellitus	1		
Sub Total:		**3**		
Musculoskeletal and connective tissue disorders	Arthralgia	1		
	Bone hypertrophy	1		
	Mobility decreased	1		
	Osteonecrosis	1		
	Spinal stenosis	1		
Sub Total:		**5**		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	1		
	Intestinal adenocarcinoma	1		
	Lipoma	1		
	Lung carcinoma cell type unspecified stage 0	1		
	Metastases to abdominal wall	1		
	Metastases to liver	1		
	Metastases to ovary	1		

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	PLACEBO	COMPARATOR
	Oesophageal carcinoma	3		
	Ovarian cancer		1	
	Ovarian germ cell teratoma		1	
	Rectal cancer	1		
	Renal cancer	1		
	Thyroid cancer	1		1
	Uterine leiomyoma	1	1	
Sub Total:		**14**	**3**	**1**
Nervous system disorders	Cerebral infarction	4	2	
	Diabetic neuropathy	1	1	
	Dizziness	1		
	Syncope	2		1
	Vertebrobasilar insufficiency	1		
Sub Total:		**9**	**3**	**1**
Renal and urinary disorders	Renal hydrocele	1		
	Ureterolithiasis	1		
Sub Total:		**2**		
Reproductive system and breast disorders	Endometriosis		1	
	Epididymal cyst	1		
	Uterine adhesions		1	
Sub Total:		**1**	**2**	

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2 OMI;BNT162B2, BNT162B2 OMI BA.1;BNT162B2, BNT162B2 OMI BA.4-5;BNT162B2S01	PLACEBO	COMPARATOR
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	1		
	Pulmonary embolism	2		
	Respiratory distress	1		
Sub Total:		**4**		
Social circumstances	Physical assault	1		
Sub Total:		**1**		
Surgical and medical procedures	Hip arthroplasty	1		
Sub Total:		**1**		
Vascular disorders	Haematoma	1		
	Hypertensive crisis	1		
Sub Total:		**2**		
Total Number of Cases:		**75**	**13**	**7**
Total Number of Events:		**94**	**15**	**9**

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

APPENDIX 2.2: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions from Post-Marketing Data Sources

BNT162B2-ALL

Cumulative Reporting Period: Through 18-DEC-2022

Interval Reporting Period: 19-JUN-2022 Through 18-DEC-2022

Total Number of Cases: 282,992 (Interval) / 1,766,357 (Cumulative)

Total Number of Adverse Events (PT): 835,193 (Interval) / 5,807,721 (Cumulative)

MedDRA Version: v.25.1J

System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdominal lymphadenopathy	45	3	20		25		
Abnormal clotting factor	14		8	1	6		
Acquired amegakaryocytic thrombocytopenia	1		1				
Acquired antithrombin III deficiency	1	1	1				
Acquired factor V deficiency	1		1				
Acquired factor VIII deficiency	2		2				
Acquired haemophilia	83	18	83				4
Acquired Von Willebrand's disease	3		3				
Activated protein C resistance	1		1				
Agranulocytosis	37	4	37				
Anaemia	1544	159	880	151	664	3	20
Anaemia folate deficiency	7	1	4		3		
Anaemia macrocytic	36	2	22	2	14		
Anaemia megaloblastic	4	1	3		1		
Anaemia neonatal							2
Anaemia of chronic disease	3	2	2		1		
Anaemia of pregnancy	1				1		
Anaemia vitamin B12 deficiency	16	1	8		8		
Anisocytosis	10		5	1	5		

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Antiphospholipid syndrome	113	31	113				
Aplasia pure red cell	7	1	7				
Aplastic anaemia	67	18	67				
Atypical haemolytic uraemic syndrome	13	7	13				
Autoimmune anaemia	11	3	11				
Autoimmune haemolytic anaemia	153	23	153				1
Autoimmune neutropenia	10		10				
Autoimmune pancytopenia	1		1				
Bandaemia	1				1		
Basophilia	4			1	4		
B-cell aplasia	1	1	1				
Bicytopenia	24	2	24				
Blood disorder	136	4	60	14	76		1
Blood loss anaemia	40	7	40				
Bone marrow disorder	20	4	14	2	6		
Bone marrow failure	24	3	24				
Bone marrow infiltration	1		1				
Bone marrow ischaemia	1	1	1				
Bone marrow oedema	47	6	18	12	29		
Bone marrow oedema syndrome	2		1		1		
Coagulation disorder neonatal	1		1				
Coagulation factor deficiency	3		1		2		
Coagulopathy	582	30	327	50	255		1
Cold type haemolytic anaemia	13	6	13				
Coombs negative haemolytic anaemia	7	1	7				
Coombs positive haemolytic anaemia	8	1	8				
Cyclic neutropenia	1				1		

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cytopenia	26	1	26				
Deficiency anaemia	2				2		
Dermatopathic lymphadenopathy	2	1	1		1		
Disseminated intravascular coagulation	135	20	135				
Disseminated intravascular coagulation in newborn	2		2				
Dysglobulinaemia	1				1		
Elephantiasis	4		4				
Elliptocytosis	2		1		1		
Eosinopenia	2				2		
Eosinophilia	180	8	98	17	82		1
Erythropenia	10	3	8	1	2		
Erythropoiesis abnormal	2		2				
Evans syndrome	13	3	13				
Extramedullary haemopoiesis	1				1		
Factor IX inhibition	1		1				
Factor VIII inhibition	2		2				
Febrile bone marrow aplasia	3		3				
Febrile neutropenia	29	2	29			1	1
Foetal anaemia	1		1				
Granulocytopenia	7	1	7				
Granulocytosis	2	1	1		1		
Granulomatous lymphadenitis	2		2				
Haemoconcentration	5	1	2	2	3		
Haemoglobinaemia	3		3				
Haemolysis	81	7	81				
Haemolytic anaemia	102	15	102				2
Haemolytic uraemic syndrome	10	1	10				

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Haemorrhagic diathesis	106	14	106			4	4
Haemorrhagic disorder	51	4	51				
Heparin-induced thrombocytopenia	18	3	18				
Hilar lymphadenopathy	46	1	14	4	32		
Hyperchromic anaemia	5	1	4		1		
Hypercoagulation	80	7	48	5	32		
Hypereosinophilic syndrome	16	5	16				
Hyperfibrinogenaemia	11		9	1	2		
Hypergammaglobulinaemia	25	1	5	1	20		
Hyperglobulinaemia	3				3		
Hyperleukocytosis	164	12	164				
Hyperplasia of thymic epithelium	1				1		
Hyperprothrombinaemia	1		1				
Hypersplenism	1				1		
Hyperviscosity syndrome	2	1	2				
Hypochromasia	6		1	1	5		
Hypochromic anaemia	19	2	11	3	8		
Hypocoagulable state	4		2	1	2		
Hypofibrinogenaemia	2		1		1		
Hypoplastic anaemia	2		2				
Hypoprothrombinaemia	1		1				
Hyposplenism	1		1				
Idiopathic CD4 lymphocytopenia	1		1				
Idiopathic neutropenia	1		1				
Immune thrombocytopenia	999	99	999			1	7
Increased tendency to bruise	321	9	95	57	226		1
Intrapulmonary lymphadenopathy	1	1	1				

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Intravascular haemolysis	2		2				
Iron deficiency anaemia	161	18	77	28	84		1
Isoimmune haemolytic disease	1		1				
Jaundice acholuric	2		2				
Leukaemoid reaction	1		1				
Leukocyte vacuolisation	1		1				
Leukocytosis	314	8	150	22	164		1
Leukopenia	294	39	294			3	4
Leukostasis syndrome	1	1	1				
Lupus anticoagulant hypoprothrombinaemia syndrome	1		1				
Lymphadenitis	3167	60	495	580	2672	1	3
Lymphadenocyst	1				1		
Lymphadenopathy	89960	710	11360	10082	78600	3	85
Lymphadenopathy mediastinal	68	6	37	1	31		
Lymphatic disorder	68	2	21	10	47		1
Lymphatic insufficiency	3		2		1		
Lymphatic obstruction	6		3		3		
Lymph node calcification	3	1	1	1	2		
Lymph node fibrosis	2				2		
Lymph node haemorrhage	4		2		2		
Lymph node pain	11714	149	2156	2353	9558		20
Lymph node rupture	1				1		
Lymph node ulcer	1		1				
Lymphocytic infiltration	25		13	2	12		
Lymphocytosis	74	2	32	6	42		
Lymphoid tissue hyperplasia	11	1	6		5		
Lymphopenia	332	11	140	18	192		2

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lymphoplasia	1	1	1				
Macrocytosis	13		6	1	7		
Mast cell activation syndrome	161	65	161				1
Mastocytosis	23	2	7	7	16	1	2
Methaemoglobinaemia	1		1				
Microangiopathic haemolytic anaemia	8		7		1		
Microcytic anaemia	47	1	23		24		
Microcytosis	10		1	3	9		
Monoclonal B-cell lymphocytosis	4	1	4				
Monocytopenia	6		1	1	5		
Monocytosis	45	1	16	3	29		1
Myelocytosis	4		1		3		
Myelosuppression	21	4	21				1
Necrotic lymphadenopathy	14	3	14				
Nephrogenic anaemia	5	2	5				
Neutropenia	293	34	293			1	4
Neutropenia neonatal	1		1				
Neutrophilia	99	1	46	9	53		
Normochromic anaemia	14		11		3		
Normochromic normocytic anaemia	22	2	9	3	13		
Normocytic anaemia	60	3	32	4	28		
Nucleated red cells	1				1		
Pancytopenia	169	14	169				
Paratracheal lymphadenopathy	15		4	2	11		
Pernicious anaemia	13	3	8	1	5		
Placental transfusion syndrome	2		2				
Plasma cell disorder	1				1		

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Platelet anisocytosis	7		4	1	3		
Platelet destruction increased	1		1				
Platelet disorder	59	1	23	3	36		
Platelet dysfunction	5		1	1	4		
Platelet production decreased	1		1				
Poikilocytosis	6		2		4		
Polychromasia	7		2		5		
Polycythaemia	48	8	24	5	24		
Polycythaemia neonatorum	1		1				
Post-anaphylaxis mast cell anergy	1		1				
Pseudolymphoma	29	4	13	1	16		
Purpura non-thrombocytopenic	19	2	10		9		
Red blood cell abnormality	21	2	6	2	15		1
Reticulocytosis	7	1	3	2	4		
Reticuloendothelial dysfunction	1		1				
Retroperitoneal lymphadenopathy	3		2		1		
Rouleaux formation	1			1	1		
Sarcoidosis of lymph node	4	3	4				
Schistocytosis	1		1				
Secondary thrombocytosis	2		2				
Sickle cell anaemia with crisis	29	2	29				
Spherocytic anaemia	2			1	2		
Spleen atrophy	1		1				
Spleen congestion	2				2		
Spleen disorder	40	3	17	11	23		
Spleen ischaemia	3		3				
Splenic artery thrombosis	9		9				

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Splenic cyst	9	1	2	2	7		
Splenic embolism	2	1	2				
Splenic granuloma	2		2				
Splenic haematoma	2	1	2				
Splenic haemorrhage	3		3				
Splenic induration	2		2				
Splenic infarction	90	8	90				
Splenic lesion	6		5		1		
Splenic necrosis	1		1				
Splenic thrombosis	8	1	8				
Splenic vein thrombosis	25	3	25				1
Splenitis	6	1	5		1		
Splenomegaly	242	10	123	24	119		
Spontaneous haematoma	237	7	71	16	166		2
Spontaneous haemorrhage	12	2	12				1
Spontaneous splenic rupture	1	1	1				
Spur cell anaemia	2			1	2		
Stress polycythaemia	1		1				
Thrombocytopenia	2174	164	2174			1	13
Thrombocytopenia neonatal	1		1				
Thrombocytopenic purpura	120	4	103	2	17		1
Thrombocytosis	129	7	64	13	65		
Thrombosis with thrombocytopenia syndrome	111	27	111				
Thrombotic microangiopathy	46	10	46				
Thrombotic thrombocytopenic purpura	118	9	118				1
Thymus disorder	11		3	3	8		
Thymus enlargement	5		2		3		

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Blood and lymphatic system disorders

		Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
Preferred Term	*Total # of Spontaneous AE*	I	C	I	C	I	C
Warm autoimmune haemolytic anaemia	17	7	17				
White blood cell disorder	60	3	18	8	42		2
Total:	116642	2003	22901	13561	93741	19	193

System Organ Class

Cardiac disorders

		Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
Preferred Term	*Total # of Spontaneous AE*	I	C	I	C	I	C
Abnormal precordial movement	1				1		
Accelerated idioventricular rhythm	1		1				
Accessory cardiac pathway	1		1				
Acquired cardiac septal defect	1	1	1				
Acquired left ventricle outflow tract obstruction	1		1				
Acute cardiac event	19	6	19				
Acute coronary syndrome	459	46	459				1
Acute left ventricular failure	13	2	13				
Acute myocardial infarction	1293	147	1293				2
Acute right ventricular failure	2		2				
Adams-Stokes syndrome	3		3				
Angina pectoris	4875	755	4875			29	73
Angina unstable	92	20	92				1
Anomalous atrioventricular excitation	3	2	2		1		
Aortic valve calcification	7	1	4		3		
Aortic valve disease	10		7		3		
Aortic valve disease mixed	3	1	3				
Aortic valve incompetence	105	16	105				
Aortic valve sclerosis	11	1	7	1	4		

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aortic valve stenosis	27	1	23		4		
Aortic valve thickening	2		2				
Arrhythmia	11956	2283	11954	1	2	50	145
Arrhythmia neonatal	3		3				2
Arrhythmia supraventricular	87	2	65	1	22		
Arrhythmic storm	5	1	5				
Arteriosclerosis coronary artery	106	8	95		11		
Arteriospasm coronary	43	6	43				
Arteritis coronary	3		3				
Athletic heart syndrome	2		1		1		
Atrial enlargement	7		3		4		
Atrial fibrillation	4040	468	4040			21	64
Atrial flutter	402	36	283	6	119	2	6
Atrial hypertrophy	1				1		
Atrial tachycardia	104	6	65	3	39		4
Atrial thrombosis	27	1	27				
Atrioventricular block	177	13	143	9	34		2
Atrioventricular block complete	157	24	157			1	4
Atrioventricular block first degree	57	1	31	6	26		
Atrioventricular block second degree	82	9	66	5	16		
Atrioventricular dissociation	3		2	1	1		
Autoimmune myocarditis	4		4				
Autoimmune pericarditis	1	1	1				
Bezold-Jarisch reflex	1				1		
Bifascicular block	3	1	3				
Bradyarrhythmia	15	1	11		4		
Bradycardia	1449	143	1449			2	14

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Bradycardia foetal	9	2	9				
Bradycardia neonatal							2
Bundle branch block	24	3	10	4	14		
Bundle branch block bilateral	4		2		2		
Bundle branch block left	166	11	109	5	57		1
Bundle branch block right	202	16	115	9	87		1
Cardiac amyloidosis	14	4	14				
Cardiac aneurysm	33	5	33				
Cardiac arrest	1651	129	1651				7
Cardiac arrest neonatal	1		1				
Cardiac asthma	15	2	15				
Cardiac contractility decreased	10	3	8	1	2		
Cardiac discomfort	1692	85	442	359	1250	1	5
Cardiac disorder	1849	97	861	172	988	1	12
Cardiac dysfunction	120	26	120				
Cardiac failure	2267	334	2267			2	13
Cardiac failure acute	271	20	271				1
Cardiac failure chronic	114	18	114				
Cardiac failure congestive	269	20	269			1	4
Cardiac failure high output	1		1				
Cardiac fibrillation	237	48	237				3
Cardiac flutter	1246	46	1246			2	12
Cardiac granuloma	1		1				
Cardiac hypertrophy	73	7	54	2	19		
Cardiac perforation	3		3				
Cardiac perfusion defect	2	1	2				
Cardiac sarcoidosis	8	1	8				

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cardiac septal hypertrophy	9	2	4	2	5		
Cardiac steatosis	4		4				
Cardiac tamponade	128	18	128				
Cardiac valve discolouration	1		1				
Cardiac valve disease	77	13	46	8	31		
Cardiac valve sclerosis	4	1	4				
Cardiac ventricular disorder	10		4	1	6		
Cardiac ventricular scarring	3	1	2		1		
Cardiac ventricular thrombosis	45	6	45				
Cardiogenic shock	251	21	251				
Cardiomegaly	425	28	266	18	159	1	3
Cardiomyopathy	351	57	350		1		1
Cardiomyopathy acute	2		2				
Cardiomyopathy alcoholic	1		1				
Cardiomyopathy neonatal	3		3				
Cardiopulmonary failure	83	3	83				
Cardiorenal syndrome	13	4	13				
Cardio-respiratory arrest	822	61	822				
Cardio-respiratory distress	11	2	11				1
Cardiotoxicity	1	1	1				
Cardiovascular deconditioning	61	4	5	38	56		
Cardiovascular disorder	2921	145	776	348	2145		6
Cardiovascular insufficiency	124	18	124			2	4
Cardiovascular symptom	48	3	27	10	21		
Carditis	182	6	182				2
Chordae tendinae rupture	6	2	6				
Chronic coronary syndrome	5	2	5				

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Chronic left ventricular failure	1		1				
Chronic myocarditis	1	1	1				
Conduction disorder	29	3	15	1	14		
Congestive cardiomyopathy	170	26	170			1	2
Coronary artery aneurysm	7	3	7				
Coronary artery dilatation	11	1	7		4		
Coronary artery disease	324	38	241	23	83		5
Coronary artery dissection	29	2	29				
Coronary artery embolism	5		5				
Coronary artery insufficiency	3		3				
Coronary artery occlusion	121	12	121				3
Coronary artery perforation	1		1				
Coronary artery stenosis	125	17	125				
Coronary artery thrombosis	142	13	142				1
Coronary ostial stenosis	4		4				
Cor pulmonale	21	2	21				
Cor pulmonale acute	40	4	40				
Cor pulmonale chronic	2		2				
Defect conduction intraventricular	15		9		6		
Degenerative aortic valve disease	2		2				
Degenerative mitral valve disease	1		1				
Diastolic dysfunction	53	4	28	1	25		
Dilatation atrial	17	1	11		6		
Dilatation ventricular	19	1	13		6		
Dressler's syndrome	11	3	8		3		
Early repolarisation syndrome	3	1	3				
Endocardial disease	1		1				

* I=Interval, C=Cumulative
* AE=Adverse Event
* Multiple adverse events coding to the same Preferred Term may have been reported in some cases. Counts are provided for the number of unique Preferred Terms reported.

System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Endocardial fibrosis	2		2				
Endocarditis fibroplastica	1		1				
Endocarditis noninfective	2	1	2				
Endocarditis rheumatic	1		1				
Eosinophilic myocarditis	14	6	14				
Extrasystoles	2258	102	853	233	1405	3	11
Foetal arrhythmia	4	3	4				
Foetal cardiac arrest	18		18				
Foetal heart rate acceleration abnormality	1		1				
Foetal heart rate deceleration abnormality	1		1				1
Foetal heart rate disorder	1		1				
Gastrocardiac syndrome	4				4		
Giant cell myocarditis	4	2	4				
Haemorrhage coronary artery	3		3				
Heart alternation	16	1	6		10		
Heart valve calcification	7		4	2	3		
Heart valve incompetence	53	12	34	4	19		
Hepatojugular reflux	9		2	1	7		
Hyperdynamic left ventricle	2		2				
Hyperkinetic heart syndrome	3	1	3				
Hypersensitivity myocarditis	7	2	7				
Hypertensive cardiomyopathy	7		7				
Hypertensive heart disease	64	5	45	4	19		
Immune-mediated myocarditis	6	4	6				
Interventricular septum rupture	1		1				
Intracardiac mass	1		1				
Intracardiac thrombus	103	14	103				

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Intrapericardial thrombosis	2		2				
Ischaemic cardiomyopathy	30	6	30				
Kounis syndrome	4		4				
Left atrial dilatation	25	2	11	3	14		
Left atrial enlargement	36		16	2	20		
Left atrial hypertrophy	1	1	1				
Left ventricular dilatation	30	5	20		10		
Left ventricular dysfunction	187	19	143	4	44		
Left ventricular enlargement	10		7	1	3		
Left ventricular failure	105	18	105				2
Left ventricular hypertrophy	133	14	77	4	56		
Long QT syndrome	8		8				
Low cardiac output syndrome	12	3	12				
Lupus endocarditis	1		1				
Malignant hypertensive heart disease	1		1				
Microvascular coronary artery disease	9		9				
Mitral valve calcification	9		5	1	4		
Mitral valve disease	24	2	15		9		
Mitral valve disease mixed	1	1	1				
Mitral valve incompetence	286	40	286				6
Mitral valve prolapse	54	6	35	2	19		
Mitral valve sclerosis	5	1	5				
Mitral valve stenosis	6		6				
Mitral valve thickening	4	1	4				
Myocardial calcification	1				1		
Myocardial fibrosis	81	8	61	3	20		
Myocardial haemorrhage	4	1	4				

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Myocardial hypoxia	10		10				
Myocardial infarction	3067	320	3067			4	43
Myocardial injury	179	61	179				
Myocardial ischaemia	266	21	266				1
Myocardial necrosis	34	3	34				1
Myocardial oedema	68	7	68				
Myocardial rupture	22		22				
Myocarditis	11427	1053	11427			9	35
Myocarditis post infection	3	1	3				
Myopericarditis	2048	245	2048			1	11
Nodal arrhythmia	5	1	4		1		
Nodal rhythm	12	1	9		3		
Palpitations	34892	990	11675	3384	23217	9	84
Papillary muscle disorder	1		1				
Papillary muscle haemorrhage	1		1				
Papillary muscle rupture	1		1				
Paroxysmal arrhythmia	14	3	10		4		
Paroxysmal atrioventricular block	6		6				
Pericardial cyst	3				3		
Pericardial disease	50	2	29	1	21		
Pericardial effusion	2019	235	2019			3	17
Pericardial fibrosis	46	7	46				
Pericardial haemorrhage	43	4	43				
Pericardial mass	3		3				
Pericardial rub	31	1	15	1	16		
Pericarditis	10595	779	10595			8	50
Pericarditis adhesive	2		2				

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pericarditis constrictive	20	4	20				
Pericarditis lupus	1		1				
Pericarditis rheumatic	1		1				
Pericarditis uraemic	1		1				
Pleuropericarditis	78	6	78				3
Pneumopericardium	2		2				
Positive cardiac inotropic effect	2				2		
Postinfarction angina	1		1				
Postural orthostatic tachycardia syndrome	466	88	287	48	179		1
Prinzmetal angina	43	6	43				1
Pulmonary valve disease	2		1		1		
Pulmonary valve incompetence	10	2	10				
Pulmonary valve stenosis	4	1	4				
Pulmonary valve thickening	1		1				
Pulseless electrical activity	48	8	48				
Rebound tachycardia	1				1		
Restrictive cardiomyopathy	2		2				
Rheumatic heart disease	5		5				
Rhythm idioventricular	2	1	2				
Right atrial dilatation	7		4	1	3		
Right atrial enlargement	10		3		7		
Right atrial hypertrophy	2		1		1		
Right ventricular diastolic collapse	1		1				
Right ventricular dilatation	33	4	22	1	11		
Right ventricular dysfunction	35	2	29	1	6		
Right ventricular enlargement	6		3		3		
Right ventricular failure	80	7	80				

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Right ventricular hypertrophy	10		8		2		1
Silent myocardial infarction	8	2	8				
Sinoatrial block	10	2	10				
Sinus arrest	18	2	18				
Sinus arrhythmia	127	5	70	7	57		
Sinus bradycardia	156	2	90	6	66		1
Sinus node dysfunction	44	8	44				
Sinus tachycardia	979	49	493	65	486	3	5
Stress cardiomyopathy	137	10	120	2	17		3
Subendocardial haemorrhage	1		1				
Subendocardial ischaemia	4	2	4				
Subvalvular aortic stenosis	1		1				
Supraventricular extrasystoles	353	18	173	31	180		3
Supraventricular tachyarrhythmia	8		5		3		
Supraventricular tachycardia	498	36	338	17	160		2
Systolic dysfunction	29	1	21		8		
Tachyarrhythmia	208	11	121	6	87		5
Tachycardia	28531	811	8651	2157	19880	5	75
Tachycardia foetal	15	3	15				1
Tachycardia induced cardiomyopathy	8	3	8				
Tachycardia paroxysmal	96	7	53	7	43		1
Torsade de pointes	16	2	16				
Toxic cardiomyopathy	4		4				
Tricuspid valve disease	6	1	6				
Tricuspid valve incompetence	141	16	141				
Tricuspid valve prolapse	1		1				
Trifascicular block	6	1	6				

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System Organ Class

Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ventricle rupture	5		5				
Ventricular arrhythmia	79	11	79				
Ventricular asystole	1		1				
Ventricular dysfunction	45	4	32	2	13		
Ventricular dyskinesia	6		4		2		
Ventricular enlargement	11		7	1	4		
Ventricular extrasystoles	957	44	477	68	480	2	4
Ventricular failure	8		8				
Ventricular fibrillation	327	36	327				3
Ventricular flutter	4		4				
Ventricular hypertrophy	26	1	17		9		
Ventricular hypokinesia	143	14	143				
Ventricular pre-excitation	4		2	1	2		
Ventricular remodelling	2		2				
Ventricular septal defect acquired	1	1	1				
Ventricular tachyarrhythmia	7	2	7				
Ventricular tachycardia	320	36	320			3	3
Wandering pacemaker	1		1				
Wolff-Parkinson-White syndrome	19	2	19				
Total:	145450	10698	93517	7106	51933	166	781

System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aberrant aortic arch	2		2				
Abnormal palmar/plantar creases	1		1				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Accessory breast	1	1	1				
Accessory muscle	3				3		
Accessory spleen	4		2		2		
Acetylcholinesterase deficiency	1	1	1				
Acquired gene mutation	3	1	2	1	1		
Acral peeling skin syndrome	2		1		1		
Acrodermatitis enteropathica	1				1		
Adactyly	1	1	1				
Adenomatous polyposis coli	4		1	2	3		
Adrenogenital syndrome	1		1				
Adrenoleukodystrophy	1				1		
Albinism	1			1	1		
Alpha-1 antitrypsin deficiency	2		1		1		
Amegakaryocytic thrombocytopenia	2		2				
Amyotrophic lateral sclerosis gene carrier	2		2				
Anal atresia	2		2				
Anencephaly	7		7				
Ankyloglossia congenital	4	1	4			1	2
Anodontia	1				1		
Anomalous pulmonary venous connection	3	1	3				
Anophthalmos	2	1	2				
Anorectal malformation	1		1				
Anotia	1		1				
Antithrombin III deficiency	7		5		2		
Aorta hypoplasia	1		1				
Aplasia	2		2				
Aplasia cutis congenita	1		1				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Arachnodactyly	1				1		
Argininosuccinate synthetase deficiency	2				2		
Arnold-Chiari malformation	8		8				
Arrhythmogenic right ventricular dysplasia	4		4				
Arterial tortuosity syndrome	1			1	1		
Arteriovenous malformation	13	4	13				2
ASAH1 related disorder	1		1				
Asplenia	1		1				
Asymmetric crying facies	1				1		
Ataxia telangiectasia	2		1		1		
Atrial septal defect	56	12	39	3	17		1
Atrioventricular septal defect	6		6				
Auditory neuropathy spectrum disorder	1		1				
Autoimmune lymphoproliferative syndrome	3		3				
Beckwith-Wiedemann syndrome	1			1	1		
Benign familial haematuria	1				1		
Benign familial pemphigus	9		1		8		
Bicuspid aortic valve	4		3		1		
Biliary hamartoma	1		1				
Birth mark	9		1	2	8		
Blindness congenital	1		1				
Block vertebra	5		2		3		
Blood incompatibility haemolytic anaemia of newborn	1	1	1				
Brachydactyly	2		2				
Brachyolmia	1		1				
BRAF gene mutation	1		1				
Brain malformation	2		2				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Branchial cyst	4		3		1		
Breast malformation	1		1				
Bronchial atresia	1	1	1				
Brugada syndrome	14	1	14				
CADASIL	2			1	2		
Cancer gene carrier	1				1		
CANDLE syndrome	1		1				
Cardiac malposition	1	1	1				
Cardiac septal defect	4	2	4				
Carnitine palmitoyltransferase deficiency	1		1				
Cataract congenital	3	1	3				
Caudal regression syndrome	2		2				
Cerebellar hypoplasia	2	1	2				
Cerebral arteriovenous malformation haemorrhagic	2	1	2				
Cerebral cavernous malformation	4	1	4				
Cerebral palsy	23	5	23				
Cerebrovascular arteriovenous malformation	6	1	6				
Chiari network	1			1	1		
Chimerism	1				1		
Chordee	3	1	1		2		
Chronic granulomatous disease	3	2	3				
Cleft lip	2		2				
Cleft lip and palate	5	1	5				
Cleft palate	4		4				
Cleft uvula	1		1				
Clinodactyly	2		1		1		
Cloacal exstrophy	3		3				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Coarctation of the aorta	3		3				
Colour blindness	26	1	15	1	11		
Combined immunodeficiency	2		2				
Congenital absence of cranial vault	2		2				
Congenital amputation	1		1				
Congenital anomaly	30	6	30				1
Congenital aortic stenosis	1		1				
Congenital aortic valve incompetence	1	1	1				
Congenital arterial malformation	1		1				
Congenital cardiovascular anomaly	1		1				
Congenital central nervous system anomaly	7	1	7				
Congenital cerebrovascular anomaly	1		1				
Congenital coagulopathy	2	2	2				
Congenital cystic kidney disease	3	1	3				1
Congenital cytomegalovirus infection	1		1				
Congenital diaphragmatic hernia	1		1				
Congenital eye disorder	2		2				
Congenital foot malformation	1		1				1
Congenital genital malformation							1
Congenital great vessel anomaly	2		2				
Congenital haematological disorder	1		1				
Congenital hand malformation	1		1				
Congenital heart valve disorder	2		2				
Congenital hydrocephalus	7	1	7				
Congenital hydronephrosis	4	1	4				
Congenital hypercoagulation	3	2	3				
Congenital hyperthyroidism	2	2	2				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Congenital inguinal hernia							1
Congenital jaw malformation	1		1				
Congenital LUMBAR syndrome	2		2				
Congenital melanocytic naevus	1	1	1				
Congenital methaemoglobinaemia	1		1				
Congenital midline defect	1	1	1				
Congenital mitral valve incompetence	1		1				
Congenital musculoskeletal disorder	1		1				1
Congenital musculoskeletal disorder of limbs	7		7				1
Congenital musculoskeletal disorder of skull	2		2				
Congenital musculoskeletal disorder of spine	7	1	7				
Congenital myasthenic syndrome	1				1		
Congenital myopathy	1		1				
Congenital neurological degeneration	1		1				
Congenital nose malformation	1		1				
Congenital nystagmus	1				1		
Congenital optic nerve anomaly	1		1				
Congenital oral malformation	1		1				
Congenital pulmonary airway malformation	4	1	4				
Congenital pyelocaliectasis	1		1				
Congenital skin dimples	1		1				
Congenital thyroid disorder							1
Congenital tongue anomaly	1	1	1				
Congenital tricuspid valve atresia	2	1	2				
Congenital ureteropelvic junction obstruction	1	1	1				
Congenital vesicoureteric reflux	1		1				
Corneal dystrophy	9	2	9				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cortical dysplasia	2		2				
Craniosynostosis	3	1	3				
Cryopyrin associated periodic syndrome	2		2				
Cryptorchism	3		2		1		
CYP2C19 polymorphism	1				1		
Cystic fibrosis	2	1	1		1		
Cystic lymphangioma	7		7				
Cytogenetic abnormality	6		5		1		
Dacryostenosis congenital	2		1		1		
Deafness congenital	3	3	3				
Dermoid cyst	9	1	9				
Developmental hip dysplasia	1		1				
Diastematomyelia	1		1				
Diastrophic dysplasia	1		1				
Dolichocolon	1				1		
Double inlet left ventricle	1		1				
Double outlet right ventricle	2		2				
Duchenne muscular dystrophy	1			1	1		
Ductus arteriosus premature closure	1		1				1
Dysmorphism	7	1	4		3		
Ectopic thyroid	1		1				
Ectrodactyly	1		1				
Ehlers-Danlos syndrome	20		9		11		
Elliptocytosis hereditary	1		1				
Encephalocele	3		3				
Epidermolysis bullosa	6	3	6				
Exomphalos	4		4				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Facioscapulohumeral muscular dystrophy	1	1	1				
Factor II mutation	5		1	1	4		
Factor IX deficiency	1		1				
Factor V deficiency	5		3		2		
Factor VII deficiency	1		1				
Factor VIII deficiency	10	1	9		1		
Factor V Leiden mutation	19		6	1	13		
Factor X deficiency	2		1		1		
Factor XI deficiency	1		1				
Factor XIII deficiency	2	1	2				
Fallot's tetralogy	8	1	8				
Familial acromegaly	1			1	1		
Familial amyotrophic lateral sclerosis	2		2				
Familial hemiplegic migraine	2		2				
Familial mediterranean fever	7		3		4		
Familial periodic paralysis	5		3		2		
Familial tremor	2		1		1		
Fibrodysplasia ossificans progressiva	2	1	2				
Foetal chromosome abnormality	4		4				
Foetal cystic hygroma	6		6				
Foetal malformation	23	1	23				
Foramen magnum stenosis	1		1				
Friedreich's ataxia	1		1				
Gastrointestinal arteriovenous malformation							1
Gastrointestinal malformation	1		1				
Gastroschisis	4		4				
Gene mutation	13	1	4	2	9		

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Gilbert's syndrome	25	2	11	1	14		
Glucose-6-phosphate dehydrogenase deficiency	4		1		3		
Glycogen storage disease type V	4		4				
Glycogen storage disorder	1				1		
Grey matter heterotopia	1		1				
Haemangioma congenital	1	1	1				
Haemophilia	14		8	2	6		
Haemorrhagic arteriovenous malformation	1		1				
Hamartoma	2		1		1		
Heart disease congenital	43	2	43				2
Hereditary angioedema	11	2	10		1	1	2
Hereditary angioedema with normal C1 esterase inhibitor	1		1				
Hereditary ataxia	3		3				
Hereditary fructose intolerance	2				2		
Hereditary haemorrhagic telangiectasia	4				4		
Hereditary motor and sensory neuropathy	8	1	4	1	4		
Hereditary neuropathy with liability to pressure palsies	4		3	1	1		
Hereditary optic atrophy	1		1				
Hereditary spherocytosis	2		1		1		
Heterotaxia	4	2	4				
Homocystinaemia	1				1		
Huntington's disease	10		7		3		
Hydranencephaly	1		1				
Hydrocele	17	1	5	3	12		
Hyperexplexia	3		1		2		
Hyperglycinaemia	3		2		1		
Hyper IgD syndrome	1				1		

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hypermobility syndrome	11		5	1	6		
Hypertelorism	1			1	1		
Hypertrophic cardiomyopathy	48	3	48				
Hypochondroplasia	1		1				
Hypophosphatasia	1		1				
Hypoplastic left heart syndrome	4		4				
Hypoplastic right heart syndrome	1	1	1				
Hypospadias	2	2	2				2
Ichthyosis	1		1				
Imperforate oesophagus	1		1				
Inborn error of metabolism	1				1		
Intestinal atresia	4		4				1
Intracranial lipoma	1		1				
Isodicentric chromosome 15 syndrome	1		1				
Janus kinase 2 mutation	2		2				
Kearns-Sayre syndrome	1				1		
Keratosis follicular	5	1	4		1		
Kidney duplex	2		1		1		
Kidney malformation	5		5				
Klippel-Trenaunay syndrome	1		1				
Labial tie	1	1	1				
Laryngomalacia	2		2				
Left-to-right cardiac shunt	1		1				
Limb hypoplasia congenital	1		1				
Limb reduction defect	3	1	3				
Lissencephaly	1	1	1				
Long QT syndrome congenital	1		1				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Low set ears	1		1				
Macrocephaly	1		1				1
Macroglossia	26		26				1
Malformation venous	1		1				
Mandibulofacial dysostosis	1		1				
MELAS syndrome	1		1				
Melkersson-Rosenthal syndrome	5	1	5				
Meningocele	1		1				
Meningomyelocele	1		1				
Metabolic myopathy	2			1	2		
Methylenetetrahydrofolate reductase gene mutation	7		1	1	6		
Methylenetetrahydrofolate reductase polymorphism	1			1	1		
Microcephaly	2	1	2				
Micrognathia	1		1				
Micropenis	5		5				
Microphthalmos	1		1				
Microtia	1	1	1				
Mitochondrial encephalomyopathy	1		1				
Mitochondrial enzyme deficiency	1	1	1				
Mitochondrial myopathy	7	2	2	3	5		
Mitral valve atresia	2		2				
Moebius II syndrome	1		1				
Mucopolysaccharidosis II	1		1				
Multiple congenital abnormalities	3		3				
Multiple endocrine neoplasia Type 1	1		1				
Muscular dystrophy	12	1	4	2	8		
Myocardial bridging	3		3				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Myoclonic dystonia	6		4	2	2		
Myoclonic epilepsy and ragged-red fibres	1				1		
Myotonic dystrophy	2		1		1		
Naevus flammeus	3		1		2		
Nail aplasia	1		1				
Neonatal alloimmune thrombocytopenia	1		1				
Neonatal haemochromatosis	1		1				
Neurofibromatosis	6		3	1	3		
Non-compaction cardiomyopathy	5	1	5				
Oculoauriculovertebral dysplasia	2	1	2				
Odontogenic cyst	1				1		
Osteogenesis imperfecta	2		2				
Pachyonychia congenita	2		1		1		
Pancreas divisum	1				1		
Parkes-Weber syndrome	1				1		
Paroxysmal extreme pain disorder	5		2	1	3		
Patent ductus arteriosus	1	1	1				2
Pectus excavatum	3	1	2		1		
Penoscrotal fusion	2	1	2				
Persistent foetal circulation	1		1				
Pfeiffer syndrome	1				1		
Phelan-McDermid syndrome	1		1				
Phimosis	6		4		2		
Platybasia	1		1				
Polycystic liver disease	1		1				
Polydactyly	3	1	2		1		
Polymicrogyria	1		1				

* I=Interval, C=Cumulative
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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Porencephaly	1		1				
Porokeratosis	2	1	2				
Porphyria	4		4				
Porphyria acute	6		6				1
Porphyria non-acute	3		3				
Potter's syndrome	2		2				
Preauricular cyst	2		1		1		
Primary ciliary dyskinesia	1				1		
Primary coenzyme Q10 deficiency	1	1	1				
Progressive familial intrahepatic cholestasis	1	1	1				
Protein C deficiency	3		1		2		
Protein S deficiency	5		5				
Proximal focal femoral deficiency	1	1	1				
PTEN gene mutation	1		1				
Pulmonary artery stenosis congenital	1		1				
Pulmonary hypoplasia	3		3				
Pulmonary malformation	3	1	3				1
Pulmonary sequestration	2		2				
Pulmonary valve stenosis congenital	2		2				1
Pyruvate dehydrogenase complex deficiency	2			2	2		
Rathke's cleft cyst	3	1	2		1		
Renal aplasia	4	1	4				
Renal dysplasia	1		1				2
Renal fusion anomaly	1		1				
Renal hypoplasia	1		1				
Retinitis pigmentosa	6		6				
Right-to-left cardiac shunt	1		1				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Rippling muscle disease	1				1		
RUNX1 gene mutation	3	2	3				
Sacralisation	2		1	1	1		
Schizencephaly	1		1				
Scimitar syndrome	1		1				
Sensory neuropathy hereditary	2		2				
Short-chain acyl-coenzyme A dehydrogenase deficiency	1		1				
Sickle cell anaemia	2		1		1		
Sickle cell disease	2		1		1		
Single atrium	1		1				
Single umbilical artery	6		5		1		
Sjogren-Larsson syndrome	1	1	1				
Skeletal dysplasia	1		1				
Skin malformation	2		2				
Spina bifida	7	1	7				
Spinal muscular atrophy	2		2				
Spinal vessel congenital anomaly	1		1				
Stargardt's disease	1				1		
Sturge-Weber syndrome	1		1				
Supernumerary nipple	3		1		2		
Syndactyly	6	2	6				
Syringomyelia	9		9				
Talipes	2		2			1	1
Telangiectasia congenital	1		1				
Thalassaemia	1		1				
Thalassaemia minor	7		2		5		
Thanatophoric dwarfism	1	1	1				

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Thyroglossal cyst	4		3		1		
Tourette's disorder	24	3	24				
Tracheo-oesophageal fistula	1		1				
Transposition of the great vessels	4		4				
Trisomy 13	2		2				
Trisomy 16	1		1				
Trisomy 18	5	1	5				
Trisomy 21	12	1	12				
Trisomy 8	1		1				
Turner's syndrome	3		1		2		
Twin reversed arterial perfusion sequence malformation	1	1	1				
Type IIa hyperlipidaemia	2		1		1		
Type V hyperlipidaemia	9		3	1	6		
Univentricular heart	1		1				
Urachal abnormality	1		1				
Urethral atresia	1		1				
Urethral valves	3		3				
Urinary tract malformation							1
VACTERL syndrome	2		2				
Vascular endothelial growth factor overexpression	2			1	2		
Vascular malformation	9	1	3	2	6		
Venous angioma of brain	4		4				
Ventricular hypoplasia	2		2				
Ventricular septal defect	17	3	17				1
Vertebral artery hypoplasia	2	1	2				
Vestibulocerebellar syndrome	3		2		1		
VEXAS syndrome	4	2	3		1		

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System Organ Class

Congenital, familial and genetic disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vitello-intestinal duct remnant	1		1				
Von Willebrand's disease	9	4	9				
Williams syndrome	1		1				
Wolf-Hirschhorn syndrome	2	1	2				
X-linked lymphoproliferative syndrome	1		1				
XXX syndrome	1		1				
Total:	1372	153	1077	49	295	3	34

System Organ Class

Ear and labyrinth disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acute vestibular syndrome	90	8	59	1	31		
Auditory disorder	278	16	79	22	199		2
Aural polyp	2		1	1	1		
Auricular swelling	43	1	12		31		
Autoimmune inner ear disease	3	1	3				
Autophony	6		2	2	4		
Cerumen impaction	11		1	1	10		
Chondrodermatitis nodularis chronica helicis	1		1				
Conductive deafness	9		9				
Deafness	1686	228	1686			7	18
Deafness bilateral	128	25	128				
Deafness neurosensory	256	36	256				
Deafness permanent	4	2	4				1
Deafness transitory	76	8	76				
Deafness unilateral	878	152	878			2	6

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System Organ Class

Ear and labyrinth disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Diplacusis	12		4	2	8		
Dysacusis	28	1	10	2	18		
Ear canal erythema	12	1	4		8		
Ear canal stenosis	6	1	2	2	4		
Ear congestion	233	1	53	13	180		
Ear deformity acquired	4				4		
Ear discomfort	2558	63	574	266	1984		1
Ear disorder	326	9	100	27	226		1
Ear haemorrhage	101	3	33	6	68	1	1
Ear inflammation	90	2	22	24	68		
Ear odour	1				1		
Ear pain	5724	83	1543	437	4181	2	15
Ear pruritus	264		51	22	213		1
Ear swelling	440	6	109	43	331		1
Endolymphatic hydrops	23	3	23				
Eustachian tube disorder	15		9	2	6		
Eustachian tube dysfunction	39	2	14		25		
Eustachian tube obstruction	35	1	10	2	25		
Eustachian tube patulous	2				2		
Excessive cerumen production	44	1	14	1	30		1
External ear disorder	7	1	5	1	2		
External ear inflammation	19	1	7	2	12		
External ear pain	48	4	17	2	31		
Haematotympanum	1		1				
Hyperacusis	1013	35	344	113	669		1
Hypoacusis	2419	109	882	207	1537		4
Inner ear disorder	99	3	40	10	59		

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System Organ Class

Ear and labyrinth disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Inner ear infarction	10	2	10				
Inner ear inflammation	45	3	22	2	23		
Labyrinthine fistula	1	1	1				
Mastoid disorder	5		1		4		
Mastoid effusion	1				1		
Meniere's disease	230	31	230				
Middle ear disorder	6		3		3		
Middle ear effusion	40		9	3	31		1
Middle ear inflammation	42	2	9	4	33		
Misophonia	13		3	1	10		
Mixed deafness	4		4				
Motion sickness	222	5	91	12	131		1
Neonatal deafness	2	1	2				
Neurosensory hypoacusis	43	3	32		11		2
Noninfective myringitis	5				5		
Otolithiasis	25		9	2	16		
Otorrhoea	67	5	21	6	46		
Otosclerosis	10		6	1	4		
Ototoxicity	5		5				
Paraesthesia ear	48		12	7	36		
Phobic postural vertigo	26	5	10	4	16		
Presbyacusis	11	1	4	1	7		
Red ear syndrome	11		1	1	10		
Sudden hearing loss	1037	147	1037			10	18
Superior semicircular canal dehiscence	3		2		1		
Tinnitus	18116	553	4869	1687	13247	3	33
Tympanic membrane disorder	32	1	9	3	23		

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System Organ Class

Ear and labyrinth disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tympanic membrane hyperaemia	5		3		2		
Tympanic membrane perforation	40	3	19	7	21		
Tympanosclerosis	1			1	1		
Vertigo	15125	295	4225	1102	10900	4	60
Vertigo labyrinthine	25		17	2	8		
Vertigo positional	756	25	286	80	470	3	8
Vestibular ataxia	6		6				
Vestibular disorder	233	13	119	13	114		1
Vestibular ischaemia	4		3	1	1		
Vestibular paroxysmia	3	2	3				
Total:	53292	1905	18149	4151	35143	32	177

System Organ Class

Endocrine disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Addison's disease	11	2	11				
Adrenal atrophy	1				1		
Adrenal cortex necrosis	2		2				
Adrenal disorder	28	1	12	1	16		
Adrenal haemorrhage	10		10				
Adrenal insufficiency	69	12	69				
Adrenal mass	9		1		8		
Adrenal thrombosis	1		1				
Adrenocortical insufficiency acute	60	4	60				
Adrenocorticotropic hormone deficiency	3	1	3				
Adrenomegaly	8		1	1	7		

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* AE=Adverse Event
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System Organ Class

Endocrine disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Androgen deficiency	2				2		
Anovulatory cycle	372	11	81	66	291		
Autoimmune hypothyroidism	12	4	12				
Autoimmune thyroid disorder	19	5	19				
Autoimmune thyroiditis	461	119	460	1	1	5	9
Basedow's disease	535	111	535			3	5
Carcinoid crisis	1		1				
Central hypothyroidism	2		2				
Cushingoid	8		3		5		
Cushing's syndrome	6	2	6				
Delayed menarche	7		2		5		
Diabetes insipidus	35	6	35				
Empty sella syndrome	2	1	2				
Endocrine disorder	63	2	23	8	40		1
Euthyroid sick syndrome	2				2		
Fertility increased	3				3		
Glucocorticoid deficiency	3		3				
Goitre	276	6	95	36	181	1	1
Growth hormone deficiency	2		2				
Haemorrhagic thyroid cyst	4	2	2		2		
Hyperadrenalism	1	1	1				
Hyperadrenocorticism	1		1				
Hyperaldosteronism	3	1	3				
Hypercalcaemia of malignancy	1				1		
Hyperoestrogenism	1				1		
Hyperparathyroidism	9		3	1	6		
Hyperparathyroidism primary	7		4	2	3		

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System Organ Class

Endocrine disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hyperparathyroidism secondary	6	1	3	2	3		
Hyperplasia adrenal	4	1	4				
Hyperprolactinaemia	13	8	13				
Hyperthyroidism	634	86	634			4	11
Hypoparathyroidism	5	2	3	1	2		
Hypophysitis	9	3	5	1	4		
Hypopituitarism	16	1	6	2	10		
Hypothalamo-pituitary disorder	14		14				
Hypothyroidic goitre	2				2		
Hypothyroidism	524	83	524			3	7
Immune-mediated adrenal insufficiency	1	1	1				
Immune-mediated hyperthyroidism	1	1	1				
Immune-mediated hypothyroidism	1		1				
Immune-mediated thyroiditis	3		3				
Inappropriate antidiuretic hormone secretion	26	3	26				
Luteal phase deficiency	7		1	1	6		
Lymphocytic hypophysitis	2			1	2		
Melatonin deficiency	1			1	1		
Myxoedema	10	5	10				
Oestrogen deficiency	4		1		3		
Oestrogenic effect	2			2	2		
Ovarian dysfunction	1				1		
Ovulation delayed	239	1	26	42	213		
Parathyroid disorder	4	1	2		2		
Pituitary apoplexy	7	1	7				
Pituitary cyst	3		1	2	2		
Pituitary-dependent Cushing's syndrome	4	1	3	1	1		

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System Organ Class

Endocrine disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pituitary enlargement	2		1		1		
Pituitary haemorrhage	3		3				
Pituitary infarction	1		1				
Polyglandular autoimmune syndrome type I	1		1				
Polyglandular autoimmune syndrome type II	1		1				
Precocious puberty	2				2		
Premature menarche	27		4		23		
Primary hyperaldosteronism	5		1	2	4		
Primary hyperthyroidism	9	1	9				
Secondary adrenocortical insufficiency	6	2	5		1		
Secondary hyperthyroidism	2		2				
Secondary hypogonadism	1		1				
Silent thyroiditis	10	1	8		2		
Thyroid atrophy	1	1	1				
Thyroid calcification	1				1		
Thyroid cyst	31	1	11	1	20		
Thyroid dermatopathy	1		1				
Thyroid disorder	373	17	100	57	273		3
Thyroid fibrosis	1	1	1				
Thyroid haemorrhage	2	1	2				
Thyroiditis	269	17	120	27	149	2	4
Thyroiditis acute	61	8	61				2
Thyroiditis chronic	5		1	2	4		
Thyroiditis subacute	316	16	160	14	156		
Thyroid mass	139	3	49	7	90	3	3
Thyroid pain	109	1	22	15	87		
Thyroid size decreased	1	1	1				

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System Organ Class

Endocrine disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Thyroid stimulating hormone deficiency	3				3		
Thyrotoxic crisis	38	4	38				
Thyrotoxic periodic paralysis	1				1		
Toxic goitre	4	1	4				
Toxic nodular goitre	9	2	9				
Total:	5018	568	3372	297	1646	21	46

System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal sensation in eye	239	3	55	17	184		
Accommodation disorder	75	1	16	9	59		
Acute macular neuroretinopathy	25	7	25				
Age-related macular degeneration	20	5	20				
Altered visual depth perception	24	1	6	1	18		
Amaurosis	33	3	33				
Amaurosis fugax	116	13	116				1
Amblyopia	15	1	5	2	10		
Anaesthesia eye	1				1		
Angle closure glaucoma	20	3	20				
Anisocoria	110	12	66	7	44		
Anisometropia	1				1		
Anterior chamber cell	1		1				
Anterior chamber flare	2		1		1		
Anterior chamber inflammation	4	1	4				
Anterior chamber opacity	1				1		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Anterior segment ischaemia	2	1	2				
Arteriosclerotic retinopathy	3		3				
Asthenopia	722	5	226	39	496		3
Astigmatism	45	4	13	6	32		
Atopic keratoconjunctivitis	1		1				
Autoimmune eye disorder	3		2		1		
Autoimmune retinopathy	1	1	1				
Autoimmune uveitis	6		6				
Bell's phenomenon	6		3	1	3		
Binocular eye movement disorder	18		8	3	10		
Birdshot chorioretinopathy	2		2				
Blepharal pigmentation	1				1		
Blepharitis	233	7	48	30	185		
Blepharitis allergic	2		1		1		
Blepharochalasis	3				3		
Blepharophimosis	1				1		
Blepharospasm	880	10	168	83	712		1
Blindness	1098	124	1098			1	6
Blindness cortical	7	1	7				
Blindness transient	309	33	309				1
Blindness unilateral	394	62	394				1
Cataract	197	42	196	1	1	6	26
Cataract cortical	3	2	3				
Cataract nuclear	4		4				
Cataract subcapsular	4		1	1	3		
Central serous chorioretinopathy	54	6	54				
Central vision loss	15	2	15				

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Chalazion	63	2	14	5	49		
Charles Bonnet syndrome	3		2		1		
Chloropsia	3		3				
Chorioretinal disorder	8	2	4	2	4		
Chorioretinal folds	1		1				
Chorioretinopathy	29		28		1		
Choroidal detachment	2		2				
Choroidal effusion	4		4				
Choroidal haemorrhage	1		1				
Choroidal infarction	1		1				
Choroidal neovascularisation	13	3	13				
Choroidal rupture	2		2				
Choroiditis	14	7	14				
Chromatopsia	29		9		20		
Ciliary muscle spasm	4		1		3		
Cogan's syndrome	3	1	3				
Colour blindness acquired	2		2				
Computer vision syndrome	2				2		
Conjunctival adhesion	2		2				
Conjunctival cyst	3				3		
Conjunctival defect	1				1		
Conjunctival discolouration	4			1	4		
Conjunctival disorder	15		3	3	12		
Conjunctival haemorrhage	471	33	471			1	6
Conjunctival hyperaemia	238	7	96	8	142		1
Conjunctival irritation	31		7	2	24		
Conjunctival oedema	43	5	19	3	24		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Conjunctival pallor	8		2	2	6		
Conjunctival suffusion	1		1				
Conjunctival telangiectasia	1				1		
Conjunctival ulcer	2		2				
Conjunctival vascular disorder	1		1				
Conjunctivitis allergic	68	2	15	5	53		
Contact lens intolerance	1				1		
Corneal bleeding	11		11				
Corneal decompensation	1		1				
Corneal defect	2		2				
Corneal degeneration	2		2				
Corneal deposits	2				2		
Corneal disorder	26		16	2	10		
Corneal endothelial cell loss	1		1				
Corneal endotheliitis	4	1	4				
Corneal epithelium defect	2		2				
Corneal erosion	13	2	7		6		
Corneal exfoliation	1		1				
Corneal infiltrates	3		2		1		
Corneal irritation	2			1	2		
Corneal lesion	6		1	1	5		
Corneal oedema	12		5	1	7		
Corneal opacity	16	3	16				1
Corneal perforation	1		1				
Corneal pigmentation	1				1		
Corneal scar	2	1	2				
Corneal thinning	1		1				

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cortical visual impairment	1	1	1				
Cyanopsia	13		6	1	7		
Cyclitis	1		1				
Cystoid macular oedema	27	8	27				
Dacryoadenitis acquired	10	3	7		3		
Dacryostenosis acquired	6		1		5		
Dark circles under eyes	62		12	8	50		
Delayed dark adaptation	1				1		
Dellen	1				1		
Dermatochalasis	13		6	1	7		
Detached Descemet's membrane	1		1				
Detachment of retinal pigment epithelium	4	2	4				
Diabetic eye disease	1				1		
Diabetic retinal oedema	2	1	1		1		
Diabetic retinopathy	3	1	3				
Diplopia	1955	99	981	127	974	2	7
Disorder of orbit	3		1		2		
Dry age-related macular degeneration	6		6				1
Dry eye	1114	23	269	125	845	2	8
Dyschromatopsia	63		32	6	31		
Dysmetropsia	2				2		
Ectropion	5	1	4		1		
Eczema eyelids	62	1	9	8	53		
Endocrine ophthalmopathy	59	23	59			6	8
Enophthalmos	2	1	2				
Epiretinal membrane	7		6		1		
Episcleritis	74		21	6	53		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Erythema of eyelid	253	4	78	20	175		3
Erythropsia	8		2		6		
Excessive eye blinking	32	1	10	2	22		
Excessive ocular convergence	1		1				
Exfoliation syndrome	1				1		
Exophthalmos	61	11	61				1
Exposure keratitis	2				2		
Extraocular muscle disorder	23	1	13	2	10		
Exudative retinopathy	1		1				
Eye allergy	86	2	25	8	61		
Eye colour change	27	1	11	2	16		
Eye discharge	239	3	65	19	174		
Eye disorder	941	25	310	55	631		6
Eye haematoma	71	6	71			1	1
Eye haemorrhage	651	84	651			5	14
Eye infarction	63	13	63				1
Eye inflammation	649	19	145	59	504	1	4
Eye irritation	1702	20	282	145	1420		3
Eyelash changes	2		1		1		
Eyelash discolouration	6		1		5		
Eyelid bleeding	15	1	6	3	9		
Eyelid cyst	17	1	9		8		
Eyelid disorder	125	3	48	11	77		1
Eyelid exfoliation	11		2	1	9		
Eyelid function disorder	103	3	50	4	53		
Eyelid haematoma	56		13	6	43		
Eyelid irritation	140	2	27	14	113		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Eyelid margin crusting	22		3	3	19		
Eyelid myoclonus	12	2	12			1	1
Eyelid myokymia	36	1	9	12	27		
Eyelid oedema	1103	16	291	83	812	2	6
Eyelid pain	176	1	36	9	140		1
Eyelid ptosis	549	32	280	26	269		2
Eyelid rash	85	1	26	8	59		
Eyelid retraction	6		3		3		
Eyelid sensory disorder	38		8	3	30		
Eyelid skin dryness	21		3	3	18		
Eyelids pruritus	157		38	8	119		
Eyelid thickening	16	1	4	1	12		
Eyelid vascular disorder	4		1		3		
Eye movement disorder	394	15	219	21	175		1
Eye oedema	255	4	73	22	182	2	4
Eye opacity	2				2		
Eye pain	6898	126	1955	540	4943	1	18
Eye paraesthesia	69	1	23	8	46		
Eye pruritus	1846	19	412	145	1434		7
Eye swelling	3206	30	901	242	2305		6
Eye symptom	33	1	12	4	21		
Eye ulcer	16	1	9		7		
Floppy eyelid syndrome	2		2				
Foreign body sensation in eyes	138	3	38	11	100		
Fuchs' syndrome	7	3	7				1
Gaze palsy	118	18	116	1	2		
Giant papillary conjunctivitis	3		1		2		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Glare	36	2	11	1	25		
Glaucoma	126	19	126			2	12
Glaucomatocyclitic crises	3	1	3				
Growth of eyelashes	1		1				
Halo vision	39	2	18	2	21		
Heteronymous diplopia	1		1				
Heterophoria	11	1	6		5		
Holmes-Adie pupil	9	1	3		6		
Homonymous diplopia	4		4				
Hyperaesthesia eye	6		2		4		
Hypermetropia	38	5	15	4	23		
Hypoaesthesia eye	137	1	49	8	88		
Hypotony of eye							1
Idiopathic orbital inflammation	6	1	6				
Inflammation of lacrimal passage	3	1	2		1		
Iridocele	1		1				
Iridocyclitis	192	29	192				1
Iris adhesions	4		4				
Iris cyst	1				1		
Iris discolouration	2				2		
Iris disorder	8		1	2	7		
Iris neovascularisation	3	1	3				
Iritis	138	7	60	11	78		2
IRVAN syndrome	1	1	1				
Keratic precipitates	6	1	6				
Keratitis	90	1	38	4	52		
Keratitis interstitial	1		1				

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Keratoconus	11	6	11				1
Lacrimal disorder	16		2	4	14		
Lacrimal gland enlargement	6		2	1	4		
Lacrimal structural disorder	1		1				
Lacrimation decreased	19		10	3	9		
Lacrimation disorder	14	1	3		11		
Lacrimation increased	1774	31	372	184	1402	1	8
Lagophthalmos	51	6	32	2	19		1
Lens dislocation	1		1				
Lens disorder	4				4		
Lenticular opacities	7	3	7				
Lid lag	1			1	1		
Lid margin discharge	1				1		
Lid sulcus deepened	12		7		5		
Limbal swelling	4		3		1		
Loss of visual contrast sensitivity	4		2	1	2		
Macular cherry-red spots	4	2	4				
Macular degeneration	63	9	63			1	4
Macular detachment	6	2	6				
Macular fibrosis	2		2				
Macular hole	15	2	15				2
Macular ischaemia	3		3				
Macular oedema	140	27	140				1
Macular opacity	1		1				
Macular rupture	2		2				
Macular scar	2			1	2		
Macular vasospasm	1	1	1				

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Maculopathy	41	4	29	2	12		
Meibomian gland discharge	1				1		
Meibomian gland dysfunction	9		2	1	7		
Meibomianitis	2		1		1		
Metamorphopsia	104	7	59	5	45		
Miosis	63	2	24	4	39		
Mydriasis	272	11	111	15	161		
Myopia	79	3	25	12	54		
Myopic chorioretinal degeneration	1		1				
Necrotising retinitis	13	2	13				
Necrotising scleritis	1		1				
Neovascular age-related macular degeneration	31	6	31				
Neurological eyelid disorder	5		1		4		
Night blindness	20		2	4	18		
Noninfective chorioretinitis	2		2				
Noninfective conjunctivitis	2				2		
Normal tension glaucoma	1	1	1				
Ocular cyst	1			1	1		
Ocular discomfort	1601	33	292	210	1309		
Ocular dysmetria	2		1		1		
Ocular hyperaemia	2376	20	546	174	1830	1	10
Ocular hypertension	85	11	85			3	4
Ocular ischaemic syndrome	7		7				
Ocular myasthenia	38	6	38				
Ocular rosacea	10	1	3	1	7		
Ocular sarcoidosis	7	5	7				
Ocular vascular disorder	124	11	97	4	27		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ocular vasculitis	10	1	10				
Oculogyric crisis	21	4	21				1
Open angle glaucoma	5	1	5				
Ophthalmic artery aneurysm	1		1				
Ophthalmic artery occlusion	8	2	8				
Ophthalmic artery thrombosis	15	2	15				
Ophthalmic vascular thrombosis	1	1	1				
Ophthalmic vein thrombosis	176	25	176				1
Ophthalmoplegia	147	20	147				1
Opsoclonus myoclonus	7	3	7				
Optic atrophy	23	10	23				
Optic disc disorder	9	1	5		4		
Optic disc haemorrhage	10	3	10				
Optic disc hyperaemia	1			1	1		
Optic discs blurred	1		1				
Optic ischaemic neuropathy	179	29	179				
Optic nerve compression	1		1				
Optic nerve disorder	50	1	29	3	21		1
Optic nerve infarction	12	1	12				
Optic nerve sheath haemorrhage	1		1				
Optic neuropathy	42	8	42			1	1
Orbital cyst	5	1	4		1		
Orbital haematoma	6	1	6				
Orbital haemorrhage	2		2				
Orbital myositis	6	1	6				
Orbital oedema	15	1	12	2	3		
Orbital swelling	13		2	1	11		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Oscillopsia	16	2	7	2	9		
Panophthalmitis	3		3				
Papilloedema	187	32	187				
Papillophlebitis	3		3				
Paralytic lagophthalmos	6		6				
Parophthalmia	6		2		4		
Periorbital discomfort	19		3	2	16		
Periorbital disorder	8			2	8		
Periorbital fat herniation	1				1		
Periorbital inflammation	3		1		2		
Periorbital irritation	3			1	3		
Periorbital oedema	330	12	136	17	194		4
Periorbital pain	62	2	26	3	36		1
Periorbital swelling	991	12	228	85	763	1	2
Photokeratitis	2	1	2				
Photophobia	3206	86	1047	303	2159	1	5
Photopsia	890	13	319	58	571	1	2
Pigmentary glaucoma	2		2				
Pinguecula	2		1		1		
Pingueculitis	1			1	1		
Polypoidal choroidal vasculopathy	1	1	1				
Posterior capsule opacification	4	1	4				
Presbyopia	20	2	5	6	15		
Pseudomyopia	3		1		2		
Pseudopapilloedema	1				1		
Pterygium	4		1		3		
Punctate keratitis	14	1	14				

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pupil fixed	27	3	27				
Pupillary deformity	2		2				
Pupillary disorder	20		7	1	13		
Pupillary reflex impaired	46	7	28	5	18		
Pupillotonia	2	2	2				
Recession of chamber angle of eye	1		1				
Refraction disorder	6		2	1	4		
Retinal aneurysm	7		7				
Retinal aneurysm rupture	3	1	3				
Retinal artery embolism	17	2	17				
Retinal artery occlusion	238	27	238				2
Retinal artery stenosis	2		2				
Retinal artery thrombosis	36	4	33		3		
Retinal cyst	2		2				
Retinal degeneration	22	1	22				
Retinal depigmentation	1		1				
Retinal detachment	238	32	238			4	8
Retinal disorder	34	1	14	4	20		
Retinal drusen	3		3				
Retinal dystrophy	3	1	3				
Retinal exudates	22	6	22				
Retinal fibrosis	1		1				
Retinal fovea disorder	3		2	1	1		
Retinal haemorrhage	163	21	163				2
Retinal infarction	11		11				
Retinal ischaemia	25	7	25				1
Retinal microangiopathy	2		2				

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Retinal neovascularisation	4		4				
Retinal oedema	29	3	29				
Retinal pigmentation	2		1		1		
Retinal pigment epitheliopathy	11	4	11				
Retinal scar	2		1		1		
Retinal tear	99	13	99				2
Retinal thickening	1	1	1				
Retinal toxicity	3		3				
Retinal vascular disorder	19	2	19				
Retinal vascular occlusion	45	7	45				
Retinal vascular thrombosis	100	1	84	5	16		1
Retinal vasculitis	23	5	23				
Retinal vein occlusion	482	65	482				4
Retinal vein thrombosis	174	12	153	7	21		1
Retinal vein varices	1				1		
Retinal vessel avulsion	1		1				
Retinal white dots syndrome	14	2	14				
Retinopathy	24	3	24			1	1
Retinopathy hypertensive	11	4	11				
Retinoschisis	3		3				
Rhegmatogenous retinal detachment	3	1	3				
Saccadic eye movement	5		1		4		
Scintillating scotoma	63	3	24	1	39		
Scleral cyst	4		1		3		
Scleral discolouration	14		4		10		
Scleral disorder	6		3		3		
Scleral haemorrhage	14	2	8	2	6		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Scleral hyperaemia	5		1		4		
Scleral oedema	3		3				
Scleral pigmentation	1				1		
Scleritis	62	11	62			1	1
Serous retinal detachment	11	3	11				
Spontaneous hyphaema	2		2				
Staphyloma	1		1				
Strabismus	107	8	56	4	51		
Subretinal fluid	7	3	7				
Subretinal haematoma	2		2				
Sudden visual loss	41	4	41				
Swelling of eyelid	1458	23	300	128	1158		3
Swollen tear duct	5		1		4		
Symblepharon	1		1				
Sympathetic ophthalmia	2	1	2				
Tear discolouration	1				1		
Tolosa-Hunt syndrome	12	4	12				
Toxic optic neuropathy	1	1	1				
Tractional retinal detachment	1		1				
Trichiasis	1	1	1				
Ulcerative keratitis	29	7	29				
Uveitis	402	53	402			3	12
Venous stasis retinopathy	4		4				
Vision blurred	9498	200	3235	658	6263	4	29
Visual acuity reduced	735	56	335	69	400		1
Visual acuity reduced transiently	21	2	4	1	17		
Visual brightness	32		12	2	20		

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System Organ Class

Eye disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Visual field defect	737	48	382	49	355		3
Visual impairment	9084	432	3018	1065	6066	5	29
Visual snow syndrome	33	3	20	3	13		
Vitreoretinal traction syndrome	3		3				
Vitreous adhesions	6		4	1	2		
Vitreous degeneration	7	2	7				
Vitreous detachment	259	27	259			1	3
Vitreous disorder	23		11		12		
Vitreous floaters	573	13	212	29	361	1	2
Vitreous haematoma	1		1				
Vitreous haemorrhage	113	17	113			2	2
Vitreous haze	12	1	12				
Vitreous opacities	42	2	11	9	31		
Vitreous prolapse	1		1				
Vitritis	9	4	9				
Vogt-Koyanagi-Harada disease	29	14	29				
Xanthopsia	9		3	2	6		
Xerophthalmia	13	2	13				
Total:	69858	2811	27531	5215	42327	65	325

System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdominal adhesions	7		6		1	1	1
Abdominal discomfort	6283	111	1186	712	5097	10	31
Abdominal distension	3193	56	864	334	2329	3	18

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdominal fat apron	1				1		
Abdominal hernia	11		7		4		1
Abdominal incarcerated hernia	2		2				
Abdominal mass	30		9	3	21	1	1
Abdominal migraine	4		1		3		
Abdominal pain	22587	370	4657	2592	17930	4	64
Abdominal pain lower	2738	57	508	332	2230	1	9
Abdominal pain upper	12705	209	3806	989	8899	6	64
Abdominal rebound tenderness	1		1				
Abdominal rigidity	131	6	50	4	81	1	2
Abdominal symptom	63	2	18	19	45		
Abdominal tenderness	149	3	60	16	89		1
Abdominal wall cyst	1		1				
Abdominal wall disorder	1				1		
Abdominal wall haematoma	11		10		1		
Abdominal wall haemorrhage	3		3				
Abdominal wall oedema	4		2		2		
Abdominal wall pain	3	1	1	2	2		
Abnormal faeces	951	22	112	69	839		
Acetonaemic vomiting	12		3	1	9		
Achlorhydria	2		1		1		
Acid peptic disease	1				1		
Acquired macroglossia	2		1		1		
Acquired oesophageal web	1				1		
Acute abdomen	43	3	43				1
Acute haemorrhagic ulcerative colitis	6	1	6				
Aerophagia	20		6		14		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Alcoholic pancreatitis	1		1				
Allergic gastroenteritis	6		2		4		
Allergic stomatitis	1				1		
Anaesthesia oral	116	1	19	6	97		
Anal blister	2			1	2		
Anal eczema	5		1	1	4		
Anal erosion	2				2		
Anal erythema	3		2		1		
Anal fissure	23	4	9	2	14		
Anal fissure haemorrhage	1			1	1		
Anal fistula	14	2	6	4	8		
Anal haemorrhage	100	11	46	6	54		
Anal hypoaesthesia	6		4	1	2		
Anal incontinence	232	19	113	18	119		1
Anal inflammation	8	1	2	2	6		
Anal paraesthesia	5		2	3	3		
Anal polyp	1	1	1				
Anal pruritus	32		6	4	26		
Anal rash	6		2	2	4		
Anal skin tags	3			2	3		
Anal spasm	2				2		
Anal sphincter atony	31	1	16	3	15		
Anal sphincter hypertonia	1				1		
Anal ulcer	4		4				
Anastomotic ulcer perforation	1		1				
Angina bullosa haemorrhagica	10	2	10				
Angular cheilitis	42	1	6	5	36		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Anorectal discomfort	38		7	5	31		
Anorectal disorder	31	5	23	2	8		
Anorectal sensory loss	1		1				
Anorectal swelling	6		2	2	4		
Aphthous ulcer	1018	19	156	82	862		5
Apical granuloma	2				2		
Appendicitis noninfective	1		1				1
Appendicolith	2		1		1		
Appendix disorder	17		13	1	4		3
Aptyalism	79	1	26	4	53		
Ascites	186	24	186			2	2
Atrophic glossitis	6		1	1	5		
Autoimmune colitis	6		6				
Autoimmune enteropathy	1		1				
Autoimmune pancreatitis	27	8	27				
Barrett's oesophagus	12	2	12				1
Bezoar	1				1		
Bile acid malabsorption	10		6	1	4		
Bowel movement irregularity	165	2	34	9	131		2
Breath odour	82	1	27	6	55		1
Brunner's gland hyperplasia	1		1				
Burning mouth syndrome	42		12	2	30		
Cardiospasm	25		10	1	15		
Change of bowel habit	70	4	29	5	41		
Chapped lips	130	2	28	13	102		
Cheilitis	213	5	42	19	171		1
Cheilosis	1				1		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Chronic gastritis	59	7	31	8	28		1
Coating in mouth	19	1	5	1	14		
Coeliac artery aneurysm	1		1				
Coeliac artery compression syndrome	2		1	1	1		
Coeliac artery stenosis	7	2	7				
Coeliac disease	74	16	74				1
Colitis	441	21	232	29	209		5
Colitis ischaemic	112	10	112				2
Colitis microscopic	78	20	78				1
Colitis ulcerative	640	77	640			19	61
Colonic fistula	1	1	1				
Constipation	1853	48	507	209	1346	5	20
Constipation neonatal	1				1		
Crohn's disease	341	50	341			19	107
Cyclic vomiting syndrome	6		2	1	4		
Defaecation disorder	47	3	15	6	32		1
Defaecation urgency	132	5	45	5	87		1
Dental alveolar anomaly	1		1				
Dental caries	20	3	6	4	14		
Dental cyst	4		1		3		
Dental discomfort	72		9	12	63		
Dental dysaesthesia	4		1	1	3		
Dental necrosis	6	2	6				
Dental paraesthesia	43		12	6	31		
Dental plaque	3		1	1	2		
Dental pulp disorder	2		1		1		
Diabetic gastroenteropathy	1				1		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Diabetic gastroparesis	3		1		2		
Diabetic gastropathy	1		1				
Diaphragmatic hernia	6	2	6				
Diarrhoea	49150	496	8751	4450	40399	36	206
Diarrhoea haemorrhagic	291	37	291			4	5
Diarrhoea neonatal	8		8				
Dieulafoy's vascular malformation	1				1		
Discoloured vomit	37		19	2	18		1
Distal intestinal obstruction syndrome	1	1	1				
Diverticular fistula	1		1				
Diverticular hernia	1			1	1		
Diverticular perforation	3		3				
Diverticulum	46	3	27	4	19		1
Diverticulum intestinal	63	3	31	8	32		
Diverticulum intestinal haemorrhagic	11		11				
Dolichocolon acquired	1		1				
Dry mouth	3136	35	682	260	2454		15
Dumping syndrome	3	1	1		2		
Duodenal obstruction	1	1	1				
Duodenal perforation							1
Duodenal stenosis	1		1				
Duodenal ulcer	23	5	23				1
Duodenal ulcer haemorrhage	13		13				
Duodenal ulcer perforation	3		3				
Duodenitis	24	3	13	2	11		
Duodenogastric reflux	28	4	12	2	16		
Dysbiosis	19	1	6	4	13		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dyschezia	88	3	38	10	50		1
Dyskinesia oesophageal	2		1		1		
Dyspepsia	2938	49	742	226	2196	3	10
Dysphagia	4706	149	1833	341	2873		24
Enamel anomaly	1				1		
Enlarged uvula	121		53	6	68		
Enteritis	122	10	60	5	62	1	2
Enterocolitis	56	5	56				
Enterocolitis haemorrhagic	27	1	27				
Enterocutaneous fistula	2		2				
Enterovesical fistula	4		4				
Eosinophilic colitis	4	1	4				
Eosinophilic gastritis	1		1				
Eosinophilic oesophagitis	14		7		7		
Epigastric discomfort	187	2	54	6	133		
Epiploic appendagitis	9	1	5		4		
Erosive duodenitis	1	1	1				
Erosive oesophagitis	4	1	4				
Eructation	490	11	114	43	376		4
Faecalith	5	2	4		1		
Faecaloma	45	3	45				2
Faecal vomiting	13	2	13				
Faeces discoloured	403	12	121	29	282		3
Faeces hard	29	4	12	1	17		
Faeces pale	59		21	5	38		
Faeces soft	329	8	61	17	268		
Femoral hernia	1				1		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Flatulence	1188	20	266	112	922	4	12
Food poisoning	60		25	3	35		
Food protein-induced enterocolitis syndrome	1	1	1				
Frequent bowel movements	312	5	70	36	242		5
Functional gastrointestinal disorder	148	10	53	14	95		1
Gastric antral vascular ectasia	14		14				
Gastric dilatation	49	2	15	4	34		
Gastric disorder	349	6	86	38	263		2
Gastric fibrosis	1		1				
Gastric haemorrhage	49	5	49				1
Gastric hypermotility	1				1		
Gastric hypomotility	2				2		
Gastric mucosa erythema	6	1	3	1	3		
Gastric mucosal lesion	4		1	1	3		
Gastric perforation	6	1	6				
Gastric polyps	9	1	3	1	6		
Gastric stenosis	1		1				
Gastric ulcer	82	12	82			1	1
Gastric ulcer haemorrhage	17	1	17				
Gastric ulcer perforation	2		2				
Gastric varices haemorrhage	2		2				
Gastric volvulus	2		2				
Gastritis	701	39	245	76	456		3
Gastritis alcoholic	1			1	1		
Gastritis erosive	28	7	28				
Gastritis haemorrhagic	4		4				
Gastritis hypertrophic	1		1				

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Gastroenteritis eosinophilic	5	1	2	1	3		
Gastrointestinal angiodysplasia	3		3				
Gastrointestinal disorder	1924	49	388	201	1536	1	5
Gastrointestinal fistula							1
Gastrointestinal haemorrhage	227	20	227			1	1
Gastrointestinal hypermotility	32		8	2	24		
Gastrointestinal hypomotility	25		9	5	16		
Gastrointestinal inflammation	170	15	77	17	93		
Gastrointestinal motility disorder	108	3	18	11	90		
Gastrointestinal mucosa hyperaemia	2				2		1
Gastrointestinal mucosal disorder	6		5		1		
Gastrointestinal necrosis	40	2	40				
Gastrointestinal obstruction	7		7				
Gastrointestinal oedema	28	7	28			1	1
Gastrointestinal pain	1403	37	331	124	1072	2	6
Gastrointestinal perforation	8		8				
Gastrointestinal polyp haemorrhage	1		1				
Gastrointestinal scarring							2
Gastrointestinal sounds abnormal	156		33	10	123	1	2
Gastrointestinal toxicity	2		1		1		
Gastrointestinal tract irritation	40		6	6	34		1
Gastrointestinal ulcer	7	1	3		4		
Gastrointestinal wall abnormal	1			1	1		
Gastrointestinal wall thickening	18	1	10	2	8		
Gastrointestinal wall thinning	1		1				
Gastrooesophageal reflux disease	1029	29	346	87	683	2	6
Gastrooesophageal sphincter insufficiency	2		1		1		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Gingival atrophy	3	1	1		2		
Gingival bleeding	630	11	177	77	453		1
Gingival blister	51		10	6	41		
Gingival cyst	2				2		
Gingival discolouration	16		4	1	12		
Gingival discomfort	70	1	9	9	61		1
Gingival disorder	56	2	11	9	45		
Gingival erosion	4		2		2		
Gingival erythema	32		10	2	22		1
Gingival hypertrophy	4		2	1	2		
Gingival oedema	46	1	4	2	42		
Gingival pain	515	3	128	42	387		
Gingival pruritus	11		2	5	9		
Gingival recession	29	4	12	3	17		2
Gingival swelling	331	2	78	29	253		
Gingival ulceration	25	1	8	2	17		
Gingivitis ulcerative	14		8	1	6		
Glossitis	227	5	66	16	161		
Glossodynia	874	6	204	78	670	1	2
Glossoptosis	7		5		2		
Haematemesis	351	34	351				4
Haematochezia	834	91	834			7	36
Haemoperitoneum	17	2	17				
Haemorrhagic ascites	2	1	2				
Haemorrhagic erosive gastritis	1	1	1				
Haemorrhagic necrotic pancreatitis	1		1				
Haemorrhoidal haemorrhage	61	4	16	10	45		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Haemorrhoids	352	6	86	53	266		3
Haemorrhoids thrombosed	148	3	62	6	86		1
Hiatus hernia	90	2	41	7	49		
Hiatus hernia strangulated	1		1				
Hyperaesthesia teeth	148		26	10	122		
Hyperchlorhydria	59	1	15	7	44	1	1
Hypertrophy of tongue papillae	18		2		16		
Hypoaesthesia oral	4276	63	1131	332	3145		7
Hypoaesthesia teeth	21		4	2	17		
Ileal perforation	1		1				
Ileal ulcer	1	1	1				
Ileus	53	6	53				
Ileus paralytic	39	4	39				
Immune-mediated pancreatitis	1		1				
Impaired gastric emptying	69	10	69				1
Incarcerated umbilical hernia	1		1				
Infantile colic	2		2				
Infantile spitting up	1				1		
Infantile vomiting	86		33	7	53		
Inflammatory bowel disease	93	24	93				3
Infrequent bowel movements	19		5	2	14		1
Inguinal hernia	37	6	20	3	17		1
Internal hernia	3		1		2		
Intestinal angina	1		1				
Intestinal angioedema	4		4				
Intestinal atony	3				3		
Intestinal barrier dysfunction	9	1	1	2	8		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Intestinal congestion	3		1	1	2		
Intestinal cyst	1		1			1	1
Intestinal dilatation	11	1	7	1	4		
Intestinal fibrosis	1				1		
Intestinal fistula	1		1				
Intestinal haematoma	1	1	1				
Intestinal haemorrhage	114	26	114				2
Intestinal infarction	39	2	39				
Intestinal ischaemia	141	13	141				1
Intestinal mass	4		3		1		
Intestinal metaplasia	1			1	1		
Intestinal mucosal tear	1		1				
Intestinal obstruction	135	11	135			5	8
Intestinal perforation	33	3	33				
Intestinal polyp	3	1	3				
Intestinal prolapse	1		1				
Intestinal pseudo-obstruction	4		4				
Intestinal stenosis	4	1	4				1
Intestinal ulcer	9	1	9				
Intestinal vascular disorder	1		1				
Intra-abdominal fluid collection	14	1	13		1		
Intra-abdominal haematoma	13	1	13				
Intra-abdominal haemorrhage	31	3	31				1
Intussusception	34	2	34				
Irritable bowel syndrome	363	8	159	40	204		2
Ischaemic enteritis	2	1	2				
Jejunal perforation	2	1	2				

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Large intestinal haemorrhage	14	4	14				1
Large intestinal obstruction	6		6				
Large intestinal stenosis	1		1				1
Large intestinal ulcer	7		7			1	1
Large intestinal ulcer haemorrhage	2		2				
Large intestine erosion	2	1	2				
Large intestine perforation	21	1	21				3
Large intestine polyp	18	2	10	2	8		1
Leukoplakia oral	8		8				
Levator syndrome	1				1		
Lip blister	231	4	53	23	178		
Lip discolouration	67	1	23	5	44		1
Lip disorder	129	1	30	9	99		1
Lip dry	256	1	58	19	198		
Lip erosion	10		6		4		
Lip erythema	102	3	23	8	79		
Lip exfoliation	39		9	5	30		
Lip haematoma	3		1	1	2		
Lip haemorrhage	39	1	17	3	22		
Lip oedema	880	12	295	59	585		10
Lip pain	342	2	94	29	248		
Lip pruritus	297	2	88	20	209		1
Lip scab	3		2	1	1		
Lip swelling	4518	56	1390	282	3128	1	8
Lip ulceration	57		16	2	41		
Loose tooth	29		12	3	17		
Lower gastrointestinal haemorrhage	10		10				

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lumbar hernia	2				2		
Lymphoid hyperplasia of intestine	1			1	1		
Malabsorption	27	3	13	2	14		1
Malignant dysphagia	1		1				
Mallory-Weiss syndrome	8	1	8				
Malocclusion	9		5		4		1
Malpositioned teeth	6		4		2		
Mechanical ileus	3		3				
Meconium peritonitis	3		3				
Megacolon	5	2	5				
Melaena	166	10	166			1	1
Mesenteric arterial occlusion	6		6				
Mesenteric artery aneurysm	2		2				
Mesenteric artery embolism	6	1	6				
Mesenteric artery stenosis	3		3				1
Mesenteric artery thrombosis	22	3	22				1
Mesenteric haematoma	2		2				
Mesenteric haemorrhage	2		2				
Mesenteric panniculitis	17		13	1	4		
Mesenteric vascular insufficiency	1		1				
Mesenteric vascular occlusion	6		6				
Mesenteric vein thrombosis	136	6	136				
Mesenteric venous occlusion	1		1				
Mesenteritis	3		1		2		
Microscopic enteritis	1			1	1		
Mouth cyst	17		4	1	13		
Mouth haemorrhage	275	9	128	23	147		1

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mouth swelling	762	5	252	61	510		
Mouth ulceration	1017	8	319	78	698		3
Mucous stools	123	5	42	9	81		
Nausea	137186	1204	22963	12075	114223	59	481
Necrotising colitis	4		4				
Necrotising enterocolitis neonatal	1		1				
Neonatal intestinal obstruction	1		1				
Neonatal intestinal perforation	1	1	1				
Neurogenic bowel	2		1		1		
Noninfectious peritonitis	1	1	1				
Noninfective gingivitis	230	5	46	29	184		
Noninfective sialoadenitis	69	3	14	9	55		
Obstruction gastric	4	2	4				
Obstructive defaecation	1			1	1		
Obstructive pancreatitis	9		9				
Obturator hernia	2		2				
Odynophagia	1601	17	283	111	1318		2
Oedema mouth	118	2	50	8	68		1
Oedematous pancreatitis	11		11				
Oesophageal achalasia	13		8		5	1	1
Oesophageal compression	1	1	1				
Oesophageal dilatation	1		1				
Oesophageal discomfort	22		5	2	17		1
Oesophageal disorder	21	1	12	1	9		
Oesophageal food impaction	2		2				
Oesophageal haemorrhage	5		5				
Oesophageal hypomotility	1	1	1				

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Oesophageal irritation	6		2		4		
Oesophageal mass	2		2				
Oesophageal motility disorder	2			1	2		
Oesophageal mucosal blister	1				1		
Oesophageal obstruction	2		2				
Oesophageal oedema	8		5		3		
Oesophageal pain	110	2	30	7	80		
Oesophageal perforation	4		4				
Oesophageal rupture	4	1	4				
Oesophageal spasm	43	3	11	1	32		
Oesophageal stenosis	9		9				
Oesophageal ulcer	8	1	8				
Oesophageal ulcer haemorrhage	2		2				
Oesophageal varices haemorrhage	8		8				
Oesophagitis	108	9	40	14	68		1
Oesophagitis ulcerative	3		3				
Omental haemorrhage	1		1				
Omental infarction	16	1	13		3		
Omental necrosis	1	1	1				
Oral blood blister	61	3	21	6	40		
Oral cavity fistula	2			1	2		
Oral discharge	3	1	2		1		
Oral discomfort	1091	10	215	104	876		2
Oral disorder	270	6	66	25	204		1
Oral dysaesthesia	83	3	21	5	62		
Oral hyperaesthesia	3		1	1	2		
Oral lichenoid reaction	8	4	5		3		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Oral lichen planus	73	7	37	9	36		
Oral mucosa erosion	31	3	14	2	17		1
Oral mucosa haematoma	8		4		4		
Oral mucosal blistering	457	9	85	103	372	1	1
Oral mucosal discolouration	8		3		5		
Oral mucosal eruption	119	1	27	13	92		
Oral mucosal erythema	118	4	33	11	85		
Oral mucosal exfoliation	39	2	13	3	26		
Oral mucosal hypertrophy	3			1	3		
Oral mucosal roughening	20		5	3	15		
Oral mucosal scab	3		1		2		
Oral pain	883	8	214	83	669	1	1
Oral papule	9		1	1	8		
Oral pigmentation	2				2		
Oral pruritus	482	5	150	52	332		
Oral purpura	4		3		1		
Overflow diarrhoea	2		1		1		
Palatal disorder	36	1	7	1	29		
Palatal oedema	178	1	91	7	87		3
Palatal swelling	129	1	45	8	84		1
Palatal ulcer	7		2	1	5		
Pancreatic atrophy	2	1	2				
Pancreatic calcification	3		2	1	1		
Pancreatic cyst	21	1	10	2	11		
Pancreatic disorder	46	4	20	7	26		
Pancreatic duct dilatation	2		2				
Pancreatic enlargement	5		3		2		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pancreatic failure	20	4	20				
Pancreatic haemorrhage	1		1				
Pancreatic infarction	1		1				
Pancreatic mass	2		2				
Pancreatic pseudocyst	5	1	4		1		
Pancreatic steatosis	12	2	6	1	6		
Pancreatitis	303	24	303			2	6
Pancreatitis acute	379	27	379			1	4
Pancreatitis chronic	15	1	15				
Pancreatitis haemorrhagic	1		1				
Pancreatitis necrotising	22	3	22				1
Pancreatitis relapsing	4		4				
Papilla of Vater sclerosis	1		1				
Paraesthesia oral	6343	46	1541	330	4802		21
Paresis anal sphincter	1				1		
Parotid duct obstruction	3		1		2		
Parotid gland enlargement	122	4	34	6	88		
Parotid lipomatosis	1				1		
Pelvic floor dysfunction	8		4	3	4		
Peptic ulcer	14	1	14				
Peptic ulcer haemorrhage	19		19				
Periodontal disease	6			1	6		
Periodontal inflammation	4				4		
Peristalsis visible	2		1		1		
Peritoneal adhesions	1		1				
Peritoneal disorder	6	1	3	2	3		
Peritoneal haematoma	2		2				

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Peritoneal perforation	1		1				
Pharyngo-oesophageal diverticulum	1		1				
Pigmentation lip	3		1	1	2		
Plicated tongue	28	4	10	4	18		
Pneumatosis intestinalis	4	2	4				
Pneumoperitoneum	5	1	5				
Poor dental condition	2				2		
Portal hypertensive gastropathy	3		3				
Portal venous gas	2		2				
Post-tussive vomiting	5		2	1	3		
Pouchitis	1		1				1
Proctalgia	106	3	26	12	80		
Proctitis	46	2	14	1	32		
Proctitis haemorrhagic	3		3				
Proctitis ulcerative	19	8	19				
Protein-losing gastroenteropathy	1		1				
Protrusion tongue	2		1	1	1		
Pulpless tooth	1				1		
Pylorospasm	1				1		
Ranula	3		2	1	1		
Rectal discharge	18	1	8	1	10		
Rectal fissure	3	2	2		1		
Rectal haemorrhage	462	37	462				10
Rectal lesion	1				1		
Rectal perforation	1		1				
Rectal polyp	5	1	2	2	3		
Rectal prolapse	9	1	5		4		1

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Rectal spasm	7	2	2	3	5		
Rectal tenesmus	36	1	9	7	27		1
Rectal ulcer	5	1	5				
Rectourethral fistula	2		2				
Reflux gastritis	73	1	20	7	53		
Regurgitation	58	3	12	1	46		1
Retching	1116	17	293	49	823		6
Retroperitoneal effusion	1		1				
Retroperitoneal fibrosis	3	1	3				
Retroperitoneal haematoma	14	3	14				
Retroperitoneal haemorrhage	8	1	8				
Retroperitoneal mass	1				1		
Saliva altered	45	4	15	6	30		
Saliva discolouration	7		2	1	5	1	1
Salivary duct obstruction	6		2	1	4		
Salivary gland calculus	5			1	5		
Salivary gland cyst	2		1		1		
Salivary gland disorder	19	1	10	1	9		
Salivary gland enlargement	109	3	32	17	77		3
Salivary gland mass	7		2	1	5		
Salivary gland mucocoele	4		2	1	2		
Salivary gland pain	93	1	18	6	75		1
Salivary hypersecretion	450	5	112	34	338		
Scalloped tongue	9		3		6		
Short-bowel syndrome	3	1	3				1
Small intestinal haemorrhage	18		18				1
Small intestinal obstruction	22	4	22			1	1

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Small intestinal perforation	4		4				
Small intestinal stenosis							1
Small intestine ulcer	1	1	1				
Splenic artery aneurysm	4	1	4				
Stasis syndrome	3		2	1	1		
Steatorrhoea	14	1	6	1	8		
Stiff tongue	36	2	19	2	17		
Stomach mass	10		3		7		
Stomatitis	843	12	161	71	682	1	4
Stomatitis necrotising	1	1	1				
Strawberry tongue	6		4		2		
Subileus	21	3	15	2	6		
Submaxillary gland enlargement	33	2	7	6	26		
Superior mesenteric artery dissection	2		2				
Superior mesenteric artery syndrome	1		1				
Swollen tongue	3511	49	1292	167	2219	1	7
Teeth brittle	7	1	2	1	5		
Teething	47		9	2	38		
Terminal ileitis	18	6	18				
Thrombosis mesenteric vessel	12		12				
Tongue atrophy	4		2	1	2		
Tongue blistering	175	3	29	36	146		
Tongue coated	143	1	29	10	114		1
Tongue cyst	5		4		1		
Tongue discolouration	198	1	38	14	160		
Tongue discomfort	737	8	131	74	606		2
Tongue disorder	385	3	132	22	253		

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System Organ Class

Gastrointestinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tongue dry	123		37	9	86		
Tongue dysplasia	1		1				
Tongue eruption	76		14	7	62		
Tongue erythema	134	1	30	15	104		1
Tongue exfoliation	11		2		9		
Tongue geographic	43		10	3	33		
Tongue haematoma	13		5		8		
Tongue haemorrhage	27		7	3	20		1
Tongue induration	1				1		
Tongue movement disturbance	72	2	40	2	32		
Tongue oedema	538	14	262	41	276		10
Tongue pigmentation	1				1		
Tongue polyp	2		1		1		
Tongue pruritus	276	6	90	8	186		1
Tongue rough	36		5	1	31		
Tongue spasm	37		15		22		1
Tongue thrust	4				4		
Tongue ulceration	165		51	10	114		
Toothache	1611	10	289	185	1322	1	5
Tooth demineralisation	1				1		
Tooth deposit	3		2		1		
Tooth development disorder	1		1				
Tooth discolouration	15		6		9		
Tooth disorder	136	6	28	17	108	1	5
Tooth erosion	5		2		3		
Tooth impacted	5		1		4		
Tooth loss	60	6	22	12	38		

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System Organ Class

Gastrointestinal disorders

		Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
Preferred Term	*Total # of Spontaneous AE*	I	C	I	C	I	C
Tooth malformation	3			2	3		
Tooth pulp haemorrhage	1				1		
Tooth resorption	2				2		1
Tooth socket haemorrhage	3		1		2		
Transient lingual papillitis	2				2		
Trichoglossia	38		10		28		
Truncus coeliacus thrombosis	7	1	7				
Ulcerative duodenitis	1		1				
Ulcerative gastritis	1				1		
Umbilical hernia	12		5	3	7		1
Upper gastrointestinal haemorrhage	65	8	65				
Uvula deviation	1				1		
Uvulitis	22		10	1	12		
Varices oesophageal	11		6	2	5		
Varicose veins of abdominal wall	1		1				
Vasculitis gastrointestinal	2		2				
Visceral venous thrombosis	12		12				
Volvulus	20	1	20				
Volvulus of small bowel	2	1	2				
Vomiting	43873	776	11117	4271	32756	19	200
Vomiting projectile	195	3	101	3	94		
Walled-off pancreatic necrosis	1				1		
Total:	354936	5360	80332	31379	274604	237	1653

System Organ Class

General disorders and administration site conditions

	Spontaneous		Non Interventional Study
	Serious	Nonserious	Serious

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal organ growth	1		1				
Abscess sterile	1				1		
Absence of immediate treatment response	1		1				
Acute phase reaction	6	1	4		2		
Adhesion	24		6	3	18		
Administration site bruise	28		3	1	25		
Administration site cyst	1			1	1		
Administration site discolouration	2		1		1		
Administration site discomfort	3		1		2		
Administration site erythema	30			2	30		
Administration site extravasation	3		1		2		
Administration site fibrosis	1				1		
Administration site haematoma	3				3		
Administration site hypersensitivity	2				2		
Administration site hypoaesthesia	2				2		
Administration site indentation	1			1	1		
Administration site induration	2				2		
Administration site inflammation	2				2		
Administration site irritation	2				2		
Administration site joint discomfort	1				1		
Administration site joint erythema	2				2		
Administration site joint movement impairment	8		2		6		
Administration site joint pain	4				4		
Administration site lymphadenopathy	8				8		
Administration site movement impairment	15		1		14		
Administration site nerve damage	1		1				
Administration site oedema	30			1	30		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Administration site pain	675		2	12	673		
Administration site paraesthesia	6				6		
Administration site plaque	1				1		
Administration site pruritus	8				8		
Administration site rash	5				5		
Administration site reaction	26		2		24		
Administration site swelling	13				13		
Administration site urticaria	1				1		
Administration site warmth	4			1	4		
Administration site wound	3	1	1		2		
Adverse drug reaction	120	3	26	7	94	1	4
Adverse event	129		15	12	114		
Adverse food reaction	16	2	7	1	9		
Adverse reaction	282	9	31	111	251		1
Alcohol interaction	14		7		7		
Antidepressant discontinuation syndrome	2				2		
Apparent death	1		1				
Application site acne	5		2		3		
Application site alopecia	1				1		
Application site bruise	7				7	1	1
Application site burn	2		1		1		
Application site coldness	3		1		2		
Application site dermatitis	1				1		
Application site discolouration	2			1	2		
Application site discomfort	3		1		2		
Application site dysaesthesia	5		1	1	4		
Application site erythema	201		3	3	198		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Application site haematoma	6		2		4		
Application site haemorrhage	7		2		5		
Application site hyperaesthesia	1				1		
Application site hypersensitivity	2				2		
Application site hypoaesthesia	27	2	6		21		
Application site induration	8				8		
Application site inflammation	5				5		
Application site joint erythema	1				1		
Application site joint inflammation	1				1		
Application site joint movement impairment	4				4		
Application site joint pain	3				3		
Application site joint swelling	6				6		
Application site lymphadenopathy	18				18		
Application site movement impairment	27		1	2	26		
Application site nerve damage	1		1				
Application site odour	1				1		
Application site oedema	7				7		
Application site pain	1515	1	6	8	1509		
Application site paraesthesia	4		1		3		
Application site perspiration	1				1		
Application site plaque	1				1		
Application site pruritus	36				36		
Application site rash	6				6		
Application site reaction	140		1		139		
Application site scab	1		1				
Application site scar	1				1		
Application site swelling	289		1	2	288		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Application site thrombosis	1		1				
Application site vesicles	6		2		4		
Application site warmth	19				19		
Asthenia	67706	1286	12581	6820	55125	8	199
Atrophy	36	3	25	2	11		
Autoresuscitation	1	1	1				
Axillary pain	17029	66	3226	2221	13803	2	18
Brain death	57	6	57				
Breakthrough pain	7		2	1	5		
Breast implant palpable	1				1		
Calcinosis	18	3	9	1	9		
Capsular contracture associated with breast implant	9		4	1	5		
Capsular contracture associated with implant	2		1		1		
Cardiac death	82	6	82				
Catheter site haematoma	1		1				
Catheter site haemorrhage	2	1	1		1		1
Catheter site injury	1		1				1
Catheter site irritation	1			1	1		
Catheter site pain	6		1	1	5		
Catheter site swelling	1	1	1				1
Catheter site thrombosis	2		2				
Challenge site reaction	2				2		
Chest discomfort	22847	544	7919	1804	14928	6	46
Chest pain	45194	1107	16656	3279	28538	8	145
Chills	142588	728	15193	13721	127395	32	278
Chronic disease	8		3		5		
Chronic fatigue syndrome	813	171	455	190	358		3

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Chronic inflammatory response syndrome	7	2	7				
Clinical death	1		1				
Complication associated with device	18		6	2	12		
Complication of device removal	2				2		
Concomitant disease aggravated	1279	25	118	223	1161		
Concomitant disease progression	36		20	3	16		
Condition aggravated	10692	855	5218	960	5474	11	47
Contrast media deposition	1			1	1		
Crepitations	78	2	26	3	52	1	1
Critical illness	5		5				
Crying	1016	13	258	92	758		3
Cyst	345	12	94	45	251	1	4
Cyst rupture	17		5	1	12		
Death	3275	281	3275			1	8
Death neonatal	8	1	8				
Decapitation	1		1				
Decreased activity	215	7	73	44	142	2	2
Decreased gait velocity	6		2		4		
Deformity	31	2	12	3	19		
Dehiscence	2			1	2		
Developmental delay	7	1	4		3		
Developmental regression	2		1		1		
Device embolisation	1		1				
Device related thrombosis	2		2				
Diet failure	1				1		
Discharge	112	1	24	19	88		
Discomfort	6901	94	1625	838	5276	1	14

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Disease complication	5		2		3		
Disease prodromal stage	2		1		1		1
Disease progression	158	14	110	6	48	1	3
Disease propensity	5			3	5		
Disease recurrence	4195	431	3141	154	1054	11	36
Disease susceptibility	36	2	3	8	33		
Drowning	30		30				
Drug-device interaction	3		2		1		
Drug-disease interaction	2		1		1		
Drug effective for unapproved indication	6			1	6		
Drug effect less than expected	6			1	6		
Drug-genetic interaction	1				1		
Drug ineffective	68798	28726	68757	7	41	1085	2239
Drug ineffective for unapproved indication	1				1		
Drug interaction	472	17	167	33	305	1	10
Drug intolerance	65	3	19	6	46	4	4
Drug resistance	9	1	5	1	4		
Drug tolerance	1				1		
Drug tolerance decreased	5		2	2	3		
Drug withdrawal syndrome	8		2		6		
Drug withdrawal syndrome neonatal	1				1		
Dysplasia	8	1	4		4		
Early satiety	5			1	5		
Effusion	67	3	30	7	37		
Electrocution	1	1	1				
Embolia cutis medicamentosa	2		2				
Enanthema	26	2	11	2	15		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Encapsulation reaction	3				3		
Energy increased	196	1	19	15	177		1
Exercise tolerance decreased	2168	168	637	441	1531		3
Exercise tolerance increased	10	1	1	5	9		
Extensive swelling of vaccinated limb	4093	67	587	426	3506		
Extravasation	11		4		7		
Eye complication associated with device	2		1		1		
Face oedema	1825	42	664	130	1161	1	9
Facial discomfort	350	7	61	32	289		
Facial pain	1825	36	562	140	1263	1	3
Fatigue	264943	2814	36781	28093	228162	116	1007
Fat necrosis	14		9		5		
Fat tissue decreased	3				3		
Fat tissue increased	19		9	2	10		
Feeling abnormal	18593	303	4740	1551	13853	6	42
Feeling cold	12567	89	2201	977	10366	3	37
Feeling drunk	626	6	153	51	473		
Feeling hot	19536	151	2933	1388	16603	1	23
Feeling jittery	365	3	88	14	277		1
Feeling of body temperature change	2268	25	811	189	1457	1	7
Feeling of relaxation	21		3	1	18		
Fever neonatal	8		8				
Fibrosis	36	3	21	5	15		
First bite syndrome	1		1				
Foaming at mouth	69	4	42	4	27		
Food interaction	4				4		
Foreign body reaction	6		2		4		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Gait deviation	14		10		4		
Gait disturbance	9037	449	3628	920	5409	7	44
Gait inability	2040	113	1098	142	942	1	6
Generalised oedema	322	16	157	29	165		
General physical health deterioration	3479	182	1522	546	1957	4	10
General symptom	45	3	14	3	31	1	2
Glassy eyes	45		11	2	34		
Granuloma	48	7	15	11	33		
Gravitational oedema	23		12		11		2
Haemorrhagic cyst	11	3	11				1
Hanging	1				1		
Hangover	298	2	89	16	209		2
Herbal interaction	1				1		
Hernia	57	2	21	8	36	1	2
Hernia pain	13	1	1	1	12		
High-pitched crying	4				4		
Humidity intolerance	2	1	1		1		
Hunger	356	1	51	20	305		2
Hyperplasia	14	1	6	2	8		
Hyperpyrexia	1159	68	1159				31
Hyperthermia	1163	14	337	45	826	1	1
Hyperthermia malignant	4		4				
Hypertrophy	23		8	3	15		
Hypothermia	493	42	493				4
Idiopathic environmental intolerance	10	1	2	1	8		
Idiosyncratic drug reaction	4	1	1		3		
Ill-defined disorder	94	4	30	12	64	2	6

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Illness	7807	119	2619	680	5188	13	58
Immediate post-injection reaction	8		3		5		
Impaired healing	172	8	45	28	127		4
Impaired self-care	28		16	4	12		
Implant site dermatitis	1				1		
Implant site discolouration	2				2		
Implant site erythema	4				4		
Implant site extravasation	4		2		2		
Implant site fibrosis	1	1	1				
Implant site haematoma	1			1	1		
Implant site haemorrhage	1		1				
Implant site hypersensitivity	3				3		
Implant site induration	3		1		2		
Implant site inflammation	4		1		3		
Implant site irritation	1				1		
Implant site nodule	2				2		
Implant site oedema	4				4		
Implant site pain	17		3	1	14		
Implant site paraesthesia	1				1		
Implant site pruritus	5			3	5		
Implant site rash	1				1		
Implant site reaction	5				5		
Implant site swelling	8		1	1	7		
Implant site urticaria	1				1		
Implant site warmth	4		1		3		
Inadequate analgesia	11		5		6		
Incarcerated hernia	2		2				

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Induration	2197	6	105	63	2092		
Inflammation	6614	173	1865	511	4749	4	17
Inflammatory pain	158	6	56	19	102		
Influenza like illness	30567	202	4822	1979	25745	9	55
Infusion site bruising	1				1		1
Infusion site erythema	4			1	4		
Infusion site extravasation	2				2		1
Infusion site haematoma	1				1		
Infusion site haemorrhage	2		2				1
Infusion site hypoaesthesia	1				1		
Infusion site induration	1				1		
Infusion site joint inflammation	2				2		
Infusion site joint pain	2				2		
Infusion site joint swelling	4				4		
Infusion site lymphadenopathy	1				1		
Infusion site mass							1
Infusion site mobility decreased	17		1	1	16		
Infusion site pain	8				8		2
Infusion site paraesthesia	1				1		
Infusion site pruritus	3				3		
Infusion site reaction	1				1		
Infusion site streaking	1				1		
Infusion site swelling	2				2		1
Infusion site urticaria	1				1		
Infusion site warmth	5		1		4		
Inhibitory drug interaction	32		9	3	23		
Injected limb mobility decreased	2340	35	259	331	2081		1

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Injection site alopecia	1				1		
Injection site atrophy	4	1	3		1		
Injection site bruising	56		3	2	53		1
Injection site coldness	2				2		
Injection site cyst	3				3		
Injection site deformation	9	1	2	1	7		
Injection site discharge	19				19		
Injection site discolouration	17			1	17		
Injection site discomfort	74		2	3	72		
Injection site erythema	1166	1	33	22	1133		
Injection site extravasation	19			1	19		
Injection site granuloma	2				2		
Injection site haematoma	50		4	1	46		
Injection site haemorrhage	48		2	2	46		
Injection site hyperaesthesia	2				2		
Injection site hypersensitivity	36		4	1	32		
Injection site hypertrophy	1				1		
Injection site hypoaesthesia	197	1	12	7	185		
Injection site indentation	24		6	5	18		
Injection site induration	189	1	2	3	187		
Injection site inflammation	103		2		101		
Injection site injury	2			1	2		
Injection site irritation	5			1	5		
Injection site joint discomfort	1				1		
Injection site joint erythema	2				2		
Injection site joint inflammation	1				1		
Injection site joint movement impairment	19		2		17		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Injection site joint pain	34	1	2		32		
Injection site joint swelling	4				4		
Injection site joint warmth	2				2		
Injection site lymphadenopathy	26		3		23		
Injection site macule	2				2		
Injection site mass	141		17		124		1
Injection site movement impairment	36		6	1	30		
Injection site muscle atrophy	7	1	3	2	4		
Injection site muscle weakness	103	2	14	16	89		
Injection site necrosis	2		2				
Injection site nerve damage	3	1	3				
Injection site nodule	10				10		
Injection site oedema	304				304		
Injection site pain	7567	7	107	58	7460		9
Injection site papule	1				1		
Injection site paraesthesia	89	3	6	1	83		
Injection site pruritus	503		12	14	491		
Injection site rash	127		5	3	122		
Injection site reaction	478	6	43	10	435		
Injection site scab	2				2		
Injection site scar	3				3		
Injection site swelling	768	1	17	12	751		3
Injection site thrombosis	1		1				
Injection site ulcer	2		1		1		
Injection site urticaria	77		6	2	71		
Injection site vesicles	13			1	13		
Injection site warmth	190		8	2	182		1

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Injury associated with device	25		4	1	21		1
Instillation site haemorrhage	1				1		
Instillation site hyperaesthesia	1				1		
Instillation site pain	2				2		
Instillation site pruritus	1			1	1		
Instillation site warmth	3		1		2		
Irritability postvaccinal	68		5	4	63		
Lipogranuloma	1				1		
Lithiasis	18		9	2	9		
Localised oedema	931	19	218	194	713		4
Local reaction	2147	14	197	133	1950		1
Loss of control of legs	121	11	121				1
Loss of therapeutic response	3		2		1		1
Malaise	157315	1207	15899	14377	141416	64	491
Masked fever	1				1		
Mass	1013	15	226	67	787	2	6
Maxillofacial pain	2				2		
Medical device discomfort	3				3		
Medical device pain	6		1	1	5		
Medical device site cyst	1		1				
Medical device site erythema						1	1
Medical device site granuloma	1				1		
Medical device site inflammation	1				1		
Medical device site joint discomfort	1			1	1		
Medical device site joint inflammation	4			1	4		1
Medical device site joint swelling	2				2		
Medical device site lymphadenopathy	1				1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Medical device site movement impairment	2				2		
Medical device site oedema	1				1		
Medical device site pain	3			1	3		
Medical device site paraesthesia	1				1		
Medical device site pruritus	1		1				
Medical device site rash	2		1		1		
Medical device site reaction	1			1	1		
Medical device site recall reaction	1				1		
Medical device site warmth						1	1
Metaplasia	4		1	1	3		
Meteoropathy	7	1	2	1	5		
Moaning	63	3	29	1	34		1
Mucosal atrophy	1				1		
Mucosal discolouration	8		1	3	7		
Mucosal disorder	107	2	25	23	82	1	1
Mucosal dryness	128	2	26	23	102		1
Mucosal erosion	4		2		2		
Mucosal exfoliation	1				1		
Mucosal haemorrhage	48	2	22	6	26		
Mucosal hyperaemia	5		2		3		
Mucosal hypertrophy	7		2		5		
Mucosal inflammation	102	3	23	14	79		3
Mucosal membrane hyperplasia	1				1		
Mucosal necrosis	1		1				
Mucosal pain	15		1	4	14		
Mucosal roughness	1				1		
Mucosal ulceration	12		5	1	7		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mucosa vesicle	5		1		4		
Multimorbidity	5		4		1		
Multi-organ disorder	29		24	1	5		
Multiple organ dysfunction syndrome	359	43	359				1
Necrobiosis	1				1		
Necrosis	68	9	68				
Neonatal multi-organ failure	1		1				
No adverse event	39			2	39		
Nodule	2230	13	174	135	2056		2
Non-cardiac chest pain	217	2	49	17	168		
Non-pitting oedema	13		4		9		
Nonspecific reaction	9	1	4		5	1	2
No reaction on previous exposure to drug	22		3		19		
Nyctalgia	3		1		2		
Obstruction	30	1	15	1	15	2	5
Oedema	4083	68	749	266	3334		7
Oedema due to cardiac disease	9	2	7	1	2		
Oedema due to hepatic disease	1		1				
Oedema due to renal disease	1		1				
Oedema mucosal	103	5	39	10	64		
Oedema peripheral	4549	127	1490	408	3059	2	20
Oral administration complication	4		1		3		
Organ failure	59	6	51		8		
Pacemaker generated arrhythmia	3		1	1	2		
Pacemaker syndrome	1		1				
Pain	92691	942	15472	11680	77219	22	200
Papillitis	12	1	3	2	9		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Paradoxical drug reaction	4		2		2		
Pelvic mass	2		2				
Perforated ulcer	2	1	2				
Perforation	7		5		2		
Performance status decreased	1072	90	257	396	815		2
Peripheral swelling	17696	303	5070	1565	12626	11	67
Phantom shocks	2		1		1		
Physical deconditioning	754	20	196	69	558		
Pneumatosis	5	1	4		1		
Polyp	57	7	34	5	23	1	2
Polyserositis	51	9	51				
Potentiating drug interaction	35		3		32		
Precancerous condition	2	2	2				2
Pre-existing condition improved	116		7	9	109		1
Pre-existing disease	37		1		36		
Premature ageing	4	1	2		2		
Premature baby death	6	2	6				
Product intolerance	13	3	4	4	9		
Prolapse	12		2		10		1
Prosthetic cardiac valve thrombosis	3		3				
Pseudoallergic reaction	11	1	4	3	7		
Pseudoangina	1		1				
Pseudocyst	4		1		3		
Pseudohernia	1				1		
Pseudopolyp	1		1				
Puncture site bruise	28		10		18		
Puncture site discharge	1		1				

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Puncture site erythema	11				11		
Puncture site haematoma	3		3				
Puncture site haemorrhage	5		1	1	4		
Puncture site induration	17			1	17		
Puncture site oedema	17		1		16		
Puncture site pain	134	3	6	2	128		
Puncture site pruritus	6				6		
Puncture site reaction	7				7		
Puncture site swelling	11		1	1	10		
Pyrexia	257556	2047	31524	27709	226032	38	587
Radiation interaction	1				1		
Rebound effect	2		1		1		
Renin-angiotensin system inhibition	1				1		
Retention cyst	4	1	2	1	2		
Scar inflammation	25		3	4	22		
Screaming	106	1	34	9	72		
Secretion discharge	365	4	89	53	276		1
Sensation of blood flow	71	1	18	6	53		
Sensation of foreign body	1670	35	516	107	1154		
Sense of oppression	377	8	89	45	288		2
Sensitivity to weather change	32		6	3	26		
Serositis	22	2	12	3	10		
Shoulder injury related to vaccine administration	376	29	196	43	180		
Sick building syndrome	1		1				
Sluggishness	686	5	80	163	606		
Soft tissue inflammation	22	1	5	2	17		
Stenosis	62	6	38	5	24		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Stent-graft endoleak	5		5				
Steroid dependence	2		1		1		
Strangulated hernia	1		1				
Sudden cardiac death	115	9	115				
Sudden death	743	48	743				2
Sudden infant death syndrome	7		7				
Sudden unexplained death in epilepsy	1		1				
Supraclavicular fossa pain	22			12	22		
Suprapubic pain	14		6	1	8		
Surgical failure	1	1	1				
Swelling	18943	172	3798	1744	15145	3	26
Swelling face	7341	128	2082	586	5259		13
Symptom masked	1				1		
Symptom recurrence	96	8	40	14	56		
Systemic inflammatory response syndrome	146	9	146				1
Systemic leakage	1		1				
Temperature intolerance	273	9	92	28	181		1
Temperature regulation disorder	724	9	83	52	641		1
Tenderness	3780	21	502	987	3278	1	15
Terminal agitation	1		1				
Terminal state	12		12				3
Therapeutic product effect decreased	53	2	10	9	43	4	17
Therapeutic product effect delayed	6		2	1	4		1
Therapeutic product effect incomplete	7	1	4		3	2	5
Therapeutic product effect increased	4		1		3		
Therapeutic product effect prolonged	2		1		1		
Therapeutic product effect variable	1				1		

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Therapeutic product ineffective	6		3		3		1
Therapeutic response changed	5				5		
Therapeutic response decreased	13		4	1	9		3
Therapeutic response delayed	1		1				
Therapeutic response increased	1				1		
Therapeutic response shortened	4		1	1	3		3
Therapeutic response unexpected	2199	5	52	195	2147		
Therapy non-responder	7	1	4	1	3		1
Therapy partial responder	77				77		
Therapy responder	1				1		
Thirst	2157	15	462	158	1695	1	4
Thirst decreased	48	2	12	7	36		
Tissue discolouration	4	1	1	1	3		
Tissue infiltration	11	2	3	2	8		
Tissue irritation	4	1	1		3		
Tissue rupture	3		2		1		
Treatment failure	7	1	4	2	3		
Treatment noncompliance	3		2	1	1		1
Ulcer	177	4	60	15	117		
Ulcer haemorrhage	14	1	14				
Unevaluable event	286	9	22	45	264	1	4
Unmasking of previously unidentified disease	10	2	8		2		
Vaccination failure	64064	26236	64062		2	63	441
Vaccination site abscess sterile	9	1	5	2	4		
Vaccination site anaesthesia	19	1	5	2	14		
Vaccination site atrophy	27		6	4	21		
Vaccination site bruising	1874	11	274	220	1600	3	12

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vaccination site calcification	4		2		2		
Vaccination site coldness	85		8	10	77		
Vaccination site cyst	22	1	4	2	18		
Vaccination site dermatitis	38		8	1	30		
Vaccination site discharge	52	1	7	6	45		1
Vaccination site discolouration	471		52	49	419	1	3
Vaccination site discomfort	2492	9	155	177	2337		4
Vaccination site dryness	24		2		22		
Vaccination site dysaesthesia	63	1	9	3	54		
Vaccination site eczema	71	1	5	13	66		
Vaccination site erosion	11			2	11		
Vaccination site erythema	34429	92	1784	6789	32645	1	17
Vaccination site eschar	1				1		
Vaccination site exfoliation	14		1	2	13		
Vaccination site extravasation	79	1	9	4	70		
Vaccination site fibrosis	3		2		1		
Vaccination site granuloma	29	1	5	7	24		
Vaccination site haematoma	4603	7	119	188	4484		1
Vaccination site haemorrhage	765	5	139	85	626	1	5
Vaccination site hyperaesthesia	156		29	22	127		
Vaccination site hypersensitivity	329		22	25	307		
Vaccination site hypertrichosis	1			1	1		
Vaccination site hypertrophy	11		2	2	9		
Vaccination site hypoaesthesia	826	4	169	57	657		1
Vaccination site induration	3437	11	237	490	3200		1
Vaccination site inflammation	16754	4	296	639	16458		4
Vaccination site injury	151	2	14	11	137		1

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vaccination site irritation	170	1	26	16	144		1
Vaccination site ischaemia	3		3				
Vaccination site joint discomfort	34		7	3	27		
Vaccination site joint effusion	5	1	2		3		
Vaccination site joint erythema	253		19	15	234		
Vaccination site joint inflammation	55	1	12	1	43		
Vaccination site joint movement impairment	678	9	118	28	560		1
Vaccination site joint pain	705	5	85	32	620		
Vaccination site joint swelling	239		11	13	228		
Vaccination site joint warmth	20		3	1	17		
Vaccination site laceration	1				1		
Vaccination site lymphadenopathy	6688	18	178	1249	6510		1
Vaccination site macule	50		1	9	49		
Vaccination site mass	2689	15	606	151	2083		3
Vaccination site movement impairment	2869	28	533	218	2336		
Vaccination site necrosis	31	5	31				
Vaccination site nerve damage	45	1	16	1	29		1
Vaccination site nodule	295	2	27	33	268		
Vaccination site oedema	4142	15	306	743	3836		2
Vaccination site pain	216866	512	9915	26591	206951	48	369
Vaccination site pallor	10		3		7		
Vaccination site papule	87		5	6	82		
Vaccination site paraesthesia	1131	10	177	104	954		4
Vaccination site phlebitis	5		1		4		
Vaccination site photosensitivity reaction	7		1		6		
Vaccination site plaque	43	1	5	4	38		
Vaccination site pruritus	14617	35	770	4606	13847		7

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vaccination site rash	2681	11	394	245	2287		3
Vaccination site reaction	19788	361	2449	3264	17339		6
Vaccination site recall reaction	7				7		
Vaccination site scab	58	2	9	3	49		
Vaccination site scar	74	2	8	14	66		
Vaccination site streaking	6		1		5		
Vaccination site swelling	47594	114	1988	7569	45606	13	99
Vaccination site thrombosis	16	1	16			1	1
Vaccination site ulcer	27		6	7	21		
Vaccination site urticaria	743	4	123	27	620		2
Vaccination site vasculitis	3		1		2		
Vaccination site vesicles	297	1	50	28	247		1
Vaccination site warmth	17077	28	709	1242	16368	1	4
Vaccine positive rechallenge	5		1		4		
Vascular stent occlusion	4	1	4				
Vascular stent stenosis	8	2	8				
Vascular stent thrombosis	18	2	18				
Vessel puncture site bruise	3				3		
Vessel puncture site erythema	2				2		
Vessel puncture site haematoma	5			1	5		
Vessel puncture site haemorrhage	4		1	1	3		
Vessel puncture site inflammation	1				1		
Vessel puncture site injury	4				4		
Vessel puncture site pain	1				1		
Vessel puncture site reaction	1		1				
Vessel puncture site swelling	2				2		
Visceral oedema	3		3				

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System Organ Class

General disorders and administration site conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Visceral pain	17		3	4	14		
Withdrawal syndrome	60		26	4	34		
Xerosis	17	1	6	3	11	1	1
Total:	1865978	72768	376696	186209	1489282	1640	6988

System Organ Class

Hepatobiliary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acute hepatic failure	47	7	47				
Acute on chronic liver failure	1	1	1				
Alcoholic liver disease	1		1				
Allergic hepatitis	4	1	4				
Alloimmune hepatitis	3	1	3				
Autoimmune cholangitis	1		1				
Autoimmune hepatitis	256	65	256				
Bile duct stenosis	3		3				
Bile duct stone	17	1	17				
Biliary cirrhosis	2		2				
Biliary colic	116	1	53	10	63		2
Biliary cyst	14	1	4	2	10		
Biliary dilatation	17	2	17				
Biliary fistula	1		1				
Biliary obstruction	1		1				
Biliary tract disorder	11	3	8		3		
Budd-Chiari syndrome	7	1	7				
Cardiac cirrhosis	5		5				

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System Organ Class

Hepatobiliary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cholangitis	46	6	46				
Cholangitis acute	10	1	10				
Cholangitis chronic	1	1	1				
Cholangitis sclerosing	11	5	11				1
Cholecystitis	119	17	119				3
Cholecystitis acute	35	3	35				
Cholecystitis chronic	1		1				
Cholecystocholangitis	1		1				
Cholelithiasis	229	16	113	17	116	1	5
Cholestasis	137	15	137				2
Cholestasis of pregnancy	4	1	4			1	2
Cholestatic liver injury	11		11				
Chronic hepatic failure	2		2				
Chronic hepatitis	6	2	6				
Cirrhosis alcoholic	3		3				
Congestive hepatopathy	23	1	23				
Deficiency of bile secretion	5		3	2	2		
Drug-induced liver injury	75	18	75				
Fatty liver alcoholic	1		1				
Gallbladder cholesterolosis	1		1				
Gallbladder disorder	68	2	33	5	35	5	8
Gallbladder enlargement	15		15				
Gallbladder hypofunction	1		1				
Gallbladder obstruction	1		1				
Gallbladder oedema	10	1	10				
Gallbladder polyp	9		3	1	6		
Gallbladder rupture	1		1				

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System Organ Class

Hepatobiliary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Granulomatous liver disease	3		3				
Hepatic artery embolism	1		1				
Hepatic artery stenosis	1		1				
Hepatic artery thrombosis	6		6				
Hepatic atrophy	3	1	3				
Hepatic calcification	2			1	2		
Hepatic cirrhosis	65	13	65				1
Hepatic cyst	63	2	22	4	41		1
Hepatic cytolysis	266	24	266				
Hepatic failure	113	8	113				3
Hepatic fibrosis	10	2	10				
Hepatic function abnormal	432	19	252	23	180		1
Hepatic haematoma	2	1	2				
Hepatic haemorrhage	9		9				
Hepatic hypertrophy	2				2		
Hepatic infarction	18	4	18				
Hepatic ischaemia	2	1	2				
Hepatic lesion	27		17	3	10		
Hepatic mass	21	1	8	2	13		
Hepatic necrosis	6		6				
Hepatic pain	288	2	75	33	213		
Hepatic perfusion disorder	2		2				
Hepatic steatosis	196	16	84	16	112		2
Hepatic vascular disorder	1		1				
Hepatic vascular thrombosis	2		2				1
Hepatic vein dilatation	1		1				
Hepatic vein occlusion	1		1				

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System Organ Class

Hepatobiliary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hepatic vein thrombosis	12	1	12				
Hepatitis	303	42	303				1
Hepatitis acute	131	17	131			1	1
Hepatitis alcoholic	2		2				
Hepatitis cholestatic	34	2	34				
Hepatitis chronic active	1		1				
Hepatitis fulminant	12	2	12				
Hepatitis neonatal	1		1				
Hepatitis toxic	18	2	18				
Hepatobiliary cyst	2				2		
Hepatobiliary disease	1				1		
Hepatocellular injury	30	1	30				
Hepatomegaly	158	15	78	14	80		1
Hepatorenal failure	4	1	4				
Hepatorenal syndrome	9	2	9				1
Hepatosplenomegaly	41	5	22	2	19		
Hepatotoxicity	11	4	11			1	1
Hydrocholecystis	7	1	7				
Hyperbilirubinaemia	55	5	55				
Hyperbilirubinaemia neonatal	2		2				
Hypertransaminasaemia	76	2	48	3	28		2
Immune-mediated cholangitis	1		1				
Immune-mediated hepatic disorder	2		2				1
Immune-mediated hepatitis	3		3				
Ischaemic hepatitis	11		11				
Jaundice	388	22	232	26	156	1	3
Jaundice cholestatic	22	2	22				

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System Organ Class

Hepatobiliary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Jaundice hepatocellular	1		1				
Liver disorder	377	24	205	27	172		2
Liver injury	125	20	125				3
Liver sarcoidosis	2		2				
Liver tenderness	8	1	4		4		
Mixed liver injury	19	2	19				
Neonatal hepatomegaly	1		1				
Nodular regenerative hyperplasia	1		1				
Non-alcoholic fatty liver	4		2		2		
Non-alcoholic steatohepatitis	3		3				
Non-cirrhotic portal hypertension	1		1				
Ocular icterus	68	1	30	2	38		
Peliosis hepatis	1		1				
Perihepatic discomfort	4			2	4		
Periportal oedema	4	1	4				
Pneumobilia	1		1				
Portal hypertension	12	3	12				
Portal vein dilatation	3		3				
Portal vein embolism	2		2				
Portal vein occlusion	4		4				
Portal vein phlebitis	3		3				
Portal vein thrombosis	189	18	189				3
Portosplenomesenteric venous thrombosis	18	1	18				
Primary biliary cholangitis	26	5	18	3	8		
Sphincter of Oddi dysfunction	4	2	4				
Steatohepatitis	2	1	2				
Subacute hepatic failure	2		2				

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System Organ Class

Hepatobiliary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Subcapsular hepatic haematoma	2	1	2				
Venoocclusive liver disease	2		2				
Total:	5102	473	3780	198	1322	10	51

System Organ Class

Immune system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acute graft versus host disease	1	1	1				
Allergic oedema	55	2	32	1	23		
Allergic reaction to excipient	73	2	39	1	34		
Allergy to animal	53	1	18	8	35		
Allergy to arthropod bite	59		14	4	45		
Allergy to arthropod sting	71	3	21	5	50		
Allergy to chemicals	46	1	16	5	30		2
Allergy to fermented products	1		1				
Allergy to metals	17		3	6	14		
Allergy to plants	5		1		4		
Allergy to sting	6				6		
Allergy to synthetic fabric	1				1		
Allergy to vaccine	775	8	333	39	442	2	9
Amyloidosis	19	5	19				
Amyloidosis senile	3		1		2		
Anamnestic reaction	13		4	2	9		
Anaphylactic reaction	7650	317	7650			4	23
Anaphylactic shock	1335	125	1335			2	14
Anaphylactoid reaction	210	9	210				1

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System Organ Class

Immune system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Anaphylactoid shock	9	1	9				
Anti-neutrophil cytoplasmic antibody positive vasculitis	77	34	77				
ASIA syndrome	8	4	8				
Atopy	38	2	7	7	31		
Atrophic thyroiditis	2	1	2				
Autoimmune disorder	845	250	845			4	10
Autoimmune endocrine disorder	1	1	1				
Autoinflammatory disease	24	5	16	2	8		
Bacille Calmette-Guerin scar reactivation	138		20	7	118		
Caffeine allergy	4	1	1	1	3		
Cell-mediated immune deficiency	4	1	4				
Chronic graft versus host disease	12		12				
Contrast media allergy	8	1	5		3		
Contrast media reaction	2		2				1
Corneal graft rejection	34	2	34				
Cross sensitivity reaction	8	1	2	1	6		
Cytokine release syndrome	14	3	14				
Cytokine storm	37	3	37				
Decreased immune responsiveness	199	34	76	30	123	1	3
Device allergy	1				1		
Drug hypersensitivity	483	12	192	29	291	5	15
Dust allergy	13	1	5	2	8		
Eosinophilic granulomatosis with polyangiitis	39	8	39				
Food allergy	361	8	126	46	235	2	5
Graft versus host disease	8		8				
Graft versus host disease in eye	1		1				
Haemophagocytic lymphohistiocytosis	109	15	109				2

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System Organ Class

Immune system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hashitoxicosis	2		2				
Heart transplant rejection	3		3				
Human seminal plasma hypersensitivity	1				1		
Humoral immune defect	2		2				
Hypersensitivity	10747	213	3897	921	6850	2	54
Hypocomplementaemia	3		1		2		
Hypogammaglobulinaemia	60	6	60				
Immune-mediated adverse reaction	47	2	30	1	17		
Immune reconstitution inflammatory syndrome	8	1	8				
Immune system disorder	948	63	327	172	621	4	7
Immunisation reaction	9279	63	554	1360	8725	6	28
Immunodeficiency	201	59	201			8	25
Immunodeficiency common variable	4		4			1	1
Immunosuppression	45	7	43	2	2		6
Infusion related hypersensitivity reaction	4		1		3		
Iodine allergy	1				1		2
Jarisch-Herxheimer reaction	2				2		
Kidney transplant rejection	8		8				
Liver transplant rejection	7	4	7				
Loefgren syndrome	15	1	15			1	3
Lung transplant rejection	3		3				
Milk allergy	21		6	5	15		
Mite allergy	44	1	11	4	33		
Multiple allergies	84	10	35	20	49		1
Multisystem inflammatory syndrome	68	17	68				
Multisystem inflammatory syndrome in adults	27	7	27				
Multisystem inflammatory syndrome in children	88	12	88				

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System Organ Class

Immune system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mycotic allergy	5			2	5		
Oral allergy syndrome	16		9	1	7		1
Overlap syndrome	11	6	8	1	3		
Perfume sensitivity	14		8	3	6		
Polymers allergy	22		9	4	13		
Primary amyloidosis	2	1	2				
Reaction to azo-dyes	1		1				
Reaction to colouring	3		2		1		
Reaction to excipient	118	2	73	6	45		
Reaction to food additive	2		1		1		
Reaction to preservatives	19	1	10	1	9	1	3
Reaction to sweetener	2			1	2		
Rubber sensitivity	9		3	1	6		
Sarcoidosis	256	50	256			2	7
Seasonal allergy	563	6	124	56	439		4
Selective IgA immunodeficiency	4		2		2		
Selective IgG subclass deficiency	2	1	2				
Sensitisation	69	2	17	7	52		
Serum sickness	36	2	21		15		
Serum sickness-like reaction	13	1	9		4		
Smoke sensitivity	6		1	3	5		
Solid organ transplant rejection	1		1				
Sunscreen sensitivity	1		1				
Systemic immune activation	9		9				
Transplant rejection	30	3	30				
Type I hypersensitivity	210	5	210			1	2
Type II hypersensitivity	4		4				

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System Organ Class

Immune system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Type III immune complex mediated reaction	30	5	30				
Type IV hypersensitivity reaction	127	1	40	4	87		1
Vaccine associated enhanced disease	26	4	26				
Vaccine associated enhanced respiratory disease	14	5	14				
Total:	36219	1423	17674	2771	18545	46	230

System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdominal abscess	14		14				
Abdominal infection	21	2	21				
Abdominal sepsis	5		5				
Abdominal wall abscess	3		3				
Abortion infected	1		1				
Abscess	278	15	112	28	166		5
Abscess bacterial	6	1	5		1		
Abscess fungal	2	1	2				
Abscess intestinal	7		7				1
Abscess jaw	4		4				
Abscess limb	68	6	35	10	33		1
Abscess neck	14	4	12		2		
Abscess of external auditory meatus	1		1				
Abscess of eyelid	6		2	3	4		
Abscess of salivary gland	3		3				
Abscess oral	25		9	2	16		
Abscess rupture	3		2		1		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abscess soft tissue	3	2	2		1		
Abscess sweat gland	3	1	1	1	2		
Acanthamoeba keratitis	2		2				
Acariasis	4		2	2	2		
Acarodermatitis	40	4	17	4	23		
Achromobacter infection	1		1				
Acinetobacter bacteraemia	1		1				
Acinetobacter infection	2		2				
Acne pustular	16	1	4	2	12		
Acquired immunodeficiency syndrome	16	11	16				
Acrodermatitis chronica atrophicans	1				1		
Actinomycosis	1		1				
Acute endocarditis	2		2				
Acute haemorrhagic conjunctivitis	2		1		1		
Acute hepatitis B	1		1				
Acute hepatitis C	1	1	1				
Acute HIV infection	1		1				
Acute sinusitis	54	2	20	9	34		
Adenopathy syphilitic	4		4				
Adenoviral conjunctivitis	4	1	2		2		
Adenovirus infection	5		2		3		
Adenovirus reactivation	1		1				
Administration site abscess	1				1		
Administration site cellulitis	2				2		
Adrenalitis	1		1				
Aerococcus urinae infection	3		2		1		
African trypanosomiasis	9	1	9				1

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Allergic bronchopulmonary mycosis	1		1				
Alpha haemolytic streptococcal infection	1	1	1				
Alveolar osteitis	4		2		2		
Amniotic cavity infection	19	3	19				1
Amoebiasis	4		3		1		
Amoebic dysentery	1	1	1				
Anal abscess	29	2	29				1
Anal candidiasis	3		1		2		
Anal fungal infection	1				1		
Anal infection	2				2		
Anisakiasis	1	1	1				
Anorectal infection	1		1				
Appendiceal abscess	4		4				
Appendicitis	693	30	693			3	20
Appendicitis perforated	75	3	75				2
Application site abscess	1				1		
Application site pustules	2		1		1		
Arboviral infection	1		1				
Arteriosclerotic gangrene	1		1				
Arthritis bacterial	30	4	30				
Arthritis gonococcal	1		1				
Arthritis infective	27	2	27				4
Arthritis viral	3		1		2		
Arthropod infestation	1		1				
Aspergillus infection	9	1	8		1		
Asymptomatic bacteriuria	6		3		3		
Asymptomatic COVID-19	1926	59	1843	3	83	3	55

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Atypical mycobacterial infection	6	2	6				
Atypical pneumonia	79	30	79				3
Babesiosis	2		2				
Bacillus infection	1		1				
Bacteraemia	50	4	50				2
Bacterial blepharitis	1			1	1		
Bacterial colitis	2		2				
Bacterial diarrhoea	4		4				
Bacterial disease carrier	5		4	1	1		
Bacterial infection	196	11	108	10	88		2
Bacterial parotitis	1		1				
Bacterial pericarditis	2		2				
Bacterial prostatitis	5	1	5				
Bacterial pyelonephritis	3	1	3				
Bacterial rhinitis	1		1				
Bacterial sepsis	18	1	18				
Bacterial translocation	2		2				
Bacterial vaginosis	58	3	11	11	47		
Bacteriuria	10		4	3	6		
Bacteroides bacteraemia	2		2				
Balanitis candida	2		2				
Bartholinitis	14	1	5	3	9		
Bartholin's abscess	7		4	1	3		
Bed bug infestation	2		1		1		
Beta haemolytic streptococcal infection	19	2	19				1
Biliary sepsis	5		5				
Biliary tract infection	3		3				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blastocystis infection	2		2				
Blister infected	26		7	1	19		1
Body tinea	13		1	1	12		
Bone abscess	3		3				
Bone tuberculosis	3		2	1	1		
Borrelia infection	41	8	41				1
Brain abscess	13	2	13				
Brain empyema	1		1				
Breakthrough COVID-19	137	78	131	4	6	1	2
Breast abscess	49	4	29	2	20	1	2
Breast cellulitis	3		3			1	1
Breast discharge infected	4	2	4				
Bronchiolitis	26	2	26			1	3
Bronchitis	900	35	286	96	614	3	12
Bronchitis bacterial	19	2	19				
Bronchitis viral	9		4		5		
Bronchopulmonary aspergillosis	9	4	9				
Bronchopulmonary aspergillosis allergic	1	1	1				
Brucellosis	1		1				
Bullous erysipelas	1	1	1				
Bullous impetigo	5		2		3		
Bursitis infective	4		4				
Campylobacter colitis	1		1				
Campylobacter gastroenteritis	15	3	15				
Campylobacter infection	15	1	8	2	7		
Candida endophthalmitis	1	1	1				
Candida infection	183	4	60	10	123		2

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Candida sepsis	3		3				
Capnocytophaga infection						1	1
Capnocytophaga sepsis	1		1				
Carbuncle	5		1	2	4	1	1
Cardiac infection	85	2	85				
Cardiac valve abscess	1		1				
Cardiac valve vegetation	6		6				
Catheter site infection	2		2				
Cat scratch disease	4		2	1	2		
Cavernous sinus thrombosis	8	3	8				
Cellulitis	805	59	805			2	23
Cellulitis gangrenous	2		2				
Cellulitis orbital	6	1	6				
Cellulitis pasteurella	1		1				
Cellulitis staphylococcal	4		4				
Central nervous system fungal infection	1		1				
Central nervous system infection	12		12				
Central nervous system viral infection	2		2				
Cerebral fungal infection	1		1				
Cervicitis	5		2	2	3		
Cestode infection	1		1				
Chikungunya virus infection	1	1	1				
Chlamydial infection	15	5	15				
Cholecystitis infective	22	3	22				
Chorioretinitis	30	9	30				
Chronic active Epstein-Barr virus infection	3		3				
Chronic hepatitis B	1	1	1				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Chronic hepatitis C	1		1				
Chronic sinusitis	62	5	16	18	46		
Chronic tonsillitis	8	5	8				1
Citrobacter infection	3		3				
Clostridial infection	6	2	6				
Clostridial sepsis	1	1	1				
Clostridium colitis	2	1	2				
Clostridium difficile colitis	27	5	27				1
Clostridium difficile infection	34	5	34				5
CNS ventriculitis	2		2				
Coccidioidomycosis	6	2	6				
Colon gangrene	3		3				
Community acquired infection	2		2				
Complicated appendicitis	20		20				
Conjunctivitis	1047	15	194	93	853		1
Conjunctivitis bacterial	21		16	1	5		
Conjunctivitis viral	13		3	1	10		
Corneal abscess	2		2				
Corneal infection	2		2				1
Coronavirus infection	60	2	34	2	26	2	5
Coronavirus pneumonia	10		10				
COVID-19	128313	53226	124808	205	3505	1025	2224
COVID-19 pneumonia	1793	178	1793			3	35
Cow pox	3		3				
Coxsackie viral infection	11	1	5	1	6		
Cranial nerve infection	5	2	5				
Creutzfeldt-Jakob disease	53	11	53				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Croup infectious	20	4	20				
Cryptococcal meningoencephalitis	1		1				
Cryptococcosis	1	1	1				
Cryptosporidiosis infection	2		1		1		
Cutaneous mucormycosis	1		1				
Cutaneous tuberculosis	1	1	1				
Cystitis	769	17	209	67	560	3	8
Cystitis bacterial	13	3	11		2		
Cystitis escherichia	9		4		5		1
Cystitis klebsiella	2		2				
Cystitis viral	1		1				
Cytomegalovirus chorioretinitis	3	2	3				
Cytomegalovirus colitis	1		1				
Cytomegalovirus enterocolitis	3	2	3				
Cytomegalovirus hepatitis	11	1	11				
Cytomegalovirus infection	78	18	78				
Cytomegalovirus infection reactivation	30	1	30				
Cytomegalovirus mononucleosis	2		2				
Cytomegalovirus pericarditis	1		1				
Cytomegalovirus syndrome	1		1				
Cytomegalovirus viraemia	9	1	9				
Dacryocanaliculitis	2		2				
Dacryocystitis	4		4				
Demodicidosis	4		2		2		
Dengue fever	42	13	20	8	22		
Dengue haemorrhagic fever	1		1				
Dental fistula	2		2				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dermatitis infected	24		16		8		
Dermatophytosis	6		1	2	5		
Dermatophytosis of nail	4				4		
Dermo-hypodermitis	24		24				
Device related infection	23	2	23				1
Device related sepsis	1		1				
Diabetic foot infection	2				2		
Diabetic gangrene	2	1	2				
Diarrhoea infectious	9	1	7	1	2		
Dientamoeba infection	3			1	3		
Diphtheria	3	1	3				
Disseminated Bacillus Calmette-Guerin infection	36	1	36				
Disseminated tuberculosis	3	1	3				
Disseminated varicella	1		1				
Disseminated varicella zoster vaccine virus infection	1		1				
Disseminated varicella zoster virus infection	8		8				
Diverticulitis	278	16	278			5	12
Diverticulitis intestinal haemorrhagic	5	1	5				
Diverticulitis intestinal perforated	4	1	4				
Douglas' abscess	1		1				
Dysentery	379	4	379				15
Ear infection	618	6	187	52	431	3	7
Ear infection bacterial	5		4	1	1		
Ear infection fungal	4		1		3		
Ear infection viral	5		1	3	4		
Ear lobe infection	3			1	3		
Ear, nose and throat infection	13		1	5	12		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ebola disease	1		1				
Echo virus infection	1		1				
Ecthyma	2				2		
Eczema herpeticum	19	2	19				
Eczema impetiginous	5	2	4		1		
Eczema infected	16	2	7	2	9		
Elsberg syndrome	2	2	2				
Embolic pneumonia	1		1				
Empyema	10	1	10				1
Encephalitis	424	65	424				
Encephalitis brain stem	17	2	17				
Encephalitis california	1		1				
Encephalitis enteroviral	1		1				
Encephalitis lethargica	1		1				
Encephalitis meningococcal	2		2				
Encephalitis viral	32	4	32				
Encephalomyelitis	42	12	42				
Encephalomyelitis viral	1		1				
Endocarditis	149	24	149				3
Endocarditis bacterial	8	2	8				
Endocarditis haemophilus	1		1				
Endocarditis staphylococcal	3		3				
Endometritis	17	1	17				
Endometritis decidual	1		1				
Endophthalmitis	3		3				
Endotoxic shock	1		1				
Enteritis infectious	14		14				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Enterobacter bacteraemia	1		1				
Enterobacter infection	7	1	7				
Enterobacter sepsis	1		1				
Enterobiasis	4			2	4		
Enterococcal bacteraemia	1		1				
Enterococcal infection	21	2	21				
Enterococcal sepsis	2	1	2				
Enterocolitis infectious	1		1				
Enterocolitis viral	1		1				
Enterovirus infection	5	1	5				
Enterovirus myocarditis	1	1	1				
Epidemic polyarthritis	1				1		
Epididymitis	88	11	88				2
Epiglottitis	18		18				
Epstein-Barr viraemia	14	2	4		10		
Epstein-Barr virus infection	169	19	81	20	88		1
Epstein-Barr virus infection reactivation	181	45	181			1	1
Erysipelas	442	91	442				5
Erysipeloid	3		2		1		
Erythema induratum	11	1	11				1
Erythema infectiosum	2			1	2		
Erythema migrans	21	2	7	1	14		
Erythrasma	3		3				
Escherichia bacteraemia	14		14				
Escherichia infection	35	2	28	4	7		
Escherichia pyelonephritis	5		5				
Escherichia sepsis	17	3	17				2

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Escherichia urinary tract infection	52		44	2	8		
Exanthema subitum	3				3		
External ear cellulitis	3		3				1
Extradural abscess	4	2	4				1
Extrapulmonary tuberculosis	2	2	2				
Eye abscess	7	1	7				
Eye infection	212	5	61	28	151		
Eye infection bacterial	7	1	4	1	3		
Eye infection intraocular	2		2				
Eye infection staphylococcal							1
Eye infection toxoplasmal	3	1	3				
Eye infection viral	7		1		6		1
Eyelid boil	3		2	1	1		
Eyelid folliculitis	1				1		
Eyelid infection	26	1	5		21		
Fallopian tube abscess	1		1				
Fascial infection	1		1				
Fasciolopsiasis	2		2				
Febrile infection	26	2	15	2	11		
Focal peritonitis	4		4				
Folliculitis	131	2	39	16	92		1
Foot and mouth disease	2				2		
Fournier's gangrene	2		2				
Fungaemia	3		3				
Fungal balanitis	1				1		
Fungal disease carrier	2				2		
Fungal foot infection	11			5	11		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Fungal infection	263	7	47	33	216	4	6
Fungal oesophagitis	1		1				
Fungal peritonitis	1		1				
Fungal rhinitis							1
Fungal skin infection	57	3	14	5	43		2
Funguria	1		1				
Funisitis	5		5				
Furuncle	266	10	68	23	198		3
Gangrene	34	9	34				
Gas gangrene	1		1				
Gastric infection	10		9	1	1		1
Gastric ulcer helicobacter	1		1				
Gastritis bacterial	3		3				
Gastritis herpes	1		1				
Gastroenteritis	498	21	172	30	326		4
Gastroenteritis adenovirus	1		1				
Gastroenteritis bacterial	6		5		1		
Gastroenteritis clostridial	1	1	1				
Gastroenteritis cryptosporidial	1	1	1				
Gastroenteritis Escherichia coli	3		3				
Gastroenteritis norovirus	3		3				
Gastroenteritis rotavirus	2		2				
Gastroenteritis salmonella	2	1	2				
Gastroenteritis viral	147	4	46	21	101		1
Gastrointestinal bacterial infection	3		1	1	2		
Gastrointestinal bacterial overgrowth	9		5	3	4		
Gastrointestinal candidiasis	4		4				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Gastrointestinal fungal infection	4	1	4				1
Gastrointestinal infection	47	4	22	6	25		1
Gastrointestinal viral infection	7		5		2		
Genital abscess	12	2	12				
Genital candidiasis	5	2	3		2		
Genital herpes	481	7	135	44	346		2
Genital herpes simplex	28		7	2	21		
Genital herpes zoster	39		18	4	21		
Genital infection	6	1	3	1	3		
Genital infection bacterial	2	1	1	1	1		
Genital infection female	8	2	2	1	6		
Genital infection fungal	30		3	18	27		
Genital infection male	1			1	1		
Genital infection viral	3		2		1		
Genital ulcer syndrome	2				2		
Genitourinary chlamydia infection	1	1	1				
Genitourinary tract infection	5	1	3		2		
Gianotti-Crosti syndrome	10		3	1	7		
Gingival abscess	16		6	1	10		
Gingivitis	297	10	53	27	244		
Gonorrhoea	3		3				
Groin abscess	12	1	12				
Groin infection	4		2		2		
H1N1 influenza	1				1		
H3N2 influenza	2				2		
Haematological infection	8		7	1	1		
Haematoma infection	4	1	4				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Haemophilus infection	7	2	7				
Haemorrhagic fever with renal syndrome	1		1				
Haemorrhagic pneumonia	4		4				
Haemorrhagic varicella syndrome	1		1				
Haemorrhoid infection	2		1		1		
Hand-foot-and-mouth disease	17	1	3	1	14		1
Hantaviral infection	1	1	1				
Helicobacter gastritis	10	3	5	2	5		
Helicobacter infection	40	2	22	4	18		1
Helminthic infection	6	2	6				
Hepatic cyst infection	2		2				
Hepatic infection	3	1	3				
Hepatitis A	9	1	4	1	5		
Hepatitis B	16	2	16				
Hepatitis B reactivation	4	1	4				
Hepatitis C	16	1	16				
Hepatitis D	1		1				
Hepatitis E	17	2	17				
Hepatitis infectious mononucleosis	8	1	8				
Hepatitis viral	14		14				
Herpangina	5	1	2		3		
Herpes dermatitis	50	1	20	6	30		
Herpes ophthalmic	200	32	200				
Herpes pharyngitis	6	1	6				
Herpes sepsis	2		2				
Herpes simplex	669	11	119	56	550		2
Herpes simplex encephalitis	18	2	18				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Herpes simplex gastritis	1		1				
Herpes simplex hepatitis	3		3				
Herpes simplex meningitis	4	1	4				
Herpes simplex meningoencephalitis	4		4				
Herpes simplex otitis externa	2				2		
Herpes simplex pharyngitis	1		1				
Herpes simplex reactivation	102	1	19	14	83		
Herpes simplex viraemia	1		1				
Herpes virus infection	823	21	135	145	688	1	3
Herpes zoster	20948	373	4625	1819	16323	5	37
Herpes zoster cutaneous disseminated	44	4	44				
Herpes zoster disseminated	25	2	25				
Herpes zoster infection neurological	29	5	29				
Herpes zoster meningitis	59	6	59				
Herpes zoster meningoencephalitis	27	1	27				1
Herpes zoster meningomyelitis	2	1	2				
Herpes zoster meningoradiculitis	6		6				
Herpes zoster necrotising retinopathy	1		1				
Herpes zoster oticus	223	25	223			1	3
Herpes zoster pharyngitis	4	2	4				
Herpes zoster reactivation	218	14	79	17	139		
Herpetic radiculopathy	3	1	1		2		
HIV infection	13	5	13				
HIV peripheral neuropathy	1		1				
Hookworm infection	2		2				
Hordeolum	226	3	50	21	176	1	1
HTLV-1 carrier	1		1				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Human ehrlichiosis	1		1				
Human herpesvirus 6 encephalitis	1		1				
Human herpesvirus 6 infection	7		6		1		
Human herpesvirus 6 infection reactivation	4	1	3	1	1		
Human herpesvirus 7 infection	1		1				
Human herpesvirus 8 infection	1	1	1				
Hypopyon	1		1				
Iatrogenic infection	2				2		
Ileal gangrene	2		2				
Immune reconstitution inflammatory syndrome associated tul	1		1				
Impetigo	78	1	27	3	51		
Implant site infection	2		2				
Incision site abscess	1		1				
Indeterminate leprosy	1		1				
Infected bite	12		8		4		
Infected bunion	1		1				
Infected cyst	14		11	1	3		
Infected dermal cyst	7		3	1	4		
Infected fistula	1		1				
Infected lymphocele	2		2				
Infected seroma	3		3				
Infected skin ulcer	9		8	1	1		
Infected vasculitis	1		1				
Infection	1322	51	682	117	640	4	21
Infection in an immunocompromised host	7		7				
Infection parasitic	13		3	3	10		
Infection protozoal	1		1				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Infection reactivation	24	3	11	2	13		
Infection susceptibility increased	341	45	107	105	234	2	5
Infection via vaccinee	1		1				
Infectious disease carrier	3		1		2		
Infectious mononucleosis	267	18	110	32	157		1
Infectious pleural effusion	19	3	19				
Infectious thyroiditis	13		3	2	10		
Infective aneurysm	1		1				
Infective chondritis	1		1				
Infective exacerbation of bronchiectasis	2		2				
Infective exacerbation of chronic obstructive airways disease	8		8				
Infective glossitis	6				6		
Infective myositis	4	2	4				
Infective pericardial effusion	6	1	6				
Infective tenosynovitis	4		4				
Infective uveitis	1		1				
Infestation	2		1	1	1		
Influenza	16644	103	1988	1067	14656	5	40
Infusion site infection	1		1				
Injection site abscess	2		1		1		
Injection site cellulitis	7	1	2		5		
Injection site infection	11				11		
Injection site pustule	1		1				
Intervertebral discitis	33	5	33				
Intestinal gangrene	1		1				
Intestinal tuberculosis	1		1				
Intrauterine infection	4		4				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Janeway lesion	2			1	2		
Japanese spotted fever	1		1				
JC virus infection	1	1	1				
Joint abscess	6	4	6				
Keratitis bacterial	1		1				
Keratitis viral	2		2				
Keratouveitis	6	1	6				
Kidney infection	179	13	179			3	4
Klebsiella bacteraemia	2		2				
Klebsiella infection	39	6	34	3	5	1	1
Klebsiella sepsis	3	1	3				
Labyrinthitis	290	8	164	7	126		3
Lactobacillus infection	1		1				
Large intestine infection	19	2	13		6		1
Laryngitis	291	7	73	32	218		2
Laryngitis bacterial	1		1				
Laryngitis viral	3			1	3		
Laryngopharyngitis	11	1	3	1	8		
Latent tuberculosis	4	1	2		2		
Legionella infection	6		6				
Lemierre syndrome	2	1	2				
Lepromatous leprosy	1		1				
Leprosy	2		2				
Leptospirosis	2	1	2				
Lice infestation	4		2		2		
Lip infection	3	1	1	1	2		
Listeriosis	3		3				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Liver abscess	22	2	22				
Localised infection	182	7	90	12	92	3	9
Lochial infection	1		1				
Lower respiratory tract infection	603	21	499	11	104	1	7
Lower respiratory tract infection bacterial	3		3				
Lower respiratory tract infection viral	3		3				
Ludwig angina	3		3				
Lung abscess	9	3	9				
Lyme carditis	3		3				
Lyme disease	161	40	161			3	4
Lymphadenitis bacterial	6	1	6				
Lymphadenitis viral	2		2				
Lymphangitis	168	21	168				4
Lymph gland infection	48	2	26	2	22		
Lymph node abscess	42	3	42				
Lymph node tuberculosis	3	1	3				
Malaria	9	2	9				
Malaria recrudescence	2		2				
Malaria relapse	2		2				
Mastitis	449	12	300	18	149	1	6
Mastitis bacterial	3		3				
Mastitis postpartum	18	1	3	1	15		
Mastoiditis	23	4	23				1
Measles	29	2	29				
Measles post vaccine	2		2				
Mediastinitis	3	1	3				
Medical device site abscess	1				1		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Meningitis	266	52	266				1
Meningitis aseptic	138	8	138				1
Meningitis bacterial	25	1	25				
Meningitis coxsackie viral	1		1				
Meningitis haemophilus	1		1				
Meningitis herpes	10	1	10				
Meningitis meningococcal	1		1				
Meningitis neonatal	1	1	1				1
Meningitis pneumococcal	7		7				
Meningitis staphylococcal	1		1				
Meningitis tuberculous	3	1	3				
Meningitis viral	70	7	70				
Meningococcal bacteraemia	1		1				
Meningococcal infection	2		2				
Meningoencephalitis bacterial	4		4				
Meningoencephalitis herpetic	49	4	49				
Meningoencephalitis viral	8		8				
Meningomyelitis herpes	2		2				
Metapneumovirus infection	3	1	1	1	2		
Microsporum infection	1				1		
Middle East respiratory syndrome	4		4				
Molluscum contagiosum	9		1		8		
Monkeypox	2	2	2				
Mononucleosis syndrome	7		3		4		
Moraxella infection	1		1				
Morganella infection	6		6				
Mucormycosis	1		1				

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System Organ Class

Infections and infestations

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mucosal infection	3		1		2		
Mumps	29		11	1	18		
Muscle abscess	6	1	6				
Mycobacterial infection	3		3				
Mycobacterium avium complex infection	2	1	2				
Mycoplasma infection	10	3	7	1	3		
Mycotoxicosis	1		1				
Myelitis	436	62	436			1	2
Myocardiac abscess	1	1	1				
Myocarditis bacterial	1		1				
Myocarditis infectious	8	1	8				
Myocarditis mycotic	2		2				
Myocarditis septic	5		5				
Myringitis	10		5	2	5		
Nail bed infection	2			1	2		
Nail infection	5		2		3		
Nasal abscess	7	1	7				
Nasal herpes	123	3	21	12	102		
Nasal vestibulitis	24	1	4	3	20		1
Nasopharyngitis	10281	111	1624	1386	8657	10	57
Necrotising fasciitis	19	1	19				
Necrotising soft tissue infection	1		1				
Necrotising ulcerative gingivostomatitis	3		3				
Necrotising ulcerative periodontitis							1
Nematodiasis	1		1				
Neonatal infection	3	1	3				
Neonatal pneumonia	1	1	1			1	2

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System Organ Class

Infections and infestations

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Neovaginal infection	1				1		
Nephritis bacterial	1		1				
Neuroborreliosis	24	4	24				2
Neurological infection	3	1	3				
Neutropenic sepsis	5		5				
Nipple infection	5		1	1	4		
Norovirus infection	10		2	1	8		
Nosocomial infection	10		8		2		
Oesophageal candidiasis	11	3	11				
Oesophageal infection	1		1				
Omphalitis	8	1	8				1
Onychomycosis	23	2	6	3	17		1
Oophoritis	6	1	6				
Ophthalmia neonatorum	1		1				
Ophthalmic herpes simplex	36	4	36				
Ophthalmic herpes zoster	788	85	788				3
Opportunistic infection	3	1	3				
Oral bacterial infection	1		1				
Oral candidiasis	178	1	50	20	128		2
Oral fungal infection	80	1	18	8	62	1	1
Oral herpes	3050	30	399	231	2651	3	13
Oral herpes zoster	11	1	2	7	9		
Oral infection	27		8	2	19		
Oral pustule	16		3	3	13		
Oral viral infection	5		1	1	4		
Orbital infection	1		1				
Orchitis	59		31	3	28		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Orf	1				1		
Oropharyngeal candidiasis	10		5	1	5		
Oropharyngitis fungal							1
Osler's nodes	1			1	1		
Osteomyelitis	47	5	47				1
Osteomyelitis acute	3		3				
Osteomyelitis bacterial	1		1				
Osteomyelitis chronic	4	1	4				
Otitis externa	86	1	27	8	59		
Otitis externa bacterial	2		1	1	1		
Otitis externa fungal	2				2		
Otitis media	126	11	44	13	82		
Otitis media acute	28		6	4	22	1	1
Otitis media bacterial	1				1		
Otitis media chronic	18	2	14		4		
Otosalpingitis	6		1		5		
Ovarian abscess	3		3				
Ovarian bacterial infection	1		1				
Overgrowth bacterial	1		1				
Pancreas infection	5		5				
Pancreatic abscess	1		1				
Papilloma viral infection	44	8	19	11	25		
Paragonimiasis	3		3				
Parainfluenzae viral laryngotracheobronchitis	1		1				
Parainfluenzae virus infection	7		6		1		
Paranasal sinus abscess	1		1				
Parapharyngeal space infection	2		2				

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Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Parasite allergy	1				1		
Parasitic gastroenteritis	5	1	5				
Paronychia	32	2	10	2	22		
Parotid abscess	1		1				
Parotitis	160	4	47	13	113	1	1
Parvovirus B19 infection	6	1	5		1		
Parvovirus infection	2		1		1		
Pathogen resistance	8		8				
Pelvic abscess	1		1				
Pelvic infection	3		3				
Pelvic inflammatory disease	36	2	36				
Penile abscess	1		1				
Peptostreptococcus infection	1		1				
Pericarditis infective	18	1	18				
Pericarditis tuberculous	1		1				
Perichondritis	20	4	13	1	7		
Pericoronitis	3		2		1		
Perihepatitis	1		1				
Perineal abscess	3	1	3				
Perineal cellulitis	1		1				
Periodontitis	39		4	10	35		
Periorbital abscess	1		1				
Periorbital cellulitis	10		10				
Periorbital infection	1		1				
Perirectal abscess	1		1				
Peritonitis	96	12	96				2
Peritonitis bacterial	6	1	6				

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Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Peritonsillar abscess	42	5	42				1
Peritonsillitis	1		1				
Periumbilical abscess	1		1				
Persistent generalised lymphadenopathy	5		4		1		
Pertussis	23	3	23				
Pharyngeal abscess	13		13				
Pharyngeal pustule	3				3		
Pharyngitis	612	13	139	72	473	2	4
Pharyngitis bacterial	10		8		2		
Pharyngitis streptococcal	76	1	19	3	57		1
Pharyngotonsillitis	14		8	2	6		
Phlebitis infective	2	1	2				
Picornavirus infection	3			1	3		
Pilonidal disease	9	1	2		7		
Plague	1		1				
Plasmodium vivax infection	1		1				
Pleural infection	3	1	3				
Pleurisy bacterial	1		1				
Pleurisy viral	5		5				
Pneumococcal bacteraemia	1		1				
Pneumococcal infection	10	1	10				
Pneumococcal sepsis	4		4				
Pneumocystis jirovecii infection	3		3				
Pneumocystis jirovecii pneumonia	18	3	18				
Pneumonia	3239	351	3239			21	95
Pneumonia aspiration	326	28	326				
Pneumonia bacterial	123	6	123				2

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Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pneumonia chlamydial	6		6				
Pneumonia cytomegaloviral	2	1	2				
Pneumonia escherichia	1		1				
Pneumonia fungal	9	4	9			1	1
Pneumonia haemophilus	2		2				
Pneumonia klebsiella	21	1	21				
Pneumonia legionella	5		5				2
Pneumonia moraxella	1		1				
Pneumonia mycoplasmal	14	4	14				
Pneumonia necrotising	1	1	1				
Pneumonia pneumococcal	26	3	26				
Pneumonia proteus	1		1				
Pneumonia pseudomonal	8	1	8				
Pneumonia respiratory syncytial viral	1		1				
Pneumonia staphylococcal	13		13				
Pneumonia streptococcal	9	1	9				
Pneumonia viral	37	1	37			1	3
Poliomyelitis	3	1	3				
Polyomavirus viraemia	1		1				
Post-acute COVID-19 syndrome	489	81	243	96	246	1	3
Postoperative wound infection	8		8			1	1
Post procedural infection	8	2	3		5	1	3
Post treatment Lyme disease syndrome	2		2				
Post viral fatigue syndrome	346	57	246	37	100		1
Prion disease	5		5				
Proctitis herpes	2				2		
Progressive multifocal leukoencephalopathy	4	2	4				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Propionibacterium infection	1		1				
Prostate infection	10		10				
Prostatic abscess	2		2				
Proteus infection	3		3				
Pseudomembranous colitis	5		5				
Pseudomonal bacteraemia	2		2				
Pseudomonal sepsis	3		3				
Pseudomonas infection	19	3	19			1	1
Psittacosis	1				1		
Psoas abscess	5	2	5				
Puerperal pyrexia	1		1				1
Pulmonary sepsis	18	1	18				
Pulmonary tuberculoma	1		1				
Pulmonary tuberculosis	34	7	34				
Pulpitis dental	106	3	27	14	79		
Puncture site infection	1		1				
Purple urine bag syndrome	1				1		
Purulence	39		9	8	30	1	1
Purulent discharge	43	5	19	4	24		
Purulent pericarditis	3	1	3				
Pustule	482	9	74	41	408	2	3
Pyelitis	19	2	19				1
Pyelonephritis	236	38	236			2	9
Pyelonephritis acute	45	10	45				
Pyelonephritis chronic	1	1	1				
Pyelonephritis fungal	1		1				
Pyoderma	5	1	5				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pyoderma streptococcal	1		1				
Pyometra	1		1				
Pyomyositis	1		1				
Pyonephrosis	1	1	1				
Pyuria	12	1	7		5		
Q fever	35		35				4
Raoultella ornithinolytica infection	1		1				
Rash pustular	268	9	62	34	206		
Rectal abscess	3		3				
Relapsing fever	20	3	20				
Renal abscess	7		7				1
Renal graft infection	1		1				
Respiratory moniliasis	1		1				
Respiratory syncytial virus bronchitis	1				1		
Respiratory syncytial virus infection	18	1	7	4	11		
Respiratory tract chlamydial infection	3	1	2		1		
Respiratory tract infection	298	25	186	35	112	1	7
Respiratory tract infection bacterial	6		4		2		
Respiratory tract infection viral	14	1	3	1	11		
Retinitis	15	1	15				
Retroperitoneal abscess	1		1				
Rhinitis	1404	19	229	188	1175		12
Rhinolaryngitis	2				2		
Rhinotracheitis	3	1	1		2		
Rhinovirus infection	21	1	10	1	11		
Rickettsiosis	1		1				
Rocky mountain spotted fever	1		1				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Root canal infection	6		1		5		1
Roseola	13	1	2	4	11		
Rotavirus infection	2		1		1		
Rubella	12		4	3	8		
Rubella in pregnancy	1		1				
Salmonella sepsis	3		3				
Salmonellosis	6	1	6				2
Salpingitis	7	3	7				
Salpingo-oophoritis	2		2				
SARS-CoV-2 sepsis	4	2	4				
Scarlet fever	9		5		4		1
Scrotal abscess	1		1				
Scrotal cellulitis	1		1				
Scrotal infection	2		2				
Scrub typhus	2		2				
Sebaceous gland infection	2				2		
Secondary syphilis	3		3				
Secondary transmission	4		3		1		
Seminal vesicular infection	1		1				
Sepsis	683	72	683			5	10
Sepsis neonatal	3		3				
Sepsis syndrome	4		4				
Septic arthritis staphylococcal	6		6				
Septic cerebral embolism	1	1	1				
Septic coagulopathy	1		1				
Septic embolus	4		4				
Septic encephalopathy	4		4				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Septic pulmonary embolism	2		2				
Septic rash	4		4				
Septic shock	261	21	261				
Serratia infection	3		3				
Severe acute respiratory syndrome	34	1	34				
Severe asthma with fungal sensitisation	2		2				
Severe fever with thrombocytopenia syndrome	2		2				
Severe invasive streptococcal infection	3	1	3				
Sexually transmitted disease	2	1	1	1	1		
Sialoadenitis	60	11	60				
Sinobronchitis	2	1	2				
Sinusitis	1532	42	406	158	1126	4	15
Sinusitis bacterial	12	2	12			1	1
Sinusitis fungal	4	3	3		1		
Skin bacterial infection	17	1	7		10		
Skin candida	7		2	1	5		
Skin infection	132	4	53	12	79	1	3
Small intestine gangrene	1		1				
Smallpox	8	2	8				
Soft tissue infection	22	1	19		3		1
Spinal cord abscess	4		4				
Spinal cord infection	8	1	8				
Splenic infection	2		2				
Spontaneous bacterial peritonitis	1		1				
Sputum purulent	16		14		2		
Staphylococcal abscess	3		1		2		
Staphylococcal bacteraemia	33	7	33				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Staphylococcal impetigo	2		1		1		
Staphylococcal infection	107	7	83	6	24		3
Staphylococcal scalded skin syndrome	3		3				
Staphylococcal sepsis	17		17				
Staphylococcal skin infection	4		2		2		
Stenotrophomonas bacteraemia	1		1				
Sternitis	5	1	5				
Streptobacillus infection	4		4				
Streptococcal abscess	2		2				
Streptococcal bacteraemia	3		3				
Streptococcal endocarditis	1		1				
Streptococcal infection	55	3	25	5	30		
Streptococcal sepsis	13	2	13				1
Streptococcal urinary tract infection	7		7				
Strongyloidiasis	1				1		
Stump appendicitis	1		1				
Subacute endocarditis	1		1				
Subacute sclerosing panencephalitis	2		2				
Subcutaneous abscess	104	6	46	5	58		1
Subdural abscess	1		1				
Subglottic laryngitis	6	1	1		5		
Subperiosteal abscess	1		1				
Superinfection	33	1	21	1	12		
Superinfection bacterial	41	8	41				
Superinfection viral	1		1				
Suspected COVID-19	7266	1558	6510	37	756	115	372
Sweat gland infection	1		1				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Sweating fever	151	1	141	1	10		1
Syphilis	18	2	18				
Syphilis genital	1		1				
Systemic bacterial infection	1		1				
Systemic candida	3		3				
Systemic infection	5	1	5				
Systemic viral infection	6	3	6				
Testicular abscess	2		2				
Tetanus	13	6	13				
Thrombophlebitis septic	2		2				
Tick-borne viral encephalitis	1	1	1				
Tinea capitis	4			1	4		
Tinea infection	11		1		10		
Tinea pedis	26		5	5	21		
Tinea versicolour	21		1	4	20		
Tongue abscess	4	1	4				
Tongue fungal infection	11	1	3	2	8		
Tonsillitis	667	16	209	56	458		4
Tonsillitis bacterial	32		25	1	7		
Tonsillitis streptococcal	7		6		1		
Tooth abscess	90	2	23	8	67		
Tooth infection	95	1	25	5	70		2
Toxic shock syndrome	10		10				
Toxic shock syndrome staphylococcal	1	1	1				
Toxic shock syndrome streptococcal	1		1				
Toxocariasis	4		4				
Toxoplasmosis	17	1	8	1	9		

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tracheitis	78	3	18	8	60		
Tracheobronchitis	6		3	1	3		
Tracheobronchitis bacterial	4		4				
Tracheostomy infection	1		1				
Trematode infection	1		1				
Trichophytosis	1				1		
Tropical spastic paresis	1		1				
Tuberculoma of central nervous system	1		1				
Tuberculosis	33	5	33			1	4
Tuberculosis of central nervous system	1		1				
Tuberculosis of eye	1	1	1				
Tuberculous pleurisy	1		1				
Tularaemia	2		2				
Type 2 lepra reaction	2		2				
Typhoid fever	2		2				
Upper aerodigestive tract infection	1				1		
Upper respiratory tract infection	241	6	83	25	158		1
Upper respiratory tract infection bacterial	1				1		
Ureaplasma infection	3				3		
Ureteritis	3		3				
Urethritis	17	1	7		10		
Urinary tract candidiasis	4		3		1		
Urinary tract infection	1947	65	845	152	1102	5	18
Urinary tract infection bacterial	63	2	45	2	18		
Urinary tract infection enterococcal	4		4				
Urinary tract infection fungal	5	1	5				
Urinary tract infection pseudomonal	1		1				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Urinary tract infection staphylococcal	4		4				
Urogenital infection bacterial	2		2				
Urosepsis	94	11	94				2
Uterine abscess	1		1				
Uterine infection	9	1	9				
Vaccination site abscess	153	4	42	21	111		1
Vaccination site cellulitis	204	3	116	4	88		
Vaccination site infection	154		37	3	117		
Vaccination site joint infection	1		1				
Vaccination site pustule	55	1	7	4	48		
Vaccine associated paralytic poliomyelitis	1		1				
Vaccine bacteria shedding	1		1				
Vaccine breakthrough infection	137	20	117	8	20		
Vaccine virus shedding	2			1	2		
Vaccinia virus infection	2		2				
Vaginal abscess	3		3				
Vaginal infection	79	1	13	8	66	1	1
Vaginitis gardnerella	3				3		
Variant Creutzfeldt-Jakob disease	1		1				
Varicella	199	2	51	16	148		1
Varicella encephalitis	1		1				
Varicella meningitis	4	4	4				
Varicella post vaccine	4			1	4		
Varicella zoster oesophagitis	1		1				
Varicella zoster pneumonia	3	1	3				
Varicella zoster virus infection	129	11	63	7	66		
Vascular device infection	5	1	5				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vestibular neuronitis	636	65	578		58	1	3
Vestibulitis	9		4	1	5		
Viraemia	2				2		
Viral cardiomyopathy	1		1				
Viral corneal ulcer	1		1				
Viral diarrhoea	3		1		2		1
Viral infection	497	17	211	48	286	1	4
Viral keratouveitis	2		2				
Viral labyrinthitis	11		4		7		
Viral myelitis	3		3				
Viral myocarditis	52	3	52				
Viral myositis	2		2				
Viral parotitis	1				1		
Viral pericarditis	51	2	51				
Viral pharyngitis	44		21	1	23		
Viral rash	107	4	37	4	70		
Viral rhinitis	1				1		
Viral sepsis	4	1	4				
Viral sinusitis	2		1		1		
Viral skin infection	3		1		2		
Viral tonsillitis	6		2	1	4		
Viral tracheitis	1			1	1		
Viral upper respiratory tract infection	15		5	1	10		
Viral uveitis	2	1	2				
Viral vasculitis	1		1				
Virologic failure	3		1		2		
Visceral leishmaniasis	1		1				

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System Organ Class

Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vulval abscess	4		4				
Vulvitis	12	1	5		7		
Vulvovaginal candidiasis	139	1	40	9	99		
Vulvovaginal human papilloma virus infection	1			1	1		
Vulvovaginal mycotic infection	234	6	22	30	212		1
Vulvovaginitis	7		3	3	4		
Waterhouse-Friderichsen syndrome	1		1				
West Nile viral infection	1		1				
Whipple's disease	1		1				
Wound abscess	3		1		2		
Wound infection	31	5	22	5	9		3
Wound infection bacterial	1		1				
Wound infection fungal							1
Wound infection staphylococcal	6		6				
Wound sepsis	2	1	2				1
Yellow fever	2		2				
Yersinia bacteraemia	1		1				
Yersinia infection	7	1	7				
Zoonotic bacterial infection	2		2				
Total:	233788	58590	169380	7476	64408	1282	3378

System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdomen crushing	1	1	1				
Abdominal injury	3		2		1		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdominal wall wound	1				1		
Abortion induced incomplete	1		1				
Accident	59	1	32	1	27		
Accidental exposure to product	203		7	6	196		1
Accidental exposure to product by child	4		1	1	3		
Accidental overdose	356	1	19	41	337		
Accidental underdose	158			124	158		
Accident at home	5		2		3		
Accident at work	7	1	4	2	3		1
Acetabulum fracture	3		3				
Administration related reaction	1				1		
Adrenal gland injury	1				1		
Adverse event following immunisation	315	18	65	74	250		
Airway burns	7		3		4		
Airway complication of anaesthesia	2		2				
Alcohol poisoning	12	1	12				1
Anaemia postoperative	3	1	2		1		
Anaesthetic complication	3		1		2		
Anaesthetic complication neurological	1		1				
Anal injury	1		1				
Anastomotic complication	1		1				
Anastomotic leak	2		2				
Anastomotic ulcer	1		1				
Animal bite	45		3	3	42		
Animal scratch	7			1	7		
Ankle fracture	30	4	26		4		3
Anterior cord syndrome	2		2				

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aortic injury	1		1				
Arterial injury	9	1	9				
Arteriovenous fistula site complication	1		1				
Arteriovenous fistula site haemorrhage	1		1				
Arteriovenous fistula thrombosis	8		8				
Arteriovenous graft thrombosis	1		1				
Arthropod bite	164	4	37	16	127	1	1
Arthropod sting	74		5	13	69		1
Asbestosis	1				1		
Atypical femur fracture	2		2				
Auricular haematoma	1		1				
Autonomic dysreflexia	9	1	9				
Axillary nerve injury	10	2	10				
Axillary web syndrome	14		4		10		
Back injury	55		23	6	32		2
Barotitis media	2				2		
Barotrauma	9		3		6		
Bite	32	2	8	2	24		
Bladder injury	5		2		3		
Bone contusion	31	1	16	2	15		1
Bone fissure	5		1		4		
Bone fragmentation	2		2				
Booster dose missed	11				11		
Brachial plexus injury	20	3	14	1	6		
Brain contusion	24	2	24				
Brain herniation	38	4	38				
Breast injury	5		5				

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Bronchial injury	1		1				
Burn oesophageal	20		6	1	14		
Burn of internal organs	10		6	1	4		
Burn oral cavity	25	3	25				
Burns first degree	1				1		
Burns second degree	29	2	12	1	17		
Burns third degree	10		10				
Bursa injury	8		3	2	5		
Buttock injury	3				3		
Carbon monoxide poisoning	1		1				
Cardiac contusion	2		2				
Cardiac herniation	1		1				
Cardiac procedure complication	4		4				
Cardiac valve rupture	3	2	3				
Cardiac vein dissection	1		1				
Cardiac vein perforation	1		1				
Cartilage injury	16		9	3	7	2	3
Central cord syndrome	1		1				
Central nervous system injury	3		1		2		
Cerebral hyperperfusion syndrome	3		3				
Cerebral ventricle collapse	9	3	9				
Cervical vertebral fracture	5	1	5				1
Cervix injury	1		1				
Chemical burn	6			1	6		
Chemical burn of skin	7		4		3		
Chemical cystitis	2				2		
Chemical poisoning	1		1				

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Chest crushing	23		23				
Chest injury	38	1	38				2
Chillblains	338	8	79	19	259		
Chloracne	1				1		
Circumstance or information capable of leading to device use	8				8		
Circumstance or information capable of leading to medicatio	531		3	40	528		
Clavicle fracture	37	3	26	1	11		2
Cold burn	5		1		4		
Cold shock response	2		1		1		
Colon injury	4		1		3		1
Comminuted fracture	3	1	3				
Complications of transplanted kidney	2		2				
Complications of transplanted lung	1	1	1				
Compression fracture	12	1	11		1		
Concussion	164	7	90	5	74	1	3
Conjunctival laceration	1				1		
Contraindicated product administered	22	1	8	1	14		
Contraindicated product prescribed	3		1		2		
Contusion	6319	113	1624	906	4695	1	20
Corneal abrasion	10		4		6		
Corneal laceration	2		1	1	1		
Coronary artery reocclusion	1	1	1				
Coronary bypass thrombosis	1		1				
Counterfeit product administered	19			2	19		
Cranial nerve injury	4		4				
Craniocerebral injury	74	10	74				1
Craniofacial fracture	1		1				

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Craniofacial injury	5	1	4		1		
Crush injury	3		3				
Deafness traumatic	6	1	4		2		
Decreased embryo viability	2		2				
Deep vein thrombosis postoperative	1		1				
Delayed effects of radiation	1			1	1		
Delayed recovery from anaesthesia	4		3		1		
Dental leakage	2		1		1		
Dental restoration failure	4			1	4		
Dermal filler overcorrection	1				1		
Dermal filler reaction	22			8	22		
Dermatitis artefacta	4			3	4		
Device difficult to use	1				1		
Device use confusion	2				2		
Device use issue	2				2		
Dialysis related complication	2		1		1		
Diaphragmatic injury	1		1				
Diffuse axonal injury	2		2				
Dislocation of vertebra	3	1	3				
Diversion colitis	1		1				
Documented hypersensitivity to administered product	1				1		
Dose calculation error	4				4		
Drug administered in wrong device	1				1		
Drug dose omission by device	1				1		
Drug exposure before pregnancy	23		3	3	20		1
Drug monitoring procedure incorrectly performed	3				3		
Drug monitoring procedure not performed							1

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Duodenal rupture	1		1				
Duplicate therapy error	3				3		
Dysphotopsia	1		1				
Ear canal injury	2		2				
Ear injury	20		9	1	11		
Electrical burn	1			1	1		
Electric injury	1		1				
Electric shock	59	3	23	6	36		
Endotracheal intubation complication	4	1	4				
Epicondylitis	186	13	64	28	122		
Epidural haemorrhage	4	1	4				
Epiphyseal injury	1				1		
Ergot poisoning	1				1		
Eschar	9		3		6		
Expired device used	1			1	1		
Expired product administered	5574	5	23	1950	5551		1
Exposure during pregnancy	558	9	109	12	449		
Exposure to allergen	2		1		1		
Exposure to chemical pollution	1		1				
Exposure to communicable disease	7		1	1	6		1
Exposure to contaminated device	1				1		
Exposure to contaminated water	2				2		
Exposure to extreme temperature	2		2				
Exposure to SARS-CoV-2	220	1	34	8	186		5
Exposure to toxic agent	4		1		3		
Exposure to unspecified agent	1				1		
Exposure to vaccinated person	15		8	1	7		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Exposure via blood	1				1		
Exposure via body fluid	1				1		
Exposure via breast milk	6011	9	317	215	5694		3
Exposure via contaminated device	1				1		
Exposure via eye contact	26			2	26		
Exposure via father	1		1				
Exposure via partner	1				1		
Exposure via skin contact	120			5	120		
Exposure via unknown route	1				1		
Extra dose administered	551		16	16	535	1	1
Extradural haematoma	10	1	10				
Extraskeletal ossification	1				1		
Eye abrasion	1			1	1		
Eye contusion	134	4	42	14	92		1
Eye injury	186	4	63	5	123		
Eyelid abrasion	2				2		
Eyelid contusion	9		1		8		
Eyelid injury	5		3		2		
Eye luxation	2		2				
Face crushing	7	1	7				
Face injury	143	9	90	9	53		4
Facial bones fracture	75	6	75				1
Failed in vitro fertilisation	3		3				
Failure to anastomose	1		1				
Fall	5083	225	2746	290	2337	9	44
Fallopian tube perforation	2	1	2				
Fascial rupture	2		1	1	1		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Fat embolism	1		1				
Femoral neck fracture	40	2	40				
Femoral nerve injury	2		2				
Femur fracture	50	2	50				1
Fibula fracture	7		7				
Flail chest	2		2				
Foetal exposure during pregnancy	101	11	71	3	30	2	13
Foetal exposure timing unspecified	1		1				
Foot fracture	42	5	33		9	2	5
Forearm fracture	1		1				1
Foreign body	10		2		8		
Foreign body aspiration	5	1	5				
Foreign body in ear	1				1		
Foreign body in eye	21		4	3	17		
Foreign body in gastrointestinal tract	2		1		1		
Foreign body ingestion	3	2	2	1	1		
Foreign body in mouth	1		1				
Foreign body in respiratory tract	4	1	1		3		
Foreign body in skin or subcutaneous tissue	2				2		
Foreign body in throat	44		44			1	1
Foreign body in urogenital tract	1		1				
Fracture	122	12	108	2	14		2
Fractured coccyx	3	1	2		1		
Fracture displacement	2		2				
Fractured sacrum	3		3				
Fractured skull depressed	1		1				
Frostbite	42		12	6	30		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Gadolinium deposition disease	1		1				
Gallbladder injury	3		2		1		
Gastrointestinal injury	6		2		4		
Gastrointestinal stoma complication	4		3		1		
Genital injury	2				2		
Gingival injury	4		1		3		
Graft complication							1
Gun shot wound	1		1				
Haemolytic transfusion reaction	1		1				
Hair injury	14	1	2	2	12		
Hand fracture	27	5	25		2		
Head injury	772	42	487	26	285		5
Heat cramps	7		3	1	4		
Heat exhaustion	46		11	3	35		
Heat illness	49		30	1	19		
Heat oedema	20		9		11		
Heat stroke	71	1	17	9	54		
Heavy exposure to ultraviolet light	1				1		
Hepatic rupture	1		1				
Hip fracture	51	1	51			2	6
Humerus fracture	26	5	26				1
Hyphaema	6	1	6				
Hypobarism	12		3		9		
Iatrogenic injury	3		3				
IIIrd nerve injury	3	1	3				
Iliotibial band syndrome	4	1	3		1		
Implantation complication	2		1		1		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Inadequate aseptic technique in use of product	7			1	7		
Inappropriate schedule of product administration	91209	83	986	33938	90223	11	70
Incisional hernia	2		1		1		
Incision site complication	3		1		2	1	1
Incision site haemorrhage	1		1				
Incision site impaired healing	1		1				
Incision site pain	9		3		6	2	2
Incision site pruritus	1				1		
Incision site rash	2				2		
Incision site swelling	3				3		
Incomplete course of vaccination	137	1	5	11	132		
Incomplete spinal fusion	1		1				
Incorrect disposal of product	3				3		
Incorrect dosage administered	43			2	43		
Incorrect dose administered	2225	41	165	407	2060	6	11
Incorrect dose administered by device	2				2		
Incorrect dose administered by product	3				3		
Incorrect drug administration rate	4			2	4		
Incorrect product administration duration	10	1	1	1	9		1
Incorrect product dosage form administered	1				1		
Incorrect product formulation administered	23			4	23		
Incorrect route of product administration	5536	27	130	606	5406		2
Induced abortion failed	1		1				
Induced abortion haemorrhage	1		1				
Inflammation of wound	17	2	5	2	12		
Infusion related reaction	8	1	6		2	2	17
Injection related reaction	84	1	52	4	32	1	2

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Injury	332	14	146	22	186	1	7
Injury corneal	6		3		3		1
Injury of conjunctiva	1				1		
Injury to brachial plexus due to birth trauma	1	1	1				
Intentional device use issue	1				1		
Intentional dose omission	20		1		19		3
Intentional overdose	9		2		7		
Intentional product misuse	20		2	2	18		2
Intentional product use issue	18			1	18		2
Intentional underdose	2		1		1		
Intercepted medication error	5			1	5		
Intercepted product administration error	3			2	3		
Intercepted product preparation error	2				2		
Intercepted product selection error	1				1		
Intercepted product storage error	1				1		
Intervertebral disc injury	4			1	4		
Intoxication by breast feeding	5		5				
Ischaemic contracture of the left ventricle	2		2				
IVth nerve injury	1		1				
Jaw fracture	22	1	22			1	1
Joint dislocation	114	10	68	3	46		2
Joint injury	192	5	69	16	123		6
Kidney contusion	1		1				
Kidney rupture	2		2				
Labelled drug-drug interaction medication error	1		1				
Lack of vaccination site rotation	3		1		2		1
Laryngeal injury	1		1				

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Laryngeal nerve dysfunction	1		1				
Lenticular injury	1				1		
Ligament injury	14	1	8		6		1
Ligament rupture	26	1	15	3	11		1
Ligament sprain	154	4	52	13	102		
Limb crushing injury	6		6				
Limb fracture	1	1	1				
Limb injury	563	16	278	26	285	2	9
Lip injury	62	4	23	1	39		1
Liver contusion	4	1	4				
Liver transplant failure	2	2	2				
Lower limb fracture	37	1	34		3		1
Lumbar vertebral fracture	18	4	18				3
Lumbosacral plexus injury	2		2				
Lymphatic duct injury	1			1	1		
Mallet finger	1				1		
Maternal drugs affecting foetus							1
Maternal exposure before pregnancy	404	17	87	31	317		10
Maternal exposure during breast feeding	706	3	188	8	518		6
Maternal exposure during delivery	1				1		
Maternal exposure during pregnancy	6357	148	1337	265	5020	20	174
Maternal exposure timing unspecified	1305	33	153	121	1152	1	8
Maternal exposure via partner during pregnancy	2	1	1		1		
Mechanical ventilation complication	1		1				
Median nerve injury	5		5				
Medical device monitoring error	4				4		
Medication error	295	34	89	18	206	1	3

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Meniscus injury	27	4	14	1	13		2
Metal poisoning	3		3				
Mouth injury	42	2	15	1	27		
Mucosal excoriation	1				1		
Multiple fractures	15	3	15				
Multiple injuries	35	1	20		15		
Multiple use of single-use product	5			1	5		
Muscle contusion	9		2		7		
Muscle hernia	2		1		1		
Muscle injury	149	13	78	9	71	1	1
Muscle rupture	94	13	94				3
Muscle strain	486	8	151	51	335		2
Musculoskeletal injury	5	1	3		2		
Nail avulsion	3			1	3		
Nail injury	6		2	1	4		
Nasal injury	25	1	10	2	15		
Near drowning	18		18				
Neck crushing	2	1	2				
Neck injury	32	1	11	6	21		
Needle fatigue	2				2		
Neovaginal pain	1				1		
Nerve injury	559	29	285	49	274	1	1
Nerve root injury	3		3				
Nerve root injury lumbar	1		1				
Nerve root injury thoracic	1		1				
Nervous system injury	8		6	2	2		
Neurological procedural complication	2	1	1		1	1	1

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Occupational exposure to product	99		2	5	97		
Occupational exposure to SARS-CoV-2	14		3		11		
Occupational exposure to sunlight	1		1				
Oesophagitis chemical	1		1				
Off label use	63448	2045	18171	7158	45277	154	450
Open fracture	3		3				
Optic nerve injury	37	7	37				2
Oral contusion	23	1	7	6	16		
Oral mucosal scar	7		4	2	3		
Overdose	6255	23	177	1046	6078		5
Palate injury	10		1		9		
Pancreatic injury	1		1				
Parasympathetic nerve injury	1		1				
Paroxysmal autonomic instability with dystonia	1		1				
Patella fracture	10	1	9		1		
Paternal exposure before pregnancy	22		2	19	20		
Paternal exposure during pregnancy	8		1	1	7		
Paternal exposure timing unspecified	1				1		
Pelvic fracture	27	1	27			1	2
Penile contusion	3			1	3		
Penis injury	3		3				
Periorbital haematoma	28	1	10	3	18		1
Periorbital haemorrhage	17	1	5	7	12		
Peripancreatic fluid collection	1		1				
Peripheral nerve injury	29	9	29				
Periprosthetic fracture	2		2				
Periprosthetic osteolysis	1		1				

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Peroneal nerve injury	10	1	7		3		
Persistent corneal epithelial defect	1				1		
Petroleum distillate poisoning	1				1		
Pharyngeal contusion	3		2	1	1		
Phrenic nerve injury	1		1				
Pneumocephalus	2		2				
Pneumoconiosis	3		3				
Pneumonitis chemical	1		1				
Pocket erosion	1				1		
Poisoning	47	4	47				
Poor quality device used	1				1		
Poor quality product administered	47285	2	16	16478	47269		
Post concussion syndrome	7		1		6		
Posterior capsule rupture	1		1				
Posterior tibial nerve injury	3		2		1		
Post laminectomy syndrome	1		1				
Post lumbar puncture syndrome	17	1	7		10		
Postmastectomy lymphoedema syndrome	1				1		
Postoperative delirium	3		3				1
Postoperative ileus	1		1				
Postoperative thrombosis	2		2				
Postoperative wound complication	4		2		2		
Post procedural complication	13		8	2	5		3
Post procedural complication circulatory	1				1		
Post procedural constipation	1				1		
Post procedural contusion	1				1		
Post procedural diarrhoea	8				8		

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Injury, poisoning and procedural complications

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Post procedural discomfort	1				1		
Post procedural erythema	1				1		
Post procedural fistula	2		2				
Post procedural haematoma	1		1				
Post procedural haematuria	1		1				
Post procedural haemorrhage	15	1	15				3
Post procedural hypothyroidism							1
Post procedural inflammation	4				4		
Post procedural myocardial infarction	2		2				
Post procedural oedema	3		2		1		
Post procedural pruritus	1				1		
Post procedural pulmonary embolism	2		2				
Post procedural stroke	1		1				
Post procedural swelling	4	1	3		1		
Post-traumatic neck syndrome	19		9	2	10		
Post-traumatic pain	16		2		14		
Post vaccination syndrome	271	77	108	126	163		
Prescribed overdose	1				1		
Prescribed underdose	3			1	3		1
Prescription drug used without a prescription	3		1		2		
Prevertebral soft tissue swelling of cervical space	1				1		
Procedural complication	108		6		102		1
Procedural dizziness	15		8		7		
Procedural haemorrhage	10	3	10			1	1
Procedural headache	4		3		1		
Procedural nausea	14		9		5		
Procedural pain	23		10		13	1	5

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Procedural pneumothorax	2	1	2				
Procedural shock	1	1	1				
Procedural site reaction	2		2				
Procedural vomiting	3		2		1		
Product administered at inappropriate site	1146	9	96	126	1050		
Product administered by wrong person	1				1		
Product administered to patient of inappropriate age	9501	7	22	770	9479		
Product administration error	14361	7	52	6751	14309		1
Product administration interrupted	7	1	1		6		1
Product appearance confusion	13			10	13		
Product communication issue	7			2	7		
Product confusion	14			6	14		
Product design confusion	1				1		
Product dispensing error	41			17	41		
Product dispensing issue	2			1	2		
Product dosage form confusion	25			24	25		
Product dose omission in error	9				9		
Product dose omission issue	149		5	5	144	2	15
Product label confusion	1807			35	1807		
Product name confusion	1				1		
Product packaging confusion	161			151	161		
Product preparation error	4075	2	31	918	4044		
Product preparation issue	2680	5	17	302	2663		1
Product prescribing error	16	1	2	1	14		
Product prescribing issue	2			1	2		
Product selection error	2				2		
Product storage error	9143		1	2185	9142		2

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Injury, poisoning and procedural complications

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Product substitution error	1				1		
Product use complaint	11		1	2	10		
Product use in unapproved indication	16		2	1	14		1
Product use issue	9209	89	664	831	8545	4	27
Pseudophakic bullous keratopathy	1		1				
Pulmonary contusion	3		3				
Radial nerve injury	17	2	15	1	2		
Radiation associated pain	5		2		3		
Radiation dysphagia	1	1	1				
Radiation injury	4		2		2		
Radiation mastitis	1		1				
Radiation neuropathy	1			1	1		
Radiation pneumonitis	3		1		2		
Radiation proctitis	1		1				
Radiation related tooth disorder	1			1	1		
Radiation sickness syndrome	2				2		
Radiation skin injury	1		1				
Radius fracture	13	1	8	1	5	1	1
Reaction to previous exposure to any vaccine	3		3				
Reactive gastropathy	9	2	4	1	5		
Recalled product administered	8			5	8		
Recall phenomenon	15	2	6	1	9		
Rectal injury	1		1				
Refractoriness to platelet transfusion	1				1		
Renal transplant failure	4		4				
Re-opening of ductus arteriosus	1				1		
Repetitive strain injury	6		3	2	3		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Reproductive tract anastomotic leak	1				1		
Respiratory fume inhalation disorder	1		1				
Retinal injury	21	4	21				
Rib fracture	114	11	99	2	15		1
Road traffic accident	185	7	131	5	54		6
Scapula fracture	4	1	4				
Scar	288	7	83	33	205		3
Sciatic nerve injury	17	1	10	3	7		
Scratch	227	3	50	12	177	1	3
Scrotal injury	1				1		
Sedation complication	8		8				
Seroma	12	1	5	1	7		
Shunt blood flow excessive	1		1				
Shunt occlusion	3		3				
Shunt stenosis	1				1		
Shunt thrombosis	3		3				
Silicosis	1		1				
Skeletal injury	17	2	8	2	9		
Skin abrasion	175	7	51	15	124		
Skin flap necrosis							1
Skin injury	71	5	22	6	49		
Skin laceration	191	9	91	13	100		1
Skin pressure mark	1				1		
Skin procedural complication	1		1				
Skin scar contracture	1				1		
Skin wound	46	3	15	5	31		
Skull fracture	22	3	22				

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Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Skull fractured base	11		11				
Snake bite	4	1	2		2		
Soft tissue foreign body	6				6		
Soft tissue injury	10		8		2		
Spinal column injury	15	3	10		5		
Spinal compression fracture	28	4	28				
Spinal cord injury	31	5	31				
Spinal cord injury cauda equina	1		1				
Spinal cord injury cervical	4		4				
Spinal cord injury thoracic	2		2			1	1
Spinal fracture	47	6	47				5
Spinal shock	1		1			1	1
Splenic injury	2		1		1		
Splenic rupture	18		18				
Splinter	3				3		
Sports injury	1				1		
Stab wound	5		1	1	4		
Sternal fracture	6		6				
Sternal injury	5			4	5		
Stoma complication	1		1				
Stoma obstruction	1		1				
Stoma site discharge	3		2		1		
Stoma site erythema	1				1		
Stoma site haemorrhage	7	1	7				
Stoma site inflammation	1				1		
Stoma site pain	2		1		1	1	1
Stoma site pruritus	2				2		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Stoma site vasculitis	1		1				
Stress fracture	10	2	8		2		
Struck by lightning	1	1	1				
Subarachnoid haematoma	4	1	4				
Subcutaneous haematoma	106	3	33	13	73		
Subdural haematoma	158	12	158				1
Subdural haemorrhage	39	3	39				
Sunburn	122	2	24	10	98		1
Superficial injury of eye	10		1	2	9		
Suture related complication	3		1		2		
Suture rupture	1				1		
Sympathetic nerve injury	2	1	2				
Synovial rupture	11		6		5		
Tattoo associated skin reaction	1			1	1		
Tendon injury	43	5	24	5	19		
Tendon rupture	101	5	64	6	37		1
Testicular injury	2		1		1		
Thermal burn	151	3	42	14	109		
Thermal burns of eye	37	1	37				
Thoracic vertebral fracture	16	2	16				1
Thyroid gland injury	1	1	1				
Tibia fracture	14	2	11		3		1
Tissue injury	17		7	4	10		
Tongue injury	20		8		12		
Tooth avulsion	5	1	5				
Tooth dislocation	2				2		
Tooth fracture	65	2	35	3	30	1	1

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tooth injury	56	3	30	3	26		
Torus fracture	2		1		1		
Toxic anterior segment syndrome	1		1				
Toxicity to various agents	56	7	42	6	14		1
Tracheal deviation	2		2				
Tracheal haemorrhage	2		2				
Tracheal obstruction	10	1	10				
Tracheostomy malfunction	2		2				
Transcription medication error	1				1		
Transfusion reaction	3		1		2		
Transfusion related complication	1		1				
Transplantation complication	1		1				
Transplant dysfunction	2		2				
Transplant failure	3		2	1	1		
Traumatic fracture	2		2				
Traumatic haematoma	24	1	12	1	12		
Traumatic haemorrhage	9	1	6		3		
Traumatic haemothorax	5		5				
Traumatic heart injury	2		2				
Traumatic intracranial haemorrhage	13		13				
Traumatic liver injury	2		2				
Traumatic lung injury	17	1	11	2	6		
Traumatic shock	2	1	1		1		
Trunk injury	3				3		
Twiddler's syndrome	1				1		
Ulna fracture	5		4		1		
Ulnar nerve injury	22		11		11		

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System Organ Class

Injury, poisoning and procedural complications

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Underdose	3584	5	17	737	3567		
Upper limb fracture	72	5	67		5		1
Ureteric injury	1	1	1				
Urethral injury	1		1				
Uterine injury	1		1				
Uterine rupture	1		1				1
Uveal prolapse	1		1				
Vaccination complication	101	7	28	14	73	1	15
Vaccination error	1655	51	63	661	1592		
Vascular access complication	1		1				
Vascular access malfunction	2		1		1		
Vascular access site dissection	1		1				
Vascular access site rash	1		1				
Vascular access site swelling	1				1		
Vascular graft occlusion	5		5				
Vascular graft stenosis	1		1				
Vascular graft thrombosis	7		7				
Vascular injury	64		24	7	40		
Vascular procedure complication	1		1				
Vascular pseudoaneurysm	9	1	6	2	3		
Vasoplegia syndrome	7		7				
Vena cava injury	1		1				
Venous injury	16	2	16				
VIIIth nerve injury	10	1	9		1		
VIIth nerve injury	8		7		1		
Vitreous injury	2		2				
Vth nerve injury	2		2				

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System Organ Class

Injury, poisoning and procedural complications

		Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
Preferred Term	*Total # of Spontaneous AE*	I	C	I	C	I	C
Vulvovaginal injury	12	1	12				
Weaning failure	2		1		1		
Wound	385	21	119	76	266	2	7
Wound complication	68	2	16	8	52	1	2
Wound contamination	1		1				
Wound dehiscence	3		2		1		
Wound haematoma	2		1		1		
Wound haemorrhage	79	1	30	9	49		2
Wound necrosis	7	2	7				
Wound secretion	37	3	20	3	17		2
Wrist fracture	25	4	24		1		1
Wrong dosage formulation	1				1		
Wrong dose	14				14		
Wrong drug	3				3		
Wrong patient	1				1		
Wrong patient received product	5			2	5		
Wrong product administered	3051	36	53	2242	2998	1	1
Wrong product stored	1				1		
Wrong schedule	21		2	2	19		
Wrong strength	1				1		
Wrong technique in device usage process	6			1	6		
Wrong technique in product usage process	1025	3	41	52	984		
Total:	325639	3736	33916	80553	291723	248	1089

System Organ Class

Investigations

	Spontaneous		Non Interventional Study
	Serious	Nonserious	Serious

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
5-hydroxyindolacetic acid in urine	1				1		
Acid base balance	1				1		
Acid base balance abnormal	5		2	2	3		
Acoustic stimulation tests	1		1				
Acoustic stimulation tests abnormal	3		1	1	2		
Acoustic stimulation tests normal	1				1		
Activated partial thromboplastin time abnormal	4		1		3		
Activated partial thromboplastin time prolonged	92	2	48	1	44		
Activated partial thromboplastin time ratio decreased	7				7		
Activated partial thromboplastin time ratio increased	4		1		3		
Activated partial thromboplastin time shortened	41		14	2	27		
ADAMTS13 activity abnormal	2		2				
ADAMTS13 activity decreased	6	1	5		1		
Adenosine deaminase increased	3		1		2		
Adenovirus test positive	2				2		
Adjusted calcium decreased	2		1		1		
Adjusted calcium increased	2			2	2		
Airway peak pressure increased	2		1		1		
Alanine aminotransferase abnormal	18		8		10		
Alanine aminotransferase decreased	14		2		12		
Alanine aminotransferase increased	542	18	228	31	314	1	4
Albumin CSF abnormal	3		3				
Albumin CSF increased	5		5				
Albumin globulin ratio abnormal	1		1				
Albumin globulin ratio decreased	16		2	1	14		
Albumin globulin ratio increased	5				5		
Albumin urine	1				1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Albumin urine absent	1		1				
Albumin urine present	8		3		5		
Alcohol test false positive	1				1		
Aldolase increased	7		4		3		
Aldosterone urine increased	1				1		
ALK gene rearrangement positive	1	1	1				
Allergy alert test	1				1		
Allergy test	1		1				
Allergy test negative	4				4		
Allergy test positive	7	1	2		5		
Alpha-1 acid glycoprotein increased	1				1		
Alpha-1 anti-trypsin increased	2		1		1		
Alpha 1 foetoprotein abnormal	1				1		
Alpha 1 foetoprotein decreased	1		1				
Alpha 1 foetoprotein increased	2				2		
Alpha 1 globulin decreased	2		1		1		
Alpha 1 globulin increased	8		1	2	7		
Alpha 2 globulin decreased	3		2		1		
Alpha 2 globulin increased	9			2	9		
Alpha-2 macroglobulin increased	1				1		
Alpha globulin increased	4				4		
Alpha tumour necrosis factor increased	2		1		1		
Amino acid level decreased	3			2	3		
Amino acid level increased	3				3		
Ammonia abnormal	1				1		
Ammonia increased	4		2		2		1
Amniocentesis abnormal	7	1	7				

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Amniotic fluid volume decreased	9	1	9				
Amniotic fluid volume increased	2		2				
Amniotic membrane rupture test positive	1		1				
Amphetamines	1				1		
Amphetamines positive	3				3		
Amylase abnormal	2				2		
Amylase decreased	12		4		8		
Amylase increased	69	2	30	6	39		
Analgesic drug level	4		3		1		
Analgesic drug level above therapeutic	1		1				
Analgesic drug level increased	1				1		
Anal pap smear abnormal	1				1		
Androgens increased	2		1		1		
Angiocardiogram	2		1		1		
Angiogram	3				3		
Angiogram abnormal	3		1		2		
Angiogram cerebral abnormal	1		1				
Angiogram pulmonary abnormal	5		2	1	3		
Angiotensin converting enzyme abnormal	1				1		
Angiotensin converting enzyme decreased	6		1		5		
Angiotensin converting enzyme increased	14		5	3	9		
Angiotensin II abnormal	1				1		
Angiotensin II decreased	1				1		
Angiotensin II receptor type 1 antibody positive	1				1		
Anion gap abnormal	1				1		
Anion gap decreased	6				6		1
Anion gap increased	16		2	3	14		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Antiacetylcholine receptor antibody positive	3		1		2		
Anti-actin antibody positive	1				1		
Anti-aquaporin-4 antibody positive	3		3				
Anti B antibody positive	1				1		
Antibody test	1				1		
Antibody test abnormal	130	2	12	10	118		
Antibody test negative	26		3		23		
Antibody test normal	1				1		
Antibody test positive	19		6	3	13		
Anticoagulation drug level	1				1		
Anticoagulation drug level above therapeutic	3				3		
Anticoagulation drug level below therapeutic	9		2		7		
Anticoagulation drug level increased	1		1				
Anticonvulsant drug level below therapeutic	2		1		1		
Anticonvulsant drug level decreased	2		2				
Anti-cyclic citrullinated peptide antibody positive	18		5	1	13		
Antidepressant drug level decreased	2				2		
Antidepressant drug level increased	1				1		
Anti-erythrocyte antibody positive	3		2		1		
Anti factor IX antibody increased	1		1				
Anti factor V antibody positive	1		1				
Anti factor VIII antibody increased	3	2	3				
Anti factor VIII antibody positive	3		3				
Anti-GAD antibody positive	9	1	3		6		
Anti-ganglioside antibody negative	1				1		
Anti-ganglioside antibody positive	6		1	1	5		
Anti-glomerular basement membrane antibody positive	1		1				

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Anti-HLA antibody test positive	1				1		
Anti-IA2 antibody positive	4		1		3		
Anti-insulin antibody increased	1				1		
Anti-insulin antibody positive	1				1		
Anti-islet cell antibody positive	3		2		1		
Anti Kell antibody test positive	1				1		
Anti-melanoma differentiation-associated protein 5 antibody	5	2	5				
Antimicrobial susceptibility test resistant	2		2				
Antimitochondrial antibody positive	4			1	4		
Anti-Muellerian hormone level decreased	15	3	7	3	8		
Anti-myelin-associated glycoprotein antibodies positive	3		3				
Anti-neuronal antibody	2		1		1		
Anti-neuronal antibody positive	1				1		
Antineutrophil cytoplasmic antibody	2		1	1	1		
Antineutrophil cytoplasmic antibody decreased	1				1		
Antineutrophil cytoplasmic antibody increased	20	2	12	2	8		
Antineutrophil cytoplasmic antibody positive	27	3	16	2	11		
Antinuclear antibody	14	1	6		8		
Antinuclear antibody increased	64	2	19	12	45		
Antinuclear antibody negative	1				1		
Antinuclear antibody positive	156	5	44	15	112		
Antiphospholipid antibodies	8		4	1	4		
Antiphospholipid antibodies positive	32	5	19	1	13		
Anti-platelet antibody	2		1	1	1		
Anti-platelet antibody positive	6	1	5		1		
Anti-platelet factor 4 antibody negative	1				1		
Anti-platelet factor 4 antibody positive	4		1		3		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Anti-polyethylene glycol antibody present	5		1	4	4		
Anti-prothrombin antibody positive	1				1		
Antipsychotic drug level below therapeutic	1				1		
Antipsychotic drug level increased	9	5	7		2		
Anti-saccharomyces cerevisiae antibody test positive	1				1		
Anti-SRP antibody positive	2		2				
Antithrombin III decreased	3		1		2		
Antithrombin III increased	2		1	1	1		
Anti-thyroid antibody	10		2		8		
Anti-thyroid antibody decreased	1				1		
Anti-thyroid antibody increased	49	3	16	4	33		
Anti-thyroid antibody positive	39	1	10	5	29		
Anti-transglutaminase antibody increased	1	1	1				
Anti-zinc transporter 8 antibody positive	2				2		
Antral follicle count low	4	1	1	1	3		
Aortic bruit	5		2		3		
Apgar score abnormal	1		1				
Apgar score low	3		3				
Apnoea test abnormal	1				1		
Apolipoprotein B increased	1				1		
Arteriogram abnormal	1		1				
Arteriogram carotid	1	1	1				
Arteriogram coronary normal	1		1				
Aspartate aminotransferase	1		1				
Aspartate aminotransferase abnormal	14		7		7		
Aspartate aminotransferase decreased	4				4		
Aspartate aminotransferase increased	448	19	163	27	285		1

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aspergillus test positive	3		2		1		
Aspiration bone marrow	1		1				
Aspiration joint	3				3		
AST/ALT ratio abnormal	5		2	1	3		
Asymmetric di-methylarginine increased	1				1		
Atrial natriuretic peptide	1	1	1				
Atrial pressure increased	3		1		2		
Audiogram abnormal	6		2		4		
Auscultation	1				1		
Autoantibody negative	1		1				
Autoantibody positive	118	16	36	30	82	1	1
Autoantibody test	6	1	3	1	3		
Bacillus test positive	2		1		1		
Bacterial test	3		2		1		
Bacterial test negative	1				1		
Bacterial test positive	42		21	1	21	1	2
Balance test	1		1				
Band neutrophil count decreased	1				1		
Band neutrophil count increased	2		1		1		1
Band neutrophil percentage increased	3		1		2		1
Bartonella test positive	3			1	3		
Base excess abnormal	1		1				
Base excess decreased	5		2		3		
Base excess increased	3				3		
Basophil count abnormal	3				3		
Basophil count decreased	7		1	1	6		
Basophil count increased	31	1	5	2	26		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Basophil percentage decreased	1				1		
Basophil percentage increased	2				2		
Bence Jones protein urine present	1				1		
Beta-2 glycoprotein antibody positive	8		3	1	5		
Beta 2 microglobulin abnormal	1				1		
Beta 2 microglobulin increased	10		6		4		
Beta 2 microglobulin urine increased	1		1				
Beta globulin	1				1		
Beta globulin abnormal	1				1		
Beta globulin decreased	3			1	3		
Beta globulin increased	5		1		4		
Bile output	1				1		
Bile output abnormal	3				3		
Bile output increased	2		1		1		
Bilirubin conjugated	2		1		1		
Bilirubin conjugated abnormal	1			1	1		
Bilirubin conjugated increased	22	2	9	3	13		
Bilirubin urine	1				1		
Bilirubin urine present	4		1		3		
Biopsy	4		1	2	3	1	1
Biopsy bone	1		1				
Biopsy bone marrow abnormal	2		2				
Biopsy breast	2		2				
Biopsy breast abnormal	2		1		1		
Biopsy cervix abnormal	1			1	1		
Biopsy endometrium	1		1				
Biopsy heart	2	1	1		1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Biopsy heart abnormal	1		1				
Biopsy intestine abnormal	1		1				
Biopsy kidney abnormal	1		1				
Biopsy lymph gland	4		1		3		
Biopsy lymph gland normal	1		1				
Biopsy muscle abnormal	1		1				
Biopsy peripheral nerve	1		1				
Biopsy skin abnormal	1		1				
Blast cell count increased	2		2				
Blast cells	1		1				
Blast cells present	2	1	1		1		
Bleeding time	1		1				
Bleeding time abnormal	3		2		1		
Bleeding time prolonged	58	3	21	7	37		1
Bleeding time shortened	2		1		1		
Blood 1,25-dihydroxycholecalciferol increased	1		1				
Blood 25-hydroxycholecalciferol decreased	5				5		
Blood acid phosphatase increased	1				1		
Blood albumin	1				1		
Blood albumin abnormal	7	1	4	1	3		
Blood albumin decreased	109	1	30	8	79	1	1
Blood albumin increased	21		5	3	16		
Blood alcohol	1	1	1				
Blood alcohol abnormal	1				1		
Blood alcohol decreased	2		1		1		
Blood alcohol increased	5		3	1	2		
Blood aldosterone increased	4			1	4		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood alkaline phosphatase	2		2				
Blood alkaline phosphatase abnormal	3		1	1	2		
Blood alkaline phosphatase decreased	19		2	2	17		
Blood alkaline phosphatase increased	157	5	52	7	105		
Blood aluminium abnormal	1			1	1		
Blood aluminium increased	2				2		
Blood androstenedione increased	3			2	3		
Blood antidiuretic hormone abnormal	1		1				
Blood antidiuretic hormone increased	1		1				
Blood arsenic increased	1			1	1		
Blood beta-D-glucan increased	1	1	1				
Blood beta-D-glucan positive	1				1		
Blood bicarbonate decreased	27	1	10	1	17		
Blood bicarbonate increased	6		1		5		
Blood bilirubin abnormal	10		3		7		
Blood bilirubin decreased	13				13		
Blood bilirubin increased	194	3	66	10	128		
Blood bilirubin unconjugated decreased	1	1	1				
Blood bilirubin unconjugated increased	6		3		3		
Blood caffeine decreased	1		1				
Blood calcium abnormal	7		2	1	5		
Blood calcium decreased	56		12	3	44		
Blood calcium increased	30		6	4	24		1
Blood catecholamines increased	2				2		
Blood chloride decreased	28		1		27		
Blood chloride increased	37		4	1	33	1	1
Blood cholesterol	4		3		1		1

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood cholesterol abnormal	17			2	17		
Blood cholesterol decreased	19		3	2	16		
Blood cholesterol increased	317	4	67	38	250		1
Blood cholinesterase decreased	10		3		7		
Blood cholinesterase increased	8		4		4		
Blood chromium decreased	1				1		
Blood chromium increased	2		2				
Blood chromogranin A increased	1				1		
Blood copper	1		1				
Blood copper decreased	2			1	2		
Blood copper increased	3				3		
Blood corticosterone decreased	1				1		
Blood corticotrophin	1		1				
Blood corticotrophin decreased	1		1				
Blood creatine abnormal	1				1		
Blood creatine decreased	8		3	1	5		
Blood creatine increased	52		15	4	37		
Blood creatine phosphokinase	5	1	3		2		
Blood creatine phosphokinase abnormal	13		4	1	9		
Blood creatine phosphokinase decreased	32		8		24		
Blood creatine phosphokinase increased	706	30	375	39	331		1
Blood creatine phosphokinase MB	4		1	1	3		
Blood creatine phosphokinase MB abnormal	1				1		
Blood creatine phosphokinase MB decreased	1				1		
Blood creatine phosphokinase MB increased	117		66	2	51		1
Blood creatine phosphokinase MM increased	2		1		1		
Blood creatine phosphokinase normal	1				1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood creatinine abnormal	17		7	1	10		
Blood creatinine decreased	53	1	10	1	43		
Blood creatinine increased	347	14	136	16	211	3	6
Blood culture positive	3		1		2		
Blood electrolytes abnormal	2	1	1	1	1		
Blood electrolytes decreased	9		7		2	1	1
Blood electrolytes increased	1				1		
Blood erythropoietin decreased	1				1		
Blood fibrinogen abnormal	7		3		4		
Blood fibrinogen decreased	24		9	1	15		
Blood fibrinogen increased	154	2	50	7	104		
Blood folate decreased	38		16	2	22		
Blood folate increased	9		1	4	8		
Blood follicle stimulating hormone abnormal	2				2		
Blood follicle stimulating hormone increased	33	1	11	5	22		
Blood gases abnormal	8		7		1		
Blood gases normal	1		1				
Blood glucagon abnormal	2				2		
Blood glucagon decreased	1				1		
Blood glucagon increased	3		1		2		
Blood glucose	4		2		2		
Blood glucose abnormal	177	6	48	15	129	1	5
Blood glucose decreased	389	4	124	30	265		1
Blood glucose fluctuation	177	5	55	19	122		
Blood glucose increased	1437	29	437	102	1000	2	7
Blood glucose normal	5	1	1		4		
Blood gonadotrophin increased	2			1	2		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood growth hormone	1				1		
Blood growth hormone abnormal	2				2		
Blood growth hormone decreased	3				3		
Blood growth hormone normal	2				2		
Blood HIV RNA increased	1		1				
Blood homocysteine decreased	1				1		
Blood homocysteine increased	18		8	2	10		
Blood immunoglobulin A	1				1		
Blood immunoglobulin A abnormal	1				1		
Blood immunoglobulin A decreased	6	1	2	1	4		
Blood immunoglobulin A increased	24		4	2	20		
Blood immunoglobulin E	2				2		
Blood immunoglobulin E abnormal	1				1		
Blood immunoglobulin E decreased	1				1		
Blood immunoglobulin E increased	95	5	32	10	63		
Blood immunoglobulin G	2		1		1		
Blood immunoglobulin G abnormal	2				2	1	1
Blood immunoglobulin G decreased	26		4	3	22		
Blood immunoglobulin G increased	50		13	3	37		
Blood immunoglobulin M abnormal	1		1				
Blood immunoglobulin M decreased	15		3	1	12		
Blood immunoglobulin M increased	21		3	3	18		
Blood insulin	2				2		
Blood insulin abnormal	6	1	3	2	3		
Blood insulin decreased	3		1	1	2		
Blood insulin increased	5		2	1	3		
Blood iron	2		1		1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood iron abnormal	10		3	2	7		
Blood iron decreased	201	13	77	21	124	1	6
Blood iron increased	37		6	5	31		
Blood ketone body	5		1	1	4		
Blood ketone body increased	10		7		3		
Blood ketone body present	2		1		1		
Blood lactate dehydrogenase abnormal	7		2		5		
Blood lactate dehydrogenase decreased	10		3	1	7		
Blood lactate dehydrogenase increased	298	9	116	12	182		
Blood lactic acid	14		3	1	11		
Blood lactic acid abnormal	4				4		
Blood lactic acid decreased	5	1	3		2		
Blood lactic acid increased	82	5	44	2	38		
Blood lead	1				1		
Blood loss assessment	1			1	1		
Blood luteinising hormone abnormal	6				6		
Blood luteinising hormone decreased	6		2		4		
Blood luteinising hormone increased	9		3	1	6		
Blood magnesium abnormal	1				1		
Blood magnesium decreased	29		10	2	19		1
Blood magnesium increased	3		1		2		
Blood methaemoglobin present	2				2		
Blood oestrogen	2				2		
Blood oestrogen abnormal	8	1	4		4		
Blood oestrogen decreased	28	1	5	6	23		
Blood oestrogen increased	24		6		18		
Blood osmolarity decreased	7		6		1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood osmolarity increased	6		1	2	5		
Blood parathyroid hormone abnormal	4	1	2		2		
Blood parathyroid hormone decreased	3				3		
Blood parathyroid hormone increased	13			1	13		
Blood pH	2		2				
Blood pH abnormal	6		6				
Blood pH decreased	7		4		3		
Blood pH increased	23		13	1	10		
Blood phosphorus	1		1				
Blood phosphorus abnormal	1				1		
Blood phosphorus decreased	26	1	9	1	17		1
Blood phosphorus increased	14		3		11		
Blood potassium abnormal	12		4		8		
Blood potassium decreased	213	6	90	9	123		1
Blood potassium increased	84	2	27	6	57		2
Blood pressure abnormal	972	46	294	155	678	1	2
Blood pressure ambulatory abnormal	5		2		3		
Blood pressure ambulatory decreased	1		1				
Blood pressure ambulatory increased	17		5		12		
Blood pressure decreased	4158	141	1778	318	2380	2	11
Blood pressure diastolic	2				2		
Blood pressure diastolic abnormal	2		1		1	1	3
Blood pressure diastolic decreased	155	3	68	4	87	1	2
Blood pressure diastolic increased	175	5	56	6	119		4
Blood pressure difference of extremities	4		1	2	3		
Blood pressure immeasurable	51	3	39	2	12		
Blood pressure increased	15475	401	5604	891	9871	8	61

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood pressure measurement	67	2	19	3	48		
Blood pressure normal	6		1	1	5		
Blood pressure orthostatic	2	1	2				
Blood pressure orthostatic abnormal	4		2		2		
Blood pressure orthostatic decreased	6		3		3		
Blood pressure orthostatic increased	1				1		
Blood pressure systolic	8	1	5		3		
Blood pressure systolic abnormal	8	1	3		5	1	2
Blood pressure systolic decreased	112		60	4	52		
Blood pressure systolic increased	580	12	273	18	307	4	11
Blood pressure systolic inspiratory decreased	1				1		
Blood prolactin	3		1		2		
Blood prolactin abnormal	1			1	1		
Blood prolactin decreased	1			1	1		
Blood prolactin increased	34	3	7	4	27		
Blood pyruvic acid increased	1		1				
Blood selenium decreased	1			1	1		
Blood smear test abnormal	3				3		
Blood sodium abnormal	7		4		3		
Blood sodium decreased	135	3	60	4	75		3
Blood sodium increased	20	2	9		11		
Blood test	10		7		3		
Blood test abnormal	262	13	118	16	144		3
Blood test normal	2		1		1		
Blood testosterone abnormal	3	1	1	1	2		
Blood testosterone decreased	24	1	6	7	18		
Blood testosterone free decreased	1				1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood testosterone increased	11		3	3	8		
Blood thrombin increased	2				2		
Blood thromboplastin increased	1				1		
Blood thyroid stimulating hormone	2				2		
Blood thyroid stimulating hormone abnormal	28	2	5	2	23		
Blood thyroid stimulating hormone decreased	138	7	41	19	97		
Blood thyroid stimulating hormone increased	306	10	77	31	229		
Blood thyroid stimulating hormone normal	1				1		
Blood triglycerides abnormal	10				10		
Blood triglycerides decreased	4		1		3		
Blood triglycerides increased	102	2	19	11	83		1
Blood urea	1				1		
Blood urea abnormal	8		1		7		
Blood urea decreased	27		8	2	19		
Blood urea increased	161	2	39	11	122		
Blood urea nitrogen/creatinine ratio decreased	1				1		
Blood urea nitrogen/creatinine ratio increased	4		1		3		
Blood uric acid	2	1	1		1		
Blood uric acid abnormal	10		1	2	9		
Blood uric acid decreased	10		1		9		
Blood uric acid increased	83		25	6	58		
Blood urine	77		33	2	44		
Blood urine present	563	13	188	47	375	1	4
Blood viscosity abnormal	4				4		
Blood viscosity decreased	2		1		1		
Blood viscosity increased	16	1	5		11		
Blood zinc abnormal	1				1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood zinc decreased	11	1	1	2	10		
Blood zinc increased	3			2	3		
B-lymphocyte count abnormal	2				2		
B-lymphocyte count decreased	8		3		5	1	1
B-lymphocyte count increased	2				2		
Body height abnormal	1				1		
Body height decreased	66	1	4	7	62		
Body mass index	1		1				
Body mass index abnormal	2				2		
Body mass index increased	10			1	10		
Body temperature	265	1	69	4	196		
Body temperature abnormal	913	12	225	163	688		2
Body temperature decreased	772	11	172	72	600	1	6
Body temperature fluctuation	430	8	128	41	302		
Body temperature increased	15775	62	917	2188	14858	5	22
Body temperature normal	6				6		
Bone density abnormal	4		1	1	3		
Bone density decreased	8		2	2	6		
Bone density increased	1		1				
Bone marrow myelogram abnormal	2		2				
Borrelia test positive	21	1	6	3	15		
Brachial pulse decreased	5	1	3		2		2
Brachial pulse increased	6	2	3		3		
Brain natriuretic peptide	1		1				
Brain natriuretic peptide abnormal	7		4	1	3		
Brain natriuretic peptide decreased	1		1				
Brain natriuretic peptide increased	153	5	77	6	76		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Brain scan abnormal	6		3		3	1	1
Brain scan normal	1				1		
Breast scan	1		1				
Breast scan abnormal	1				1		
Breath sounds	32	3	7	2	25		
Breath sounds abnormal	147	5	75	14	72		3
Brucella test positive	1		1				
Calcium ionised decreased	5		3		2		
Calcium ionised increased	3		1		2		
Campylobacter test positive	5		1	1	4		
Capillary fragility increased	6		2		4		
Capillary nail refill test	1				1		
Capillary nail refill test abnormal	17		7	1	10		
Capillary permeability	1				1		
Capillary permeability increased	5		5				1
Carbohydrate antigen 125 increased	14		3	1	11		
Carbohydrate antigen 15-3 increased	9		2	1	7		
Carbohydrate antigen 19-9 increased	5	1	3		2		
Carbon dioxide abnormal	2				2		
Carbon dioxide decreased	13		1	1	12		
Carbon dioxide increased	11		5		6		
Carboxyhaemoglobin decreased	1		1				
Carboxyhaemoglobin increased	3		1		2		
Carcinoembryonic antigen increased	19		19				
Cardiac clearance	1				1		
Cardiac function test abnormal	8	1	4		4		
Cardiac imaging procedure abnormal	3		2		1		

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Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cardiac index increased	1		1				
Cardiac monitoring abnormal	1			1	1		
Cardiac murmur	180	5	83	13	97		5
Cardiac murmur functional	2		1		1		
Cardiac output	2		1		1		
Cardiac output decreased	18	4	14	2	4		
Cardiac stress test abnormal	8		3		5		
Cardiac stress test normal	1				1		
Cardio-ankle vascular index	1				1		
Cardiolipin antibody	2		1		1		
Cardiolipin antibody positive	14		2	2	12		
Cardiopulmonary exercise test abnormal	2		1		1		
Cardiothoracic ratio increased	8		2		6		
Cardiovascular autonomic function test abnormal	1			1	1		
Cardiovascular examination abnormal	1	1	1				
Cardiovascular function test abnormal	1		1				
Carotid bruit	4		3		1		
Carotid intima-media thickness increased	2		2				
Carotid pulse	4		1		3		
Carotid pulse abnormal	3				3		
Carotid pulse decreased	1				1		
Carotid pulse increased	1				1		
Catecholamines urine increased	1				1		
Catheterisation cardiac	8		5		3		
Catheterisation cardiac abnormal	1				1		
CD19 lymphocytes decreased	2			1	2		
CD19 lymphocytes increased	1				1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
CD30 expression	1			1	1		
CD4/CD8 ratio	1	1	1				
CD4/CD8 ratio decreased	1				1		
CD4/CD8 ratio increased	6				6		
CD4 lymphocyte percentage increased	1				1		
CD4 lymphocytes decreased	12		4	3	8		
CD4 lymphocytes increased	3			1	3		
CD8 lymphocyte percentage decreased	2			1	2		
CD8 lymphocytes decreased	3				3		
CD8 lymphocytes increased	2		1		1		
Cell marker decreased	1		1				
Cell marker increased	2	1	1		1		
Cells in urine	2		2				1
Central venous pressure abnormal	2		1		1		
Ceruloplasmin decreased	2				2		
Ceruloplasmin increased	1				1		
Chemokine increased	2		1		1		
Chest expansion decreased	3				3		
Chest scan	1				1		
Chest X-ray	7		2		5		
Chest X-ray abnormal	46	1	22	3	24		
Chest X-ray normal	4		1		3		
Chlamydia test positive	7	1	1	1	6		
Chromosome analysis abnormal	1		1				
Circulating anticoagulant positive	4	1	3	1	1		
Clostridium test	1	1	1				
Clostridium test positive	7	2	7				

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Investigations

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Clot retraction	3		2		1		
Clot retraction abnormal	1				1		
Coagulation factor decreased	2	1	1		1		
Coagulation factor increased	11		6	2	5		
Coagulation factor VIII level	1			1	1		
Coagulation factor VIII level abnormal	1		1				
Coagulation factor VIII level decreased	5		2	1	3		
Coagulation factor VIII level increased	10	1	6	1	4		
Coagulation factor VII level decreased	1		1				
Coagulation factor VII level increased	1				1		
Coagulation factor V level abnormal	2		1		1		
Coagulation factor V level decreased	1		1				
Coagulation factor XIII level decreased	2		1		1		
Coagulation factor XII level increased	1			1	1		
Coagulation test abnormal	19		9		10		
Coagulation time	1				1		
Coagulation time abnormal	2		1		1		
Coagulation time prolonged	29		9	3	20		
Coagulation time shortened	11	1	4	1	7		
Cold agglutinins	2				2		
Cold agglutinins positive	1				1		
Colonoscopy	2				2		
Colonoscopy abnormal	2				2		
Colonoscopy normal	1				1		
Coma scale	2		2				
Coma scale abnormal	62	1	54	3	8		
Coma scale normal	1		1				

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Investigations

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Complement factor abnormal	1				1		
Complement factor C1 increased	1				1		
Complement factor C3	1			1	1		
Complement factor C3 decreased	7		3		4		
Complement factor C3 increased	9		1	2	8		
Complement factor C4 decreased	4		1		3		
Complement factor C4 increased	3			2	3		
Complement factor decreased	5		4		1		
Complement factor increased	9	2	4	1	5		
Computerised tomogram	1		1				
Computerised tomogram abdomen	1				1		
Computerised tomogram abdomen abnormal	2		2				
Computerised tomogram abnormal	22	2	8	3	14		
Computerised tomogram head	3	1	3				
Computerised tomogram head abnormal	5	1	2		3		
Computerised tomogram liver abnormal	1				1		
Computerised tomogram normal	1				1		
Computerised tomogram pancreas abnormal	2		2				
Computerised tomogram thorax	3				3		
Computerised tomogram thorax abnormal	6		3		3		
Conjunctival staining	2				2		
Coombs direct test positive	4		3	1	1		
Coombs test positive	4		1	1	3		
Corneal reflex decreased	24		15		9		
Coronavirus test	3		3				
Coronavirus test negative	1				1		
Coronavirus test positive	11		7		4		2

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System Organ Class

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cortisol abnormal	8		1	2	7		
Cortisol decreased	22	4	13		9		
Cortisol free urine increased	1		1				
Cortisol increased	17		3		14		
Coxiella test positive	2		2				
Coxsackie virus test positive	4		2		2		
C-reactive protein	10		2		8		
C-reactive protein abnormal	61	3	27	4	34		
C-reactive protein decreased	26		7	1	19		1
C-reactive protein increased	2662	79	1148	143	1514		5
Creatine urine decreased	1		1				
Creatine urine increased	3			1	3		
Creatinine renal clearance abnormal	2		1		1		
Creatinine renal clearance decreased	9		5	1	4		
Creatinine renal clearance increased	2		1		1		
Creatinine urine decreased	3		1	1	2		
Creatinine urine increased	2		1		1		
Cryoglobulins present	1				1		
Crystal urine	2		1		1		
Crystal urine present	1				1		
CSF cell count abnormal	3		3				
CSF cell count decreased	1				1		
CSF cell count increased	29	2	29				
CSF culture positive	2		2				
CSF glucose decreased	4	1	4				
CSF glucose increased	13	1	13				
CSF immunoglobulin increased	9	2	9				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
CSF lactate increased	2		2				
CSF lymphocyte count abnormal	1		1				
CSF lymphocyte count increased	7	1	7				
CSF mononuclear cell count decreased	1				1		
CSF mononuclear cell count increased	2	1	2				
CSF myelin basic protein increased	4		4				
CSF neutrophil count positive	1		1				
CSF oligoclonal band	6	2	6				
CSF oligoclonal band present	20		20				
CSF polymorphonuclear cell count increased	2		2				
CSF pressure	2		1		1		1
CSF pressure abnormal	2		2				
CSF pressure decreased	3	2	2		1		
CSF pressure increased	11	2	11				
CSF protein	1		1				
CSF protein abnormal	3	1	3				
CSF protein decreased	5	1	1	1	4		
CSF protein increased	120	10	120				
CSF red blood cell count positive	6		6				
CSF test abnormal	33	6	33				
CSF virus identified	1		1				
CSF volume decreased	2		2				
CSF volume increased	5	2	3		2		
CSF white blood cell count increased	6	1	6				
CSF white blood cell count positive	1		1				
Culture negative	1		1				
Culture positive	2		1		1		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Culture throat positive	1		1				
Culture urine positive	6		1		5		
Culture wound	1				1		
Cyst aspiration	1		1				
Cyst aspiration abnormal	1		1				
Cystatin C increased	3		1		2		
Cystoscopy	1		1				
Cytogenetic analysis abnormal	1		1				
Cytokine abnormal	2				2		
Cytokine increased	6	1	3	1	3		
Cytokine test	1		1				
Cytology abnormal	3		2		1		
Cytomegalovirus test positive	32		9	2	23	1	1
Dehydroepiandrosterone increased	1				1		
Dengue virus test positive	15	8	10	1	5		
Dermatologic examination abnormal	2		1		1		
Diagnostic procedure	1				1		
Differential white blood cell count	2		1		1		
Differential white blood cell count abnormal	9		3		6		1
Diffusion-weighted brain MRI abnormal	6		3		3		
Digestive enzyme abnormal	6				6		
Digestive enzyme decreased	2				2		
Disability assessment scale score increased	1		1				
DNA antibody positive	1				1		
Donor specific antibody present	1	1	1				
Double stranded DNA antibody positive	2		1		1		
Drug clearance increased	1		1				

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Drug level above therapeutic	1				1		
Drug level decreased	10		2	2	8		
Drug level fluctuating	1		1				
Drug level increased	10		3	1	7		
Drug screen positive	4		2		2		
Drug specific antibody	1				1		1
Drug specific antibody absent	2		1		1	1	1
Drug specific antibody present							1
Ear, nose and throat examination abnormal	4		1		3		
Eastern Cooperative Oncology Group performance status wo	2		1		1		
ECG P wave inverted	2		1		1		
ECG signs of myocardial ischaemia	2	1	2				
Echocardiogram	23		1		22		
Echocardiogram abnormal	79	1	12	6	67		
Echocardiogram normal	8		1		7		
Ejection fraction	6		4		2		
Ejection fraction abnormal	20		11	2	9		
Ejection fraction decreased	226	24	156	12	70		1
Electrocardiogram	46		2		44		
Electrocardiogram abnormal	712	15	223	31	489	2	3
Electrocardiogram ambulatory	5	1	1		4		
Electrocardiogram ambulatory abnormal	7		2	2	5		
Electrocardiogram change	36	1	23	2	13		
Electrocardiogram J wave abnormal	2	1	2				
Electrocardiogram J wave increased	1				1		
Electrocardiogram low voltage	6		2		4		
Electrocardiogram normal	28		2		26		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Electrocardiogram PR prolongation	9	1	7		2		
Electrocardiogram PR segment depression	24		2		22		
Electrocardiogram PR segment elevation	2		1		1		
Electrocardiogram PR shortened	13	2	13				
Electrocardiogram P wave abnormal	3		1		2		
Electrocardiogram QRS complex	1				1		
Electrocardiogram QRS complex abnormal	5		3		2		
Electrocardiogram QRS complex prolonged	17	2	17				
Electrocardiogram QRS complex shortened	25	3	25				
Electrocardiogram QT interval	1				1		
Electrocardiogram QT interval abnormal	4	1	4				
Electrocardiogram QT prolonged	51	4	51				1
Electrocardiogram QT shortened	1		1				
Electrocardiogram Q wave abnormal	10		10				
Electrocardiogram repolarisation abnormality	53	2	53				
Electrocardiogram R on T phenomenon	1		1				
Electrocardiogram ST segment	1				1		
Electrocardiogram ST segment abnormal	32	3	21	1	11		
Electrocardiogram ST segment depression	89	10	89				
Electrocardiogram ST segment elevation	427	24	427				
Electrocardiogram ST segment normal	1				1		
Electrocardiogram ST-T change	6		6				
Electrocardiogram ST-T segment abnormal	9		9				
Electrocardiogram ST-T segment depression	2		2				
Electrocardiogram ST-T segment elevation	4		4				
Electrocardiogram T wave abnormal	27		13	2	14		
Electrocardiogram T wave alternans	1		1				

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Electrocardiogram T wave amplitude decreased	6	1	2		4		
Electrocardiogram T wave amplitude increased	4	1	4				
Electrocardiogram T wave inversion	103	11	103				1
Electrocardiogram T wave peaked	5		3		2		
Electroencephalogram abnormal	36	6	21	4	15		
Electromyogram	1	1	1				
Electromyogram abnormal	8	1	4		4		
Electrophoresis abnormal	4		1		3		
Electrophoresis protein abnormal	4			1	4		
Emergency care examination	3		1		2		
Endocrine test abnormal	1				1		
Endoscopy abnormal	1			1	1		
Endoscopy upper gastrointestinal tract	1				1		
Enterobacter test positive	1				1		
Enterococcus test positive	2	1	1		1		
Enterovirus test positive	1				1		
Enzyme activity increased	1				1		
Enzyme level abnormal	1				1		
Enzyme level increased	6		3		3		
Eosinophil cationic protein increased	1			1	1		
Eosinophil count	2		1		1		
Eosinophil count abnormal	7		2		5		
Eosinophil count decreased	44		6	4	38		
Eosinophil count increased	139	4	57	8	82		
Eosinophil percentage abnormal	1		1				
Eosinophil percentage decreased	6		1		5		
Eosinophil percentage increased	13		3	2	10		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Epinephrine abnormal	4		1		3		
Epinephrine decreased	1		1				
Epinephrine increased	23	1	8	4	15		
Epstein-Barr virus antibody	2				2		
Epstein-Barr virus antibody positive	32		5	3	27		
Epstein-Barr virus antigen positive	5	1	3		2		
Epstein-Barr virus test positive	23		6	2	17		
Erythroblast count abnormal	1		1				
Erythroblast count increased	2	1	1		1		
Escherichia test positive	16		8		8		
Exercise electrocardiogram	1		1				
Exercise electrocardiogram abnormal	7		4		3		
Exercise electrocardiogram normal	1				1		
Expanded disability status scale	2			2	2		
Expanded disability status scale score increased	2	2	2				
Face and mouth X-ray	1		1				
Factor VIII activity decreased	2			2	2		
Faecal calprotectin	1		1				
Faecal calprotectin decreased	2				2		
Faecal calprotectin increased	31	2	12	2	19		
Faecal fat increased	2		1		1		
Faecal volume decreased	4				4		
Faecal volume increased	13	1	3	1	10		
False negative investigation result	1		1				
False negative pregnancy test	4		1	1	3		
False positive investigation result	13	2	4		9		
False positive radioisotope investigation result	1			1	1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
False positive tuberculosis test	1				1		
Female sex hormone level	2				2		
Female sex hormone level abnormal	7	2	5		2		
Femoral pulse	1				1		
FEV1/FVC ratio decreased	1		1				
Fibrin	1				1		
Fibrin abnormal	3	1	2		1		
Fibrin D dimer	20		2		18		
Fibrin D dimer decreased	11		3	1	8		
Fibrin D dimer increased	2181	75	923	108	1258	1	5
Fibrin D dimer normal	2				2		
Fibrin degradation products increased	21		14	1	7		
Fibrin increased	1				1		
Fibrinogen degradation products increased	2		1		1		
Fibrinolysis	3		2	1	1		
Fibrinolysis abnormal	1		1				
Fibrinolysis increased	3		3				
Fibroblast growth factor 23	1				1		
Fibroblast growth factor 23 increased	1				1		
Fluid balance negative	1	1	1				
Foetal heart rate abnormal	48	2	44	1	4		
Foetal heart rate decreased	9		9				1
Foetal heart rate increased	2		2				
Foetal monitoring	1		1				
Foetal monitoring abnormal	3		1	1	2		
Foetal non-stress test	1				1		
Foetal non-stress test abnormal	1		1				

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Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Forced expiratory flow	1		1				
Forced expiratory flow decreased	1		1				
Forced expiratory volume abnormal	1		1				
Forced expiratory volume decreased	2	1	1		1		
Forced expiratory volume increased	3		3				
Forced vital capacity decreased	1		1				
Foveal reflex abnormal	1		1				
Fractional exhaled nitric oxide abnormal	1		1				
Fractional exhaled nitric oxide increased	1			1	1		
Fractional exhaled nitric oxide normal	1				1		
Free prostate-specific antigen increased	1		1				
Free thyroxine index decreased	1		1				
Full blood count	5		2		3		
Full blood count abnormal	152	15	61	21	91		1
Full blood count decreased	17		5	3	12		
Full blood count increased	8		4	1	4		
Full blood count normal	5			1	5		
Functional residual capacity decreased	4		2		2		
Fundus autofluorescence	1			1	1		
Fungal test positive	10		5		5		
Gamma-glutamyltransferase	1		1				
Gamma-glutamyltransferase abnormal	11		6		5		
Gamma-glutamyltransferase decreased	10		4		6		
Gamma-glutamyltransferase increased	356	11	114	28	242		
Gastric pH	1		1				
Gastric pH decreased	37	1	8	6	29		
Gastrointestinal scan	1		1				

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Gastrointestinal stoma output increased	1		1				
General physical condition	3		2		1		
General physical condition abnormal	135	7	47	17	88		
General physical condition normal	1				1		
Globulins decreased	4			2	4		
Globulins increased	7		2		5		
Glomerular filtration rate abnormal	7		1	2	6		
Glomerular filtration rate decreased	194	5	68	13	126		1
Glomerular filtration rate increased	16		3	2	13		1
Glucocorticoids abnormal	1				1		
Glucose tolerance increased	1				1		
Glucose tolerance test abnormal	1		1				
Glucose urine present	12		3		9		
Glutamate dehydrogenase decreased	1				1		
Glutamate dehydrogenase increased	2				2		
Glutamate dehydrogenase level abnormal	1			1	1		
Glutathione s-transferase decreased	1				1		
Glycolysis increased	1		1				
Glycosylated haemoglobin abnormal	4		2		2		
Glycosylated haemoglobin decreased	2				2		
Glycosylated haemoglobin increased	150	7	39	16	111		
Gram stain positive	1		1				
Granulocyte count decreased	12	1	1	2	11		
Granulocyte count increased	7		4		3		
Granulocyte percentage decreased	1				1		
Granulocyte percentage increased	1				1		
Granulocytes abnormal	4			1	4		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Grip strength	3		1		2		
Grip strength decreased	500	13	190	64	310		1
Gustometry	1				1		
Gynaecological examination	2		1		1		
Gynaecological examination normal	2				2		
Haematocrit abnormal	12		2	2	10		
Haematocrit decreased	156	3	34	8	122	2	3
Haematocrit increased	67		20	6	47		
Haematology test abnormal	8	1	6		2		
Haemoglobin	1		1				
Haemoglobin abnormal	25	2	12	2	13		1
Haemoglobin decreased	614	31	273	38	341	2	10
Haemoglobin distribution width increased	1				1		
Haemoglobin increased	73		24	9	49		
Haemoglobin normal	1			1	1		
Haemoglobin urine	2		1		1		
Haemoglobin urine present	6		1		5		
Haptoglobin decreased	10		10				
Haptoglobin increased	6		3		3		
Head circumference abnormal	2		1		1		
Head lag	10		9		1		
Heart rate	241	4	118	4	123		
Heart rate abnormal	793	21	315	96	478		4
Heart rate decreased	1472	32	661	103	811	5	13
Heart rate increased	13221	325	4216	1355	9005	7	43
Heart rate irregular	2343	67	859	281	1484		7
Heart rate normal	9		2	2	7		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Heart rate variability decreased	13		7	2	6		
Heart rate variability increased	18	1	15	1	3		
Heart sounds	7		4		3		
Heart sounds abnormal	52	1	21	4	31		
Heavy metal abnormal	2		1	1	1		
Heavy metal increased	3	1	1		2		
Helicobacter test	1				1		
Helicobacter test positive	11	2	5		6		1
Heparin-induced thrombocytopenia test positive	6		4	1	2		
Hepatic enzyme	1				1		
Hepatic enzyme abnormal	65	3	28	3	37		
Hepatic enzyme decreased	2		2				1
Hepatic enzyme increased	412	19	187	24	225	1	7
Hepatitis A antibody abnormal	1				1		
Hepatitis A antibody negative	1	1	1				
Hepatitis A antibody positive	4		1		3		
Hepatitis A virus test positive	2				2		
Hepatitis B antibody abnormal	2		1	1	1		
Hepatitis B antibody negative	1				1		
Hepatitis B antibody positive	2		1		1		
Hepatitis B core antibody positive	1				1		
Hepatitis B surface antibody positive	5		1		4		
Hepatitis B surface antigen positive	1				1		
Hepatitis B test negative	1				1		
Hepatitis B virus test positive	1				1		
Hepatitis C antibody positive	2			1	2		
Hepatitis C virus test positive	2		1		1		

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Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Herpes simplex test positive	19	1	3	2	16		
Herpes virus test	1				1		
High density lipoprotein	1				1		
High density lipoprotein abnormal	2		2				
High density lipoprotein decreased	41		5	1	36		
High density lipoprotein increased	22		2	1	20		
Histamine abnormal	12		3	2	9		
Histamine level	1	1	1				
Histamine level increased	25	1	7	3	18		
Histone antibody positive	1				1		
HIV antibody	1				1		
HIV antibody positive	6		1		5		
HIV antigen positive	1				1		
HIV test	1		1				
HIV test false positive	7				7		
HIV test negative	1		1				
HIV test positive	8	1	3		5		
HLA-B*27 positive	7		2	1	5		
Homans' sign	1				1		
Homans' sign positive	5	1	1		4		
Hoover's sign of leg paresis	1		1				
Hormone level abnormal	1043	37	210	287	833		1
Human chorionic gonadotropin abnormal	1				1		
Human chorionic gonadotropin decreased	6		1	2	5		
Human chorionic gonadotropin increased	6		2		4		
Human chorionic gonadotropin positive	2				2		
Human epidermal growth factor receptor decreased	3		2		1		

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Human epidermal growth factor receptor increased	2				2		
Human herpes virus 6 serology positive	2	1	1		1		
Human metapneumovirus test positive	1				1		
Human papilloma virus test negative	1				1		
Human papilloma virus test positive	6	1	4	1	2		
Human rhinovirus test positive	2				2		
Hypophonesis	1				1		
Hysteroscopy	3	2	3				
Iliac bruit	1		1				
Imaging procedure abnormal	3		1	1	2		
Imaging procedure artifact	1		1				
Immature granulocyte count increased	11		1	4	10		
Immunoglobulins	1		1				
Immunoglobulins abnormal	6		1	2	5		
Immunoglobulins decreased	9		2	4	7		
Immunoglobulins increased	21		5	2	16		1
Immunology test	6		1	1	5		
Immunology test abnormal	11	1	4		7		
Immunosuppressant drug level decreased	1				1		
Inflammation scan	1		1				
Inflammatory marker decreased	2				2		
Inflammatory marker increased	391	26	203	43	188	3	7
Inflammatory marker test	1				1		
Influenza A virus test positive	3		1	1	2		
Influenza B virus test positive	1				1		
Influenza virus test positive	1				1		
Inspiratory capacity abnormal	4			1	4		

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Investigations

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Inspiratory capacity decreased	13		6		7		
Insulin C-peptide decreased	4		2		2		
Insulin tolerance test abnormal	1				1		
Intelligence test	1		1				
Interferon beta level increased	2		2				
Interferon gamma release assay positive	4		2		2		
Interleukin-2 receptor increased	8		2		6		
Interleukin level decreased	3			1	3		
Interleukin level increased	23	1	10	6	13		
International normalised ratio abnormal	37		17	4	20		
International normalised ratio decreased	92	1	33	4	59		1
International normalised ratio fluctuation	26	1	11		15		
International normalised ratio increased	260	3	128	7	132		
Intestinal transit time	1			1	1		
Intestinal transit time abnormal	3				3		
Intestinal transit time decreased	4				4		
Intestinal transit time increased	1				1		
Intra-abdominal pressure increased	1				1		
Intraocular pressure increased	167	10	68	9	99		
Intraocular pressure test	18		3	5	15		
Intraocular pressure test abnormal	21	1	6	2	15		
Investigation	3		1		2		
Investigation abnormal	12		3	1	9		1
Iodine uptake decreased	3		1		2		
Iodine uptake increased	1		1				
Iron binding capacity total abnormal	2		1		1		
Iron binding capacity total decreased	1				1		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Iron binding capacity total increased	1		1				
Iron binding capacity unsaturated increased	2				2		
JC polyomavirus test positive	2			2	2		
Joint position sense decreased	1		1				
KL-6 increased	3		1	1	2		
Klebsiella test positive	6	1	3	1	3		1
Laboratory test abnormal	93	2	39	5	54	2	4
Laboratory test interference	2				2		
Laboratory test normal	1				1		
Lactate dehydrogenase urine increased	1		1				
Lactobacillus test positive	1				1		
Laparoscopy	1		1				
Laparoscopy abnormal	1		1				
Laryngoscopy	1				1		
Lasegue's test positive	3		1	1	2		
LE cells present	2				2		
Left ventricular end-diastolic pressure increased	5		3		2		
Legionella test positive	2				2		
Leucine aminopeptidase increased	3				3		
Leukocyte alkaline phosphatase increased	1		1				
Light chain analysis abnormal	1				1		
Light chain analysis increased	13	2	3	2	10		
Limb girth decreased	2		1		1		
Limb girth increased	5	1	1	1	4		
Lipase abnormal	4		1		3		
Lipase decreased	6				6		
Lipase increased	107	3	33	6	74		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lipids	1		1				
Lipids abnormal	12		3		9		
Lipids decreased	1				1		
Lipids increased	14		4	1	10		
Lipoprotein (a) increased	6			2	6		
Lipoprotein increased	2				2		
Listeria test positive	2				2		
Liver function test	1				1		
Liver function test abnormal	333	17	147	31	186		2
Liver function test decreased	7		2		5		
Liver function test increased	220	12	100	13	120		
Liver-kidney microsomal antibody positive	1		1				
Liver scan	1		1				
Liver scan abnormal	1		1				
Low density lipoprotein	1		1				
Low density lipoprotein abnormal	5		1	1	4		
Low density lipoprotein decreased	6		1		5		
Low density lipoprotein increased	157	5	22	20	135		1
Lumbar puncture	11	1	6		5		
Lumbar puncture abnormal	4		4				
Lung diffusion test abnormal	1		1				
Lung diffusion test decreased	2		2				
Lymph node palpable	206	3	22	28	184		
Lymph nodes scan abnormal	9	1	4		5		
Lymphocyte count	5			1	5		
Lymphocyte count abnormal	17		3	3	14		
Lymphocyte count decreased	215	5	53	18	162		4

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lymphocyte count increased	119	1	27	13	92		
Lymphocyte morphology abnormal	22		6		16		
Lymphocyte percentage abnormal	3		1		2		
Lymphocyte percentage decreased	28		2		26		1
Lymphocyte percentage increased	9		1		8		
Lymphocyte stimulation test positive	2		1		1		
Lysozyme increased	2		1		1		
Magnetic resonance imaging	4		1		3		
Magnetic resonance imaging abdominal	1				1		
Magnetic resonance imaging abnormal	48	3	19	7	29		1
Magnetic resonance imaging breast abnormal	1				1		
Magnetic resonance imaging head	5	1	2		3		
Magnetic resonance imaging head abnormal	31	2	20	3	11		
Magnetic resonance imaging heart	6			1	6		
Magnetic resonance imaging spinal abnormal	7	1	5		2		
Male genital examination abnormal	1		1				
Mammogram abnormal	15	1	3	2	12		
Mast cell degranulation present	2		1		1		
Matrix metalloproteinase-3 increased	5		1		4		
Maximal voluntary ventilation	2		1		1		
Maximum heart rate	6	1	4	1	2		
Maximum heart rate increased	4		3		1		
Mean arterial pressure decreased	3		2		1		
Mean arterial pressure increased	9		3		6		
Mean cell haemoglobin	3		1		2		
Mean cell haemoglobin concentration	1				1		
Mean cell haemoglobin concentration abnormal	3		2		1		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mean cell haemoglobin concentration decreased	37		3	1	34		
Mean cell haemoglobin concentration increased	28		2	4	26		
Mean cell haemoglobin decreased	34		4		30		2
Mean cell haemoglobin increased	23		2	1	21		
Mean cell volume abnormal	14		4		10		
Mean cell volume decreased	35		5		30		2
Mean cell volume increased	41		9	5	32		
Mean platelet volume decreased	15		4	1	11		
Mean platelet volume increased	20		3		17		
Measles antibody positive	1				1		
Megakaryocytes	1				1		
Megakaryocytes abnormal	1				1		
Megakaryocytes increased	4	1	3		1		
Menstruation normal	53	1	5	11	48		
Metabolic function test abnormal	6		1	1	5		
Metamyelocyte count increased	4		2		2		
Metamyelocyte percentage increased	2				2		
Mini mental status examination abnormal	1		1				
Misleading laboratory test result	1				1		
Monoblast count decreased	2		1		1		
Monoblast count increased	2				2		
Monoclonal immunoglobulin increased	2		1	1	1		1
Monoclonal immunoglobulin present	4				4		
Monocyte count abnormal	8		2		6		
Monocyte count decreased	30		7	4	23		
Monocyte count increased	114	3	22	6	92		
Monocyte percentage abnormal	2		1		1		

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Monocyte percentage decreased	2		1		1		
Monocyte percentage increased	15		1		14		1
Mononuclear cell count increased	4		3		1		
Mumps antibody test positive	1				1		
Muscle enzyme	1				1		
Muscle enzyme increased	8		3	2	5		
Muscle strength abnormal	120	7	34	22	86		1
Mycobacterium tuberculosis complex test positive	2				2		1
Mycoplasma test positive	12	1	5		7		
Myelocyte count decreased	1				1		
Myelocyte count increased	5		2		3		
Myocardial necrosis marker	1		1				
Myocardial necrosis marker increased	164	18	164			1	2
Myocardial strain imaging	7		3		4		
Myocardial strain imaging abnormal	5		2		3		
Myoglobin blood decreased	3		1		2		
Myoglobin blood increased	25	3	19		6		
Myoglobin urine	1			1	1		
Nasopharyngeal swab	1		1				
Natural killer cell activity abnormal	1			1	1		
Natural killer cell activity decreased	2			1	2		
Natural killer cell count decreased	7	1	1	2	6		
Natural killer cell count increased	2			1	2		
Natural killer T cell count decreased	1		1				
Natural killer T cell count increased	3				3		
Nerve conduction studies	1				1		
Nerve conduction studies abnormal	24		9	4	15		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Nerve stimulation test abnormal	3			2	3		
Neurological examination abnormal	17		4	1	13		
Neurological examination normal	3				3		
Neurone-specific enolase increased	3	1	3				
Neurotransmitter level altered	2			1	2		
Neutralising antibodies negative	3				3		
Neutrophil count	3		2		1		
Neutrophil count abnormal	21		7		14		1
Neutrophil count decreased	140	1	59	8	81	1	2
Neutrophil count increased	245	2	61	12	184		1
Neutrophil gelatinase-associated lipocalin increased	1		1				
Neutrophil/lymphocyte ratio decreased	1				1		
Neutrophil/lymphocyte ratio increased	1				1		
Neutrophil morphology abnormal	1		1				
Neutrophil percentage abnormal	3		2		1		
Neutrophil percentage decreased	11		2	1	9		
Neutrophil percentage increased	26		5	1	21		1
NIH stroke scale abnormal	1				1		
NIH stroke scale score decreased	2		1		1		
NIH stroke scale score increased	2		1		1		
Nitrite urine present	8		2		6		1
Non-high-density lipoprotein cholesterol increased	6				6		
Norepinephrine increased	3				3		
Norovirus test positive	1				1		
N-terminal prohormone brain natriuretic peptide	1		1				
N-terminal prohormone brain natriuretic peptide decreased	1				1		
N-terminal prohormone brain natriuretic peptide increased	166	16	103	5	63		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Nutritional assessment	1				1		
Nutritional condition abnormal	3	1	1		2		1
NYHA classification	1		1				
Occult blood	3		1	1	2		
Occult blood positive	13		6	1	7		
Oculomotor study abnormal	1		1				
Oesophagogastroscopy normal	1				1		
Oestradiol abnormal	1		1				
Oestradiol decreased	3			1	3		
Oestradiol increased	8		1		7		
Ophthalmological examination	1		1				
Ophthalmological examination abnormal	3				3		
Opiates	1				1		
Opiates positive	1		1				
Orthopaedic examination abnormal	2		1		1		
Orthostatic heart rate response increased	1				1		
Osmolar gap increased	1				1		
Osteoprotegerin ligand decreased	1				1		
Otoscopy abnormal	1				1		
Oxygenation index	1			1	1		
Oxygen consumption decreased	35	3	11	5	24		1
Oxygen consumption increased	4		2		2		
Oxygen saturation	24		10	6	14		
Oxygen saturation abnormal	131	4	45	31	86	1	2
Oxygen saturation decreased	2983	117	2067	91	916	3	25
Oxygen saturation immeasurable	11	1	9	1	2		
Oxygen saturation increased	13		5	1	8		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Oxygen saturation normal	6			5	6		
Pain assessment	3		1		2		
Pain threshold decreased	7		2	2	5		
Palpatory finding abnormal	3		1		2		
Pancreatic enzymes decreased	2				2		
Pancreatic enzymes increased	20	1	15	2	5		
PaO2/FiO2 ratio decreased	1		1				
Paracentesis	1				1		
Parasite stool test positive	2				2		
Parasitic test positive	1		1				
Parvovirus B19 test positive	6		1		5		
Pathology test	1				1		
PCO2 abnormal	1		1				
PCO2 decreased	16	1	7		9		
PCO2 increased	16	1	5		11		
Peak expiratory flow rate	1		1				
Peak expiratory flow rate abnormal	3		3				
Peak expiratory flow rate decreased	20		20				
Pedal pulse abnormal	1		1				
Perfusion brain scan abnormal	1				1		
Peripheral pulse decreased	5		4		1		
Phalen's test positive	2		1		1		
pH body fluid	1		1				
pH body fluid abnormal	3				3		
pH body fluid decreased	2				2		
pH body fluid increased	2	1	2				
Philadelphia chromosome positive	2		2				

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
pH urine	4		1		3		
pH urine abnormal	1		1				
pH urine increased	8		2		6		
Physical capacity evaluation	4			2	4		
Physical examination abnormal	2		1		1		
Pituitary scan abnormal	1				1		
Placenta growth factor	1		1				
Plasma cells increased	1				1		
Plasma viscosity abnormal	2		2				
Platelet aggregation abnormal	4		2		2		
Platelet aggregation increased	4		2		2		
Platelet count	2				2		
Platelet count abnormal	38	3	18	1	20		1
Platelet count decreased	1085	33	576	37	509	2	10
Platelet count increased	282	3	77	24	205	1	3
Platelet count normal	1		1				
Plateletcrit abnormal	1		1				
Plateletcrit decreased	4				4		
Plateletcrit increased	3		1		2		
Platelet distribution width decreased	7		1		6		
Platelet distribution width increased	4		1	1	3		
Platelet factor 4	2		2				
Platelet factor 4 decreased	1		1				
Platelet factor 4 increased	3	1	3				
Platelet function test abnormal	3		1		2		
Platelet morphology abnormal	6				6		
Pleural fluid analysis abnormal	3		3				

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
PO2 abnormal	3		1	2	2		
PO2 decreased	45	2	27		18		
PO2 increased	8	1	4		4		
Polymerase chain reaction	4		2		2		
Polymerase chain reaction positive	21		7		14		
Positron emission tomogram	1			1	1		
Positron emission tomogram abnormal	5				5		
Prealbumin decreased	1		1				
Pregnancy test	2				2		
Pregnancy test false positive	2		1		1		
Pregnancy test negative	7				7		
Pregnancy test positive	2				2		
Pregnancy test urine negative	1		1				
Procalcitonin abnormal	2				2		
Procalcitonin decreased	5				5		
Procalcitonin increased	35		17		18		
Product residue present	4		2		2		
Progesterone abnormal	4			1	4		
Progesterone decreased	19	1	4	4	15		
Progesterone increased	3		1		2		
Prohormone brain natriuretic peptide abnormal	1				1		
Prohormone brain natriuretic peptide increased	11		5	1	6		
Promyelocyte count increased	1				1		
Prostate examination abnormal	1				1		
Prostatic specific antigen abnormal	1				1		
Prostatic specific antigen decreased	15			6	15		
Prostatic specific antigen increased	95	3	29	15	66	1	1

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Protein albumin ratio	1				1		
Protein C decreased	3		1		2		
Protein C increased	26	1	14		12		
Protein S abnormal	1		1				
Protein S decreased	5		3		2		
Protein S increased	3		1	1	2		
Protein total abnormal	9	1	5	1	4		
Protein total decreased	59	1	9	5	50		1
Protein total increased	40	1	13	3	27		
Protein urine	27	1	10	4	17		
Protein urine absent	1		1				
Protein urine present	83	3	31	2	52		
Proteus test positive	3		1	1	2		
Prothrombin consumption time shortened	1				1		
Prothrombin level abnormal	3		1		2		
Prothrombin level decreased	8		4		4		
Prothrombin level increased	8	1	5		3		
Prothrombin time abnormal	10	1	3	1	7		
Prothrombin time prolonged	54	1	19	1	35		1
Prothrombin time ratio abnormal	1				1		
Prothrombin time ratio decreased	6		2		4		
Prothrombin time ratio increased	11		2	1	9		
Prothrombin time shortened	33		10		23		
Pseudomonas test positive	2		1		1		
Psoriasis area severity index decreased	2		1		1		
Pulmonary arterial pressure abnormal	1		1				
Pulmonary arterial pressure increased	29	1	18		11		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pulmonary arterial wedge pressure decreased	1				1		
Pulmonary arterial wedge pressure increased	1		1				
Pulmonary function test	1		1				
Pulmonary function test abnormal	7		4	1	3		
Pulmonary function test decreased	110	12	41	26	69		1
Pulmonary imaging procedure abnormal	1				1		
Pulmonary physical examination abnormal	1		1				
Pulse abnormal	483	18	155	97	328		
Pulse absent	106	10	75	4	31		
Pulse pressure abnormal	4			2	4		
Pulse pressure decreased	12	1	8		4		
Pulse pressure increased	29		5	5	24		
Pulse volume decreased	21		7		14		
Pulse waveform	1	1	1				
Pulse waveform abnormal	5	1	1		4		
Pupil dilation procedure	2			1	2		
Pupillary light reflex tests abnormal	5		4	1	1		
Pus in stool	1		1				
Pyruvate kinase increased	2				2		
QRS axis abnormal	12		5	1	7		
Quality of life decreased	657	20	203	95	454		3
Radial pulse abnormal	26		20		6		
Radial pulse decreased	5		3		2		
Radial pulse increased	3		2		1		
Radioisotope uptake increased	3	2	3				
Red blood cell analysis abnormal	1		1				
Red blood cell anisocytes present	1		1				

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Red blood cell count abnormal	13	1	6		7	1	1
Red blood cell count decreased	217	6	58	19	159		2
Red blood cell count increased	81		14	10	67		
Red blood cell morphology abnormal	4		3		1		
Red blood cell nucleated morphology	1				1		
Red blood cell rouleaux formation present	3		1	1	2		
Red blood cell schistocytes present	1		1				
Red blood cell sedimentation rate	2	1	1		1		
Red blood cell sedimentation rate abnormal	19		10		9		
Red blood cell sedimentation rate decreased	14		2	1	12		
Red blood cell sedimentation rate increased	409	13	139	24	270		1
Red blood cells urine	5		3		2		
Red blood cells urine positive	21	1	9		12		1
Red cell distribution width abnormal	2	1	2				
Red cell distribution width decreased	13		3		10		
Red cell distribution width increased	41	1	8	1	33		2
Renal function test	1			1	1		
Renal function test abnormal	41		20	2	21		
Renin	1				1		
Renin decreased	2			2	2		
Renin increased	4				4		
Respiratory rate	7		1	1	6		
Respiratory rate decreased	133	5	60	13	73		
Respiratory rate increased	518	8	230	46	288		6
Respiratory sinus arrhythmia magnitude	1				1		
Respiratory sinus arrhythmia magnitude abnormal	1		1				
Respiratory syncytial virus test positive	4		1	1	3		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Reticulocyte count decreased	4		1	1	3		
Reticulocyte count increased	9		5	1	4		
Reticulocyte percentage increased	1				1		
Retinogram abnormal	2		2				
Rhesus antibodies positive	2		1		1		
Rhesus antigen negative	1				1		
Rhesus antigen positive	1		1				
Rheumatoid factor	6	2	2	1	4		
Rheumatoid factor decreased	1			1	1		
Rheumatoid factor increased	89	6	34	14	55		
Rheumatoid factor positive	29		12	2	17		
Right atrial volume abnormal	1		1				
Right atrial volume decreased	1				1		
Right ventricular ejection fraction decreased	1		1				
Right ventricular systolic pressure increased	2		2				
Rinne tuning fork test abnormal	1				1		
Romberg test positive	19	3	11	1	8		
Roseolovirus test positive	2				2		
Rubella antibody positive	2				2		
Rubivirus test positive	1				1		
Rubulavirus test positive	2				2		
Salmonella test positive	4	1	3		1		
SARS-CoV-1 test negative	2				2		
SARS-CoV-1 test positive	4		1		3		
SARS-CoV-2 antibody test	20		3		17		
SARS-CoV-2 antibody test negative	399		28	1	371		
SARS-CoV-2 antibody test positive	101	1	14		87		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
SARS-CoV-2 test	7		5		2		
SARS-CoV-2 test false negative	2				2		
SARS-CoV-2 test false positive	19		4	2	15		
SARS-CoV-2 test negative	98		26	4	72		
SARS-CoV-2 test positive	1078	27	826	3	252		27
Scan abdomen abnormal	1		1				
Scan abnormal	2		1		1		
Scan gallium abnormal	1		1				
Scan lymph nodes	3		1		2		
Scan myocardial perfusion abnormal	1		1				
Schellong test	1				1		
Schirmer's test abnormal	2			1	2		
Semen analysis abnormal	3			1	3		
Semen viscosity decreased	1				1		
Semen viscosity increased	1				1		
Semen volume abnormal	1				1		
Semen volume decreased	4				4		
Semen volume increased	3			1	3		
Sensory level	4		2		2		
Sensory level abnormal	263	15	59	46	204		1
Seroconversion test negative	5	1	3		2		
Serology abnormal	2			1	2		
Serology negative	3				3		
Serratia test positive	2		1		1		
Serum amyloid A protein increased	1				1		
Serum colour abnormal	1		1				
Serum ferritin	1		1				

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Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Serum ferritin abnormal	8		6		2		
Serum ferritin decreased	108	7	50	20	58		
Serum ferritin increased	173	4	62	10	111		
Serum serotonin decreased	2			2	2		
Serum serotonin increased	1				1		
Shift to the left	4		1		3		
Shift to the right	1				1		
Sigmoidoscopy abnormal	1		1				
Sinus rhythm	71	6	28	7	43		1
Skeletal muscle enzymes	2			2	2		
Skin temperature	40	1	21		19		
Skin test positive	25		5	1	20		
Skin turgor decreased	5		2	1	3		
Skull X-ray	2		1		1		
Slow vital capacity	1				1		
Smear cervix	2		1		1		
Smear cervix abnormal	12	1	3	1	9		
Smear cervix normal	1			1	1		
Smear site unspecified abnormal	1	1	1				
Smooth muscle antibody positive	4		4				
Soluble fibrin monomer complex increased	1		1				
Somatosensory evoked potentials abnormal	3		1		2		
Specific gravity urine decreased	3		1		2		
Specific gravity urine increased	3		1		2		
Sperm analysis abnormal	1				1		
Spermatozoa abnormal	5	1	1		4		
Sperm concentration abnormal	2		2				

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Sperm concentration decreased	9	2	6	1	3		
Sperm concentration increased	1				1		
Spinal myelogram abnormal	1				1		
Spirometry abnormal	4		2	1	2		
Sputum abnormal	35	3	12	2	23		
Sputum normal	1				1		
Staphylococcus test positive	12	1	5	1	7		
Stenotrophomonas test positive	2		2				
Streptobacillus test positive	1				1		
Streptococcus test positive	17	1	9	1	8		
Stress echocardiogram abnormal	2		1		1		
Stroke volume decreased	2		2				
Strongyloides test positive	1				1		
Surfactant protein increased	2			1	2		
Sweat test	1		1				
Swollen joint count	2		1	1	1		
Swollen joint count increased	1		1				
Synovial fluid analysis abnormal	2		1	1	1		
Synovial fluid crystal present	2				2		
Synovial fluid white blood cells positive	2		2				
Systemic lupus erythematosus disease activity index abnorm	1		1				
Systemic lupus erythematosus disease activity index decrea	1				1		
Tandem gait test abnormal	3			1	3		
Temperature difference of extremities	34	2	18	2	16		1
Temperature perception test abnormal	12	1	5	3	7		
Temperature perception test decreased	9		1	1	8		
Temperature perception test increased	15		1	2	14		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tender joint count	2		1		1		
Thermometry abnormal	3				3		
Thrombin-antithrombin III complex abnormal	1				1		
Thrombin-antithrombin III complex increased	1		1				
Thrombin time shortened	1	1	1				
Thyroglobulin increased	10		4		6		
Thyroid function test	1			1	1		
Thyroid function test abnormal	37		9	1	28		1
Thyroid function test normal	2		1		1		
Thyroid gland scan abnormal	2		1		1		
Thyroid hormones decreased	9		4		5		
Thyroid hormones increased	47	3	18	3	29		
Thyroid stimulating immunoglobulin	1				1		
Thyroid stimulating immunoglobulin increased	5	1	2	1	3		
Thyroxine	1				1		
Thyroxine abnormal	3		1		2		
Thyroxine decreased	9		2	1	7		
Thyroxine free	3	3	3				
Thyroxine free abnormal	3				3		
Thyroxine free decreased	12		1		11		
Thyroxine free increased	22	1	9		13		
Thyroxine increased	25	1	5	2	20		
Tidal volume decreased	1		1				
Tilt table test positive	1		1				
T-lymphocyte count abnormal	1			1	1		
T-lymphocyte count decreased	5	1	2		3		
T-lymphocyte count increased	14		2	3	12		

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Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Total bile acids increased	3		1		2		
Total cholesterol/HDL ratio abnormal	1				1		
Total cholesterol/HDL ratio decreased	2				2		
Total cholesterol/HDL ratio increased	5				5		
Total complement activity decreased	3	1	2		1		
Total complement activity increased	4		2		2		
Total complement activity test	1				1		
Total lung capacity abnormal	3		2		1		
Total lung capacity decreased	67	6	25	15	42		
Total neuropathy score	1		1				
Total sperm count decreased	1				1		
Toxicologic test abnormal	2				2		
Toxoplasma serology positive	2				2		
Transaminases	2		1		1		
Transaminases abnormal	7		3	1	4		
Transaminases decreased	2		1		1		
Transaminases increased	236	8	92	15	144		
Transferrin abnormal	2		1		1		
Transferrin decreased	9	1	4		5		
Transferrin increased	5		2		3		
Transferrin saturation	1		1				
Transferrin saturation abnormal	2				2		
Transferrin saturation decreased	9		4		5		
Transferrin saturation increased	4		1		3		
Treponema test false positive	1				1		
Treponema test positive	8		1		7		
Tri-iodothyronine	1				1		

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Investigations

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tri-iodothyronine abnormal	1		1				
Tri-iodothyronine decreased	12		6		6		
Tri-iodothyronine free abnormal	1				1		
Tri-iodothyronine free decreased	6				6		
Tri-iodothyronine free increased	15		2	3	13		
Tri-iodothyronine increased	11		3		8		
Troponin	55		3	1	52		
Troponin abnormal	98	3	41	5	57		
Troponin decreased	19	1	9		10		
Troponin I	3		1		2		
Troponin I abnormal	7		4		3		
Troponin I decreased	5		1		4		
Troponin I increased	240	8	138	4	102		1
Troponin increased	1474	48	711	52	763		4
Troponin I normal	1				1		
Troponin normal	2				2		
Troponin T	2	1	1		1		
Troponin T increased	205	6	140	4	65		
Tryptase decreased	3				3		
Tryptase increased	8	1	4		4		
Tuberculin test positive	5		3		2		
Tumour marker abnormal	3		2		1		
Tumour marker decreased	7				7		
Tumour marker increased	39	5	17	1	22		
Tympanometry abnormal	2		2				
Ubiquinone decreased	1	1	1				
Ultrasound abdomen abnormal	3	1	1	1	2		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ultrasound breast abnormal	4		1	1	3		
Ultrasound Doppler abnormal	3			1	3		1
Ultrasound foetal abnormal	2		2				
Ultrasound kidney abnormal	1				1		
Ultrasound liver abnormal	2				2		
Ultrasound ovary abnormal	1				1		
Ultrasound scan	1				1		
Ultrasound scan abnormal	6		2		4		
Ultrasound scan normal	1				1		
Ultrasound thyroid abnormal	3	1	2	1	1		
Ultrasound uterus abnormal	1				1		
Unevaluable specimen	1		1				
Urea urine	1				1		
Urea urine abnormal	2		1		1		
Urea urine decreased	2		1	1	1		
Urea urine increased	1		1				
Urinary lipids present	1				1		
Urinary occult blood	11	1	8		3		
Urinary occult blood positive	20		8		12		
Urinary sediment abnormal	5				5		
Urinary sediment present	6		2	1	4		
Urine albumin/creatinine ratio decreased	1			1	1		
Urine albumin/creatinine ratio increased	6		4		2		
Urine analysis abnormal	71	1	23	3	48		3
Urine bilirubin decreased							1
Urine bilirubin increased							1
Urine calcium increased	2		1	1	1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Urine chromium increased	1		1				
Urine copper	4		3		1		
Urine copper increased	1		1				
Urine cytology	1		1				
Urine cytology abnormal	3		2		1		
Urine ketone body	6	1	2	1	4		
Urine ketone body present	22		10	2	12		1
Urine leukocyte esterase positive	6		2		4		1
Urine output	11		5		6		
Urine output decreased	119	4	61	5	58		
Urine output increased	37		9	3	28		
Urine oxalate increased							1
Urine porphobilinogen increased	1		1				
Urine potassium decreased	2		1		1		
Urine potassium increased	1				1		
Urine protein/creatinine ratio increased	6		2		4		
Urine sodium abnormal	1				1		
Urine sodium decreased	2		1		1		
Urine sodium increased	2		2				
Urine uric acid increased	2		1	1	1		
Urobilinogen urine increased	7				7		
Vaccine induced antibody absent	8		2		6	1	1
Vaginal pH abnormal	2		1	1	1		
Vaginal pH increased	1				1		
Varicella virus test positive	29	3	10	2	19		
Vascular resistance pulmonary	1		1				
Vascular resistance pulmonary increased	1		1				

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vascular resistance systemic increased	1			1	1		
Vascular test abnormal	2		1		1		
Venogram	2		1	1	1		
Venogram abnormal	1		1				
Venous bruit	1				1		
Venous oxygen partial pressure decreased	2				2		
Venous oxygen saturation decreased	11		5	3	6		
Venous pressure	3			2	3		
Venous pressure increased	1				1		
Venous pressure jugular	2			1	2		
Venous pressure jugular increased	6		2		4		
Ventilation/perfusion scan	1		1				
Ventricular internal diameter abnormal	1		1				
Very low density lipoprotein increased	1				1		
Vestibular function test abnormal	6		5	1	1		
Vibration test abnormal	3		1		2		
Viral load	2		1		1		
Viral load increased	1	1	1				
Viral test	2		2				
Viral test positive	5		1		4		
Visual acuity tests	1		1				
Visual analogue scale	28		3		25		
Visual evoked potentials abnormal	2		1		1		
Visual field tests abnormal	3		1		2		
Visual tracking test abnormal	1				1		
Vital capacity	1		1				
Vital capacity decreased	6	2	3	1	3		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vital functions abnormal	14	2	8		6		
Vital signs measurement	1				1		
Vitamin B12 abnormal	5		3		2		
Vitamin B12 decreased	55		15	5	40		3
Vitamin B12 increased	25		10	1	15		
Vitamin B1 decreased	1				1		
Vitamin B1 increased	1				1		
Vitamin B2 decreased	1				1		
Vitamin B6 decreased	2				2		
Vitamin B6 increased	5		1		4		
Vitamin D	1		1				
Vitamin D abnormal	4		2	1	2		
Vitamin D decreased	98	1	15	10	83		1
Vitamin D increased	3			1	3		
Vitamin K increased	1		1				
Volume blood	1				1		
Volume blood decreased	2	1	2				
Von Willebrand's factor activity decreased	2		2				
Von Willebrand's factor activity increased	5		3		2		
Von Willebrand's factor antigen decreased	1			1	1		
Von Willebrand's factor antigen increased	1				1		
Waist circumference decreased	1		1				
Waist circumference increased	10	2	7		3		
Walking distance test abnormal	3	1	1		2		
Wall motion score index abnormal	4		2		2		
Weber tuning fork test abnormal	3				3		
Weight	1				1		

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System Organ Class

Investigations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Weight abnormal	16		3	3	13		1
Weight decreased	3918	238	1428	483	2490	7	35
Weight increased	1122	54	258	222	864	5	22
West Nile virus test positive	1		1				
White blood cell analysis abnormal	1				1		
White blood cell count	4		1		3		
White blood cell count abnormal	35		20	2	15	1	2
White blood cell count decreased	460	15	155	34	305	3	8
White blood cell count increased	910	22	336	43	574	1	4
White blood cell count normal	1				1		
White blood cell morphology abnormal	2		1		1		
White blood cells urine	18	1	5		13		
White blood cells urine positive	40		9	1	31		3
X-ray abnormal	8		4		4		
X-ray gastrointestinal tract abnormal	1		1				
X-ray limb abnormal	1				1		
X-ray with contrast upper gastrointestinal tract	1		1				
Yersinia test positive	1	1	1				
Total:	109820	3052	37130	9680	72690	98	553

System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal loss of weight	180	22	104	18	76		
Abnormal weight gain	64	4	25	19	39		
Acetonaemia	8		5		3		

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acidosis	47	2	33	3	14		
Acidosis hyperchloraemic	1		1				
Adult failure to thrive	6		6				
Alcoholic ketoacidosis	1		1				
Alcohol intolerance	61	4	18	11	43		
Alkalosis	8		2		6		
Apoptosis	1			1	1		
Appetite disorder	196	5	41	11	155		1
Body fat disorder	3			1	3		
Breast milk substitute intolerance	1		1				
Cachexia	74	18	74				1
Calcification metastatic	1				1		
Calcium deficiency	4		2	1	2		
Calcium metabolism disorder							1
Carbohydrate intolerance	4		2		2		
Catabolic state	3	1	1	2	2		
Cell death	47	2	23	3	24		1
Central obesity	2				2		
Cerebral salt-wasting syndrome	2		2				
Cholesterosis	1		1				
Chvostek's sign	2		1	1	1		
Copper deficiency	2			1	2		
Dairy intolerance	16		7	3	9		1
Decreased appetite	15017	251	3915	1313	11102	6	39
Decreased insulin requirement	9		2	1	7		
Dehydration	1743	47	869	63	874	1	9
Diabetes mellitus	520	80	520			7	35

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Diabetes mellitus inadequate control	265	28	265			1	2
Diabetic complication	7		6		1		
Diabetic ketoacidosis	123	16	123				
Diabetic ketosis	7	1	7				
Diabetic metabolic decompensation	38	5	38				
Diet refusal	15		10		5		
Dyslipidaemia	66	5	26	3	40		
Eating disorder symptom	26		8		18		
Electrolyte depletion	6	1	2	2	4		
Electrolyte imbalance	78	8	43	7	35	4	4
Enzyme abnormality	5		1		4		
Failure to thrive	6		6				
Fat intolerance	2			1	2		
Feeding disorder	973	19	420	80	553		2
Feeding intolerance	10	1	2	2	8		
Fluid imbalance	9		4		5		
Fluid intake reduced	70		36		34		
Fluid retention	550	7	160	75	390		1
Folate deficiency	82	3	29	9	53		
Food aversion	133	3	32	18	101		1
Food craving	93	1	17	10	76		1
Food intolerance	247	17	73	67	174		
Food refusal	53		32	3	21		
Fructose intolerance	6	2	3	1	3		
Fulminant type 1 diabetes mellitus	11	4	11				
Galactose intolerance	1		1				
Glucose tolerance impaired	44	3	17	4	27		

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Glucose tolerance impaired in pregnancy	1				1		
Gluten sensitivity	51	2	19	14	32		
Glycopenia	1				1		
Gout	590	13	177	44	413	1	1
Haemochromatosis	10	1	4	2	6		
Haemosiderosis	5	1	4		1		
Histamine intolerance	140	14	41	40	99		
Hyperalbuminaemia	2		1	1	1		
Hyperammonaemia	5	1	3		2		
Hyperamylasaemia	3				3		
Hypercalcaemia	38	3	25	2	13		
Hypercarotinaemia	1		1				
Hypercatabolism	1		1				
Hyperchloraemia	4		1		3		
Hypercholesterolaemia	121	9	47	17	74		1
Hypercreatininaemia	6		3	1	3		
Hyperferritinaemia	30	1	10		20		
Hyperglycaemia	565	14	262	25	303		3
Hyperglycaemic hyperosmolar nonketotic syndrome	8		8				
Hyperhomocysteinaemia	17	1	7	3	10		
Hyperinsulinaemic hypoglycaemia	1		1				
Hyperkalaemia	114	16	114				2
Hyperlactacidaemia	18		14		4		
Hyperlipasaemia	17	2	6	1	11		
Hyperlipidaemia	58	2	20	7	38		
Hypermagnesaemia	1		1				
Hypermetabolism	23		4	2	19		

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hypernatraemia	63	5	40	1	23		1
Hyperosmolar state	1	1	1				
Hyperphagia	32		16	1	16		
Hyperphosphataemia	3		1	1	2		
Hyperproteinaemia	10		2	2	8		
Hypertriglyceridaemia	36	2	10	1	26		
Hyperuricaemia	42	2	19	7	23		
Hypervitaminosis	1				1		
Hypervitaminosis B	1		1				
Hypervitaminosis B12	3		1		2		
Hypervolaemia	43	3	26	1	17		
Hypoalbuminaemia	85	3	47	8	38		1
Hypocalcaemia	42	2	30	1	12		
Hypochloraemia	10		9		1		
Hypocholesterolaemia	2				2		
Hypoferritinaemia	5			1	5		
Hypoglycaemia	667	16	300	26	367		4
Hypoglycaemia neonatal	4		4				1
Hypoglycaemia unawareness	2		1		1		
Hypokalaemia	346	31	346			1	5
Hypokalaemic syndrome	5		2		3		
Hypomagnesaemia	14	1	9		5		
Hypometabolism	18	2	5	8	13		
Hyponatraemia	303	20	188	12	115	1	2
Hyponatraemic syndrome	5		3		2		
Hypophagia	332	13	158	32	174		1
Hypophosphataemia	21	1	10	1	11		1

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hypoproteinaemia	18		11	1	7		
Hypovitaminosis	39	1	15	6	24		
Hypovolaemia	17		9	2	8		
Hypozincaemia	1				1		
Impaired fasting glucose	9		4		5		
Impaired insulin secretion	3		1	1	2		
Increased appetite	241	1	26	20	215		2
Increased insulin requirement	45	2	13	7	32		
Insulin-requiring type 2 diabetes mellitus	1		1				
Insulin resistance	51	3	22	7	29		
Insulin resistant diabetes	3	1	3				
Iodine deficiency	1			1	1		
Iron deficiency	240	9	54	75	186		1
Iron overload	4		1		3		
Ketoacidosis	35	3	35				
Ketosis	5	1	3		2		
Ketosis-prone diabetes mellitus	2	1	2				
Lack of satiety	4			1	4		
Lactic acidosis	47	7	47				
Lactose intolerance	59	7	19	10	40		
Latent autoimmune diabetes in adults	11	2	10		1		
Lipid metabolism disorder	5	1	2		3		
Lipoedema	44	14	44			2	2
Lipomatosis	4	1	3		1		
Macroamylasaemia	1		1				
Magnesium deficiency	8		1	4	7		
Malnutrition	95	3	45	12	50		

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Marasmus	33	2	32		1		
Metabolic acidosis	97	3	70	7	27		
Metabolic alkalosis	6				6		
Metabolic disorder	59	5	19	14	40		
Metabolic syndrome	6		3		3		
Mineral deficiency	8		1	4	7		
Mineral metabolism disorder	10		5	1	5		
Mitochondrial cytopathy	16	9	16				
Mitochondrial toxicity	2	2	2				
Neonatal hypocalcaemia	1		1				
Neonatal hyponatraemia	1		1				
Neonatal insufficient breast milk syndrome	15	1	5		10		
Obesity	42	1	11	11	31		
Oligodipsia	14		1	5	13		
Overfeeding of infant	1				1		
Overweight	26		4	6	22		
Oxidative stress	2		1	1	1		
Pancreatogenous diabetes	2	1	2				
Periarthritis calcarea	2		1	1	1		
Phagocytosis	1			1	1		
Polydipsia	149	7	39	13	110		
Poor feeding infant	91	2	18	9	73		1
Postprandial hypoglycaemia	5		3		2		
Propofol infusion syndrome	1		1				
Protein deficiency	7	1	2	1	5		
Protein intolerance	1			1	1		
Pseudo-Bartter syndrome	1				1		

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pseudogynaecomastia	1	1	1				
Refeeding syndrome	1	1	1				
Salt craving	11		3	2	8		
Salt intoxication	1				1		
Selenium deficiency	3	1	2	1	1		
Shock hypoglycaemic	3		3				
Sodium retention	1		1				
Starvation	5		5				
Steroid diabetes	3	2	3				
Tetany	137	6	60	14	77		
Trace element deficiency	2		1	1	1		
Trousseau's sign	3		2	1	1		
Tumour lysis syndrome	3		3				
Type 1 diabetes mellitus	298	69	298			1	4
Type 2 diabetes mellitus	162	42	162			1	4
Underweight	16	1	5	2	11		
Vitamin B12 deficiency	71	7	29	6	42		
Vitamin B1 deficiency	6		1	3	5		
Vitamin B6 deficiency	6		1	1	5		
Vitamin B complex deficiency	9	2	5	2	4		
Vitamin C deficiency	6		1		5		
Vitamin D deficiency	177	4	49	32	128		
Water intoxication	3		3				
Weight fluctuation	32	3	4	5	28	2	2
Weight gain poor	8		1	2	7		
Weight loss poor	9		4		5		
Zinc deficiency	6		1	2	5		

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System Organ Class

Metabolism and nutrition disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Total:	27452	972	10290	2292	17162	28	138

System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acute aseptic arthritis	12	2	12				
Amplified musculoskeletal pain syndrome	4				4		
Amyotrophy	43	6	43				
Ankle deformity	3			2	3		
Ankylosing spondylitis	259	57	259			9	32
Antisynthetase syndrome	24	4	18	1	6		
Arthralgia	138251	1585	19495	15290	118756	58	370
Arthritis	3190	142	1208	274	1982	4	20
Arthritis allergic	2		1		1		
Arthritis enteropathic	1		1				
Arthritis reactive	364	74	364				5
Arthrofibrosis	2		2				
Arthropathy	702	27	222	69	480	3	6
Articular calcification	8	1	5		3		
Articular disc disorder	1				1		
Asymmetric thigh fold	1				1		
Autoimmune arthritis	33	7	33				
Autoimmune myositis	45	6	45				
Axial spondyloarthritis	8	3	6	2	2		
Axillary mass	1731	4	384	226	1347		
Back disorder	110	2	26	13	84	1	5

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Back pain	21905	338	5357	2082	16548	11	63
Bone atrophy	1		1				
Bone cyst	10		2	4	8		1
Bone deformity	6		1		5		
Bone demineralisation	3	1	1	1	2		
Bone development abnormal	1				1		
Bone disorder	97	3	24	8	73	1	3
Bone erosion	2		1	1	1		
Bone formation increased	1				1		
Bone hypertrophy	1				1		
Bone infarction	2		2				
Bone lesion	12	2	4		8		
Bone loss	4	1	3		1		
Bone metabolism disorder	1			1	1		
Bone pain	5353	105	1053	565	4300	2	10
Bone swelling	141		42	12	99		
Bursa disorder	24		4	2	20		
Bursal fluid accumulation	17		5	2	12		
Bursal haematoma	3		2		1		
Bursitis	868	40	266	118	602	2	4
Calcification of muscle	4	1	2	1	2		
Callus formation delayed	1				1		
Camptocormia	3		1		2		
Carpal collapse	1		1				
Cartilage atrophy	1				1		
Cartilage hypertrophy	1		1				
Cervical spinal stenosis	23	7	23				1

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Chest wall cyst	1		1			1	1
Chest wall haematoma	3		3				
Chest wall mass	7		2		5		
Chondritis	8	1	3		5		
Chondrocalcinosis	47	2	26	2	21		1
Chondromalacia	1		1				
Chondropathy	20	1	7		13		
Chondrosis	1				1		
Chronic recurrent multifocal osteomyelitis	1				1		
Clubbing	3		1		2		
Coccydynia	99	4	23	10	76		1
Collagen disorder	54	10	28	7	26		
Compartment syndrome	18	3	18				
Connective tissue disorder	173	2	29	8	144		
Connective tissue inflammation	10		5		5		
Costochondritis	546	11	213	29	333		
CREST syndrome	1		1				
Crystal arthropathy	15	1	10		5		
Dactylitis	27		9	6	18		
Decreased nasolabial fold	7		4		3		
Deformity thorax	4		2		2		
Degenerative bone disease	8			1	8		
Diffuse idiopathic skeletal hyperostosis	1			1	1		
Drooping shoulder syndrome	5		3		2		
Dupuytren's contracture	24	8	24				
Dysponesis	2	1	1		1		
Eagle's syndrome	1				1		

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Elbow deformity	5	2	2	2	3		
Enostosis	1				1		
Enteropathic spondylitis	1				1		
Enthesopathy	77	6	42	7	35		
Eosinophilic fasciitis	14	5	14				
Epiphyses premature fusion	1		1				
Exostosis	31	6	13	3	18		1
Extremity contracture	37	1	8	8	29		
Facet joint syndrome	9	1	2	3	7		1
Facial asymmetry	181	14	104	11	77		1
Facial myokymia	15	8	15				
Fasciitis	41	5	19	3	22		
Femoroacetabular impingement	1				1		
Fibromyalgia	920	55	398	100	522	3	6
Finger deformity	64	4	20	10	44	1	1
Fistula	17	2	12		5		1
Fistula discharge	4		1	1	3		
Flank pain	719	21	209	75	510	1	1
Fluctuance	3				3		
Focal myositis	4	2	2		2		
Foot deformity	66	3	23	10	43	1	3
Fracture pain	6		2		4		
Gouty arthritis	26	1	10	5	16		
Gouty tophus	4	1	3		1		
Greater trochanteric pain syndrome	36	2	16	4	20		
Groin pain	1018	23	301	121	717		3
Growing pains	13	1	3	2	10		

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Growth accelerated	1		1				
Growth disorder	4	1	2		2		
Growth failure	1		1				
Growth retardation	1		1				
Haemarthrosis	47	3	47				1
Haematoma muscle	59	2	26	6	33		
Haemophilic arthropathy	2		2				
Hand deformity	50	5	25	5	25	1	2
Head deformity	5		3		2		
Hip deformity	3		1	1	2		
Hydroxyapatite crystal deposition disease	2			1	2		
Hypercreatinaemia	3			2	3		
Hypotonia neonatal	3		3				1
Idiopathic inflammatory myopathy	6		6				
Immobilisation syndrome	15	1	11		4	1	1
Immune-mediated arthritis	7	3	7				
Immune-mediated myositis	13	3	13			1	1
Immunoglobulin G4 related disease	12	4	12				
Inclusion body myositis	6	3	6				
Infantile back arching	1	1	1				
Infrapatellar fat pad inflammation	2				2		
Inguinal mass	19		12	2	7		
Interspinous osteoarthritis	1		1				
Intervertebral disc annular tear	4		2		2		
Intervertebral disc compression	6	1	3		3		
Intervertebral disc degeneration	59	5	18	7	41		2
Intervertebral disc disorder	94	4	27	14	67		

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Intervertebral disc displacement	1		1				
Intervertebral disc protrusion	281	17	92	37	189		6
Intervertebral disc space narrowing	9		3	1	6		
Jaw clicking	25	1	7	2	18		
Jaw cyst	5				5		
Jaw disorder	110	2	27	9	83	1	2
Jaw fistula						1	1
Joint adhesion	2				2		
Joint ankylosis	71	4	18	4	53		
Joint contracture	30	1	9	7	21		
Joint deposit	3		3				
Joint destruction	6	1	6				
Joint effusion	303	15	116	32	187		
Joint hyperextension	12		8		4		1
Joint impingement	5	2	2	3	3		
Joint instability	45	2	15	9	30		
Joint laxity	11	2	6	3	5		
Joint lock	171	4	73	14	98	1	1
Joint microhaemorrhage	3		2	1	1		
Joint noise	174	4	73	15	101		3
Joint range of motion decreased	2193	51	809	169	1384	1	8
Joint space narrowing	5			2	5		
Joint stiffness	1718	42	593	199	1125		5
Joint swelling	4877	159	1545	549	3332	4	16
Joint vibration	14		4	1	10		
Joint warmth	121	5	46	15	75		1
Juvenile idiopathic arthritis	38	9	38			1	5

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Juvenile polymyositis	2	1	2				
Juvenile psoriatic arthritis	3	2	3				
Knee deformity	7	1	1	1	6		
Kyphoscoliosis	2		1		1		
Kyphosis	8		3	2	5		
Ligament disorder	17	2	10	2	7		1
Ligamentitis	12	1	6		6		
Ligament laxity	4	1	2		2		
Ligament pain	45	1	9	8	36		
Ligamentum flavum hypertrophy	2	2	2				
Limb asymmetry	1		1				
Limb deformity	27	2	9	3	18		
Limb discomfort	26860	379	2889	2616	23971	4	59
Limb mass	317	4	107	16	210		2
Locomotive syndrome	4		2	1	2		
Loose body in joint	4		1	1	3		
Lordosis	9		3	1	6		
Lumbar spinal stenosis	19	3	8	1	11		
Lupus-like syndrome	29	6	29			1	1
Lupus myositis	1		1				
Mandibular mass	5		2		3		
Mastication disorder	185	8	63	16	122		1
Masticatory pain	8			1	8		
Medial tibial stress syndrome	19	2	11	2	8		
Meniscal degeneration	2			1	2		
Metatarsalgia	16	2	5	6	11		
Mitochondrial myopathy acquired	2	1	2				

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mixed connective tissue disease	29	8	29				1
Mobility decreased	5413	206	1506	1169	3907	4	14
Morphoea	48	15	22	7	26		
Mucoid degeneration of the anterior cruciate ligament	1				1		
Muscle atrophy	403	53	185	70	218		
Muscle contracture	300	8	72	30	228		1
Muscle discomfort	432	11	53	93	379		2
Muscle disorder	325	17	102	41	223		1
Muscle fatigue	1030	17	421	82	609		7
Muscle fibrosis	2				2		
Muscle haemorrhage	25	3	25				
Muscle hypertrophy	9	1	9				
Muscle hypoxia	6		3	3	3		
Muscle infarction	2		2				
Muscle mass	30	2	10		20		1
Muscle necrosis	11	1	11				
Muscle oedema	41	1	14	5	27		
Muscle rigidity	427	12	161	21	266		4
Muscle spasms	11834	286	3483	1145	8351	4	24
Muscle swelling	265	4	74	33	191		
Muscle tightness	1981	55	453	182	1528		2
Muscle twitching	4088	191	1173	572	2915		3
Muscular weakness	12615	553	4850	1259	7765	8	42
Musculoskeletal chest pain	2127	41	656	190	1471		5
Musculoskeletal deformity	1		1				
Musculoskeletal discomfort	1876	44	381	311	1495		3
Musculoskeletal disorder	636	16	205	96	431	1	7

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Musculoskeletal pain	5594	78	1036	370	4558	1	6
Musculoskeletal stiffness	10233	163	2744	1402	7489	6	35
Myalgia	200602	1751	20380	21401	180222	49	426
Myalgia intercostal	41		10	1	31		
Myofascial pain syndrome	49	2	18	8	31		
Myofascial spasm	3		1		2		
Myofascitis	9		4		5		
Myoglobinaemia	1		1				
Myokymia	105	3	34	27	71		
Myopathy	109	8	57	8	52		
Myopathy toxic	1		1				
Myosclerosis	60	12	60			2	3
Myositis	688	44	303	70	385	1	5
Myositis-like syndrome	1				1		
Neck deformity	10		3		7		
Neck mass	350	8	101	23	249	2	3
Neck pain	14800	205	3881	1517	10919	5	34
Necrotising myositis	10	2	10				
Neuropathic arthropathy	3		3				
Neuropathic muscular atrophy	9	2	9				
Nodal osteoarthritis	19		1	5	18		
Nose deformity	6		2		4		
Nuchal rigidity	324	10	79	12	245		2
Oligoarthritis	29	1	22	2	7		
Osteitis	121	10	34	17	87		
Osteitis condensans	1		1				
Osteoarthritis	705	37	244	108	461	3	13

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Osteoarthropathy	9		1		8		
Osteochondritis	5				5		
Osteochondrosis	16	6	16				
Osteolysis	10		4		6		
Osteo-meningeal breaches	1		1				
Osteonecrosis	35	10	35				2
Osteonecrosis of jaw	5	1	5				
Osteopenia	30	1	11	6	19		1
Osteoporosis	68	2	21	10	47		4
Osteoporotic fracture	6	1	6				
Osteosclerosis	4		1	1	3		
Pain in extremity	105846	1255	19710	11548	86136	42	465
Pain in jaw	2493	33	673	205	1820	1	8
Palindromic rheumatism	25	3	25				1
Palmar fasciitis	2		1	1	1		
Paraneoplastic arthritis	2		2				
Patellofemoral pain syndrome	8		3	4	5		
Pathological fracture	8	2	6		2		
Pelvic misalignment	4		1	1	3		
Periarthritis	1029	81	528	134	501	1	4
Periarticular disorder	1		1				
Periostitis	17		2	1	15		
Peripheral spondyloarthritis	4	4	4				
Plantar fascial fibromatosis	8		3	1	5		
Plantar fasciitis	105	2	32	19	73		
Plica syndrome	2				2		
Polyarthritis	439	86	439				

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Polychondritis	13	3	13				
Polymyalgia rheumatica	1295	275	1295			3	7
Polymyositis	51	11	51				1
Posterior tibial tendon dysfunction	2		1		1		
Posture abnormal	65	4	23	7	42		
Pseudothrombophlebitis	1		1				
Psoas sign	2			2	2		
Psoriatic arthropathy	269	60	269			14	58
Pubic pain	21		5	3	16		
Purple glove syndrome	1		1				
Pustulotic arthro-osteitis	1	1	1				
Resorption bone increased	2		1		1		
Retrognathia	1		1				
Reynold's syndrome	6		6				
Rhabdomyolysis	335	39	335			1	1
Rheumatic disorder	682	36	212	128	470		
Rheumatic fever	20	4	20				
Rheumatoid arthritis	1726	356	1726			40	237
Rheumatoid bursitis	1		1				
Rheumatoid nodule	11		6	1	5		
Rib deformity	2			1	2		
Rotator cuff injury of hip	1				1		
Rotator cuff syndrome	366	21	160	47	206	1	8
Sacral pain	136	7	29	19	107		1
Sacroiliac joint dysfunction	26	3	6	8	20		
Sacroiliitis	42	3	20	7	22		
SAPHO syndrome	7	2	7				

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Sarcopenia	9	2	4	1	5		
Scapular dyskinesis	3		1		2		
Sclerodactylia	3		3				
Scleroderma	58	19	58				1
Scleroderma-like reaction	1	1	1				
Scoliosis	34	2	13	4	21		
Seronegative arthritis	68	16	68				
Shoulder deformity	10	1	5		5		
Shoulder girdle pain	7	1	1	3	6		
Sinus tarsi syndrome	1				1		
Sjogren's syndrome	193	39	193				
SLE arthritis	6		6				
Slipping rib syndrome	8	1	3	1	5		
Snapping hip syndrome	2				2		
Soft tissue atrophy	3		1		2		
Soft tissue disorder	21		9	2	12		
Soft tissue haemorrhage	5		2	1	3		
Soft tissue mass	11		6		5		
Soft tissue necrosis	2		2				
Soft tissue swelling	131		21	7	110		
Somatic dysfunction	10	1	3	4	7		
Spinal deformity	20		6	4	14		
Spinal disorder	100	4	45	9	55	1	3
Spinal flattening	3			1	3		
Spinal fusion acquired	1		1				
Spinal instability	13	2	5	2	8		
Spinal osteoarthritis	170	11	59	22	111	1	1

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Spinal pain	1483	35	429	185	1054		4
Spinal retrolisthesis	1				1		
Spinal stenosis	60	6	31	8	29	2	3
Spinal synovial cyst	1		1				
Spondylitis	125	6	61	11	64		1
Spondyloarthropathy	16	2	10	2	6		
Spondylolisthesis	11	1	6	2	5		
Spondylolysis	4		1	1	3		
Stenocephaly	1		1				
Still's disease	103	21	103			1	2
Sympathetic posterior cervical syndrome	4	1	4				
Symphysiolysis	10	2	3	2	7		
Synovial cyst	303	6	78	32	225	1	3
Synovial disorder	8		3		5		
Synovitis	162	12	71	18	91		3
Systemic lupus erythematosus	391	74	391			2	15
Systemic scleroderma	25	12	25				
Temporomandibular joint syndrome	158	7	50	13	108		1
Tendinous contracture	5		1		4		
Tendon calcification	15		5	3	10		
Tendon discomfort	79	2	9	23	70		
Tendon disorder	242	16	94	32	148		
Tendonitis	778	41	257	106	521		5
Tendon laxity	2		1		1		
Tendon pain	478	23	132	63	346		4
Tendon sheath disorder	19	2	2		17		
Tenosynovitis	195	11	73	27	122		

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System Organ Class

Musculoskeletal and connective tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tenosynovitis stenosans	17		5	2	12		
Thoracic spinal stenosis	2		2				
Toe walking	1				1		
Torticollis	266	4	44	41	222		
Trendelenburg's symptom	2		2				
Trigger finger	133	4	47	12	86	1	3
Trigger points	15		3		12		
Trismus	333	11	113	23	220		
Undifferentiated connective tissue disease	4	1	3		1		
Undifferentiated spondyloarthritis	4	2	4				
Vertebral end plate inflammation	2		1		1		
Vertebral foraminal stenosis	9	1	3	2	6		
Vertebral lesion	6	1	4		2		
Vertebral osteophyte	6			1	6		
Vertebral wedging	2		1		1		
Weight bearing difficulty	946	108	235	288	711	1	3
Winged scapula	27	3	14	4	13		
Wrist deformity	6		2	3	4		
Total:	616410	10108	108955	66290	507455	314	2156

System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
5q minus syndrome	1		1				
Abdominal neoplasm	6	1	3	1	3		
Acinic cell carcinoma of salivary gland	1		1				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acoustic neuroma	15		15				
Acrochordon	13		5	4	8		
Acute leukaemia	30	2	30				
Acute lymphocytic leukaemia	23	4	23				
Acute megakaryocytic leukaemia	1		1				
Acute monocytic leukaemia	1		1				
Acute myeloid leukaemia	57	12	57				
Acute myeloid leukaemia recurrent	9	2	9				
Acute myelomonocytic leukaemia	1		1				
Acute promyelocytic leukaemia	4	2	4				
Adenocarcinoma	9	2	9				
Adenocarcinoma gastric	2		2				
Adenocarcinoma metastatic	2		2				
Adenocarcinoma of colon	3		3				
Adenocarcinoma of the cervix	2	2	2				
Adenocarcinoma pancreas	4	2	4				
Adenoid cystic carcinoma	1	1	1				
Adenolymphoma	1				1		
Adenoma benign	7	1	3		4		
Adrenal adenoma	10		2	1	8		
Adrenal gland cancer	3		3				
Adrenal neoplasm	3		2	1	1		
Adult T-cell lymphoma/leukaemia	2		2				
Anal cancer	2	1	2				
Anaplastic large-cell lymphoma	1	1	1				
Anaplastic thyroid cancer	2		2				
Angiocentric lymphoma	3		3				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Angiofibroma	1		1				
Angioimmunoblastic T-cell lymphoma	7	2	7				
Angioimmunoblastic T-cell lymphoma recurrent	1		1				
Angiolipoma	1		1				
Angiomyolipoma	7	2	7				
Angiosarcoma	4	3	4				
Anogenital warts	26	5	11	2	15		
Appendix cancer	1		1				
Astrocytoma	1		1				
Basal cell carcinoma	36	6	36				1
Basosquamous carcinoma	1		1				
B-cell lymphoma	35	12	35				1
B-cell lymphoma recurrent	1	1	1				
B-cell lymphoma stage IV	1	1	1				
B-cell small lymphocytic lymphoma	1		1				
B-cell type acute leukaemia	5		5				
Benign bone neoplasm	1		1				
Benign breast neoplasm	17		7	4	10		1
Benign gastrointestinal neoplasm	2		1		1		
Benign hepatic neoplasm	3		1		2		
Benign hydatidiform mole	13	1	13				
Benign lung neoplasm	1		1				
Benign lymph node neoplasm	3		1		2	1	2
Benign neoplasm	6		2	1	4		
Benign neoplasm of adrenal gland	1			1	1		
Benign neoplasm of cervix uteri	1				1		
Benign neoplasm of eye	1	1	1				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Benign neoplasm of prostate	1	1	1				
Benign neoplasm of skin	1				1		
Benign neoplasm of testis	1		1				
Benign neoplasm of thyroid gland	4		1	1	3		1
Benign ovarian tumour	3		2	1	1		
Benign salivary gland neoplasm	4		3		1		
Benign uterine neoplasm	1		1				
Bile duct cancer	5		5				1
Biliary adenoma	1		1				
Bladder adenocarcinoma stage unspecified	1		1				
Bladder cancer	23	6	23			1	1
Bladder cancer recurrent	4		4				1
Bladder neoplasm	7	2	6	1	1		
Bladder transitional cell carcinoma	1	1	1				
Blast cell crisis	1		1				
Blast cell proliferation	1		1				
Blastic plasmacytoid dendritic cell neoplasia	1		1				
Bone cancer	9	2	9				
Bone cancer metastatic	3	1	3				
Bone neoplasm	27	1	9	1	18		
Borderline mucinous tumour of ovary	1		1				
Borderline ovarian tumour	3	1	3				
Bowen's disease	2		2				
B precursor type acute leukaemia	1	1	1				
Brain cancer metastatic	3		3				
Brain neoplasm	58	9	58			1	5
Brain neoplasm benign	1		1				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Brain neoplasm malignant	3	1	3				
Breast adenoma	2		1		1		
Breast cancer	226	55	226			2	4
Breast cancer female	45	15	45				3
Breast cancer in situ	1		1				
Breast cancer male	4		4				
Breast cancer metastatic	30	11	30				
Breast cancer recurrent	24	9	24				
Breast cancer stage I	1		1				
Breast cancer stage II	3		3				
Breast cancer stage III	3		3				
Breast cancer stage IV	3		3				
Breast neoplasm	15	3	12	1	3		
Bronchial carcinoma	11	2	11				
Bronchial neoplasm	1		1				
Burkitt's lymphoma	2		2				
Burkitt's lymphoma stage I	2		2				
Burkitt's lymphoma stage IV	1	1	1				
Cancer fatigue	1				1		
Cancer pain	4		2	2	2		2
Carcinoid tumour	3	1	3				
Carcinoid tumour of the gastrointestinal tract	1		1				
Carcinoid tumour pulmonary	2	1	2				
Carcinoma in situ	1		1				
Cardiac neoplasm unspecified	3		3				
Cardiac valve fibroelastoma	6	2	6				
Cartilage neoplasm	1				1		

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Castleman's disease	18	4	18				
Central nervous system lymphoma	6	2	6				
Cerebral haemangioma	2		2				
Cervix cancer metastatic	1		1				
Cervix carcinoma	16	7	16				
Cervix carcinoma recurrent	1		1				
Cervix carcinoma stage 0	4	2	4				
Cervix warts	1			1	1		
Chloroma	1		1				
Cholangiocarcinoma	7		7				
Cholangiosarcoma	1		1				
Cholesteatoma	1		1			1	1
Chondroma	1		1				
Chondromatosis	2				2		
Chondrosarcoma	1		1				
Choroidal haemangioma	1				1		
Choroid melanoma	1	1	1				
Chronic leukaemia	5	1	5				
Chronic lymphocytic leukaemia	62	10	62				
Chronic lymphocytic leukaemia (in remission)	1				1		
Chronic lymphocytic leukaemia recurrent	3	1	3				
Chronic lymphocytic leukaemia stage 0	1		1				
Chronic lymphocytic leukaemia transformation	1		1				
Chronic myeloid leukaemia	17	4	17				
Chronic myeloid leukaemia recurrent	1		1				
Chronic myelomonocytic leukaemia	5		4		1		
Clear cell renal cell carcinoma	3		3				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Colon cancer	45	9	45			1	2
Colon cancer metastatic	4		4				
Colon cancer stage IV	2		2				
Colon neoplasm	7		7				
Colorectal adenocarcinoma	1		1				
Colorectal adenoma	3	1	2		1		
Colorectal cancer	5	2	5				
Cranial nerve neoplasm benign	1		1				
Craniopharyngioma	1		1				
Cutaneous lymphoma	8	2	8				
Cutaneous T-cell lymphoma	11	5	11				
Dedifferentiated liposarcoma	1	1	1				
Dermatofibrosarcoma protuberans	1		1				
Desmoid tumour	2		2				
Diaphragm neoplasm	1		1				
Diffuse large B-cell lymphoma	25	5	25				
Diffuse large B-cell lymphoma stage IV	2	1	2				
Double hit lymphoma	1		1				
Ear neoplasm	4		1	1	3		
Elastofibroma	2	1	1		1		
Enchondromatosis	2	1	2				
Endocrine neoplasm	1		1				
Endocrine neoplasm malignant	1		1				
Endometrial adenocarcinoma	5	2	5				
Endometrial cancer	15	3	15				
Endometrial cancer metastatic	2	1	2				
Endometrial cancer stage I	1	1	1				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Epithelioid mesothelioma	1		1				
Epithelioid sarcoma	2		2				
Epstein Barr virus positive mucocutaneous ulcer	2		2				
Erythroplasia	1		1				
Essential thrombocythaemia	18	3	18				
Ewing's sarcoma	1		1				
Extranodal marginal zone B-cell lymphoma (MALT type)	2	1	2				
Eye haemangioma	1				1		
Eyelid tumour	3				3		
Eye naevus	6		2	2	4		
Fallopian tube cancer	2	1	2				
Fallopian tube neoplasm	1		1				
Fibroadenoma of breast	27	4	15	3	12		
Fibroma	17	5	6	2	11		
Fibrosarcoma	1	1	1				
Fibrous histiocytoma	5		2		3		
Focal nodular hyperplasia	3		1		2		
Follicle centre lymphoma, follicular grade I, II, III	1		1				
Follicular lymphoma	21	8	21				
Follicular lymphoma stage I	1		1				
Follicular lymphoma stage II	4	4	4				
Follicular lymphoma stage III	2	1	2				
Follicular lymphoma stage IV	1		1				
Gallbladder adenocarcinoma	1		1				
Gallbladder cancer	3	1	3				
Gallbladder cancer metastatic	1		1				
Gammopathy	4	1	2		2		

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ganglioneuroma	1		1				
Gastric adenoma	2		1		1		
Gastric cancer	15	5	15				
Gastric cancer recurrent	1		1				
Gastric cancer stage IV	2		2				
Gastric haemangioma	1		1				
Gastric neoplasm	1		1				
Gastrointestinal adenocarcinoma	1		1				
Gastrointestinal cancer metastatic	1		1				
Gastrointestinal carcinoma	15	5	15				
Gastrointestinal lymphoma	1		1				
Gastrointestinal neoplasm	3	1	1		2		
Gastrointestinal stromal tumour	2		2				
Genital neoplasm malignant female	1	1	1				
Gestational trophoblastic tumour	1		1				
Giant cell tumour of tendon sheath	1		1				
Gingival cancer	1	1	1				
Glioblastoma	32	7	32				
Glioblastoma multiforme	4	2	4				
Glioma	8	1	8				
Glomus tumour	1	1	1				
Good syndrome	1		1				
Haemangioma	80	3	34	8	46		1
Haemangioma of bone	2			1	2		
Haemangioma of breast	2				2		
Haemangioma of liver	28	2	14	4	14		
Haemangioma of skin	34		8	1	26		1

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Haemangioma of spleen	2		2				
Haemangioma rupture	1		1				
Haemangiopericytoma	1		1				
Haematological malignancy	3	1	3				
Haematopoietic neoplasm	2		2				
Hairy cell leukaemia	1		1				
Hepatic adenoma	6	2	6				
Hepatic cancer	24	6	24				
Hepatic cancer metastatic	3		3				
Hepatic cancer recurrent	1		1				
Hepatic neoplasm	15	5	15				
Hepatocellular carcinoma	11	2	11				
HER2 positive breast cancer	2		2				
High-grade B-cell lymphoma	2		2				
High grade B-cell lymphoma Burkitt-like lymphoma	1		1				
Histiocytic necrotising lymphadenitis	21	5	16		5		
Histiocytosis	4		4				
Hodgkin's disease	39	15	39				
Hodgkin's disease mixed cellularity stage unspecified	2		2				
Hodgkin's disease recurrent	1		1				
Hormone receptor positive breast cancer	2	1	2				
Hormone receptor positive HER2 negative breast cancer	1		1				
Huerthle cell carcinoma	1		1				
Hypergammaglobulinaemia benign monoclonal	7	1	4	1	3	1	1
Infantile haemangioma	1	1	1				
Infected neoplasm	1				1		
Inflammatory carcinoma of the breast	7	1	7				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Inflammatory pseudotumour	2		1		1		
Insulinoma	1	1	1				
Intestinal adenocarcinoma	1		1				
Intra-abdominal haemangioma	2		2				
Intraductal papilloma of breast	1				1		
Intraductal proliferative breast lesion	4	2	4				
Intravascular papillary endothelial hyperplasia	1		1				
Invasive breast carcinoma	4	3	4				
Invasive ductal breast carcinoma	25	9	25				
Invasive lobular breast carcinoma	5	3	5				
Joint neoplasm	1				1		
Kaposi's sarcoma	12	1	12				
Kaposi's sarcoma AIDS related	1		1				
Keratoacanthoma	4	1	1	1	3		
Langerhans' cell histiocytosis	4		4				
Large granular lymphocytosis	1		1				
Large intestine benign neoplasm	1				1		
Laryngeal cancer	2	1	2				
Laryngeal neoplasm	1	1	1				
Laryngeal papilloma	1		1				
Leiomyoma	34	3	9	6	25		
Leiomyosarcoma	4	1	4				1
Lentigo maligna	3	3	3				
Leser-Trelat sign	1	1	1				
Leukaemia	71	14	71				
Leukaemia recurrent	7	2	7				
Leukaemic infiltration	1		1				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Leukaemic lymphoma	1		1				
Lip and/or oral cavity cancer	6		6				
Lip and/or oral cavity cancer recurrent	1		1				
Lip neoplasm malignant stage unspecified	2		2				
Lipoma	120	4	34	15	86		
Liposarcoma	3		3				
Liver carcinoma ruptured	1		1				
Lobular breast carcinoma in situ	2		2				
Lung adenocarcinoma	19	5	19				
Lung adenocarcinoma recurrent	1		1				
Lung adenocarcinoma stage IV	1		1				
Lung cancer metastatic	23	5	23				
Lung carcinoma cell type unspecified recurrent	3		3				
Lung carcinoma cell type unspecified stage 0	2	1	2				
Lung carcinoma cell type unspecified stage I	1		1				
Lung carcinoma cell type unspecified stage IV	2		2				
Lung neoplasm	6	1	6				
Lung neoplasm malignant	84	19	84			1	2
Lung squamous cell carcinoma stage I	1		1				
Lymphangioma	6	1	4	1	2		
Lymphangiosis carcinomatosa	1	1	1				
Lymphatic system neoplasm	3		1		2		
Lymphocytic leukaemia	3	2	3				
Lymphoma	225	45	225				1
Lymphoproliferative disorder	8	2	8				
Malignant ascites	4		4				
Malignant fibrous histiocytoma	1		1				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Malignant lymphoid neoplasm	2	1	2				
Malignant melanoma	29	8	29			1	1
Malignant neoplasm of eye	1		1				
Malignant neoplasm of pleura	1		1				
Malignant neoplasm of renal pelvis	1		1				
Malignant neoplasm of unknown primary site	3	1	3				
Malignant neoplasm progression	19	1	19				1
Malignant nervous system neoplasm	2		2				
Malignant oligodendroglioma	1		1				
Malignant palate neoplasm	1		1				
Malignant peritoneal neoplasm	7	3	7				2
Malignant pleural effusion	5	1	5				
Malignant polyp	1		1				
Malignant splenic neoplasm	1		1				
Mantle cell lymphoma	8		8				
Mantle cell lymphoma recurrent	2		2				
Marginal zone lymphoma	3		3				
Marrow hyperplasia	4	1	2	1	2		
Medulloblastoma	1		1				
Melanocytic naevus	56		10	9	46		
Melanoma recurrent	6		6				
Meningioma	49	10	49				
Meningioma benign	2		2				
Mesenteric neoplasm	1		1				
Mesothelioma	3		3				
Metastases to abdominal cavity	1		1				
Metastases to adrenals	2		2				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Metastases to bone	23	8	23				
Metastases to breast	1		1				
Metastases to central nervous system	21	6	21			1	1
Metastases to heart	1		1				
Metastases to liver	38	7	38				
Metastases to lung	22	4	22				
Metastases to lymph nodes	48	8	48			1	1
Metastases to meninges	3		3				
Metastases to neck	1		1				
Metastases to ovary	1	1	1				
Metastases to peritoneum	8	2	8				
Metastases to pituitary gland	2	1	2				
Metastases to skin	6	3	6				
Metastases to spinal cord	1	1	1				
Metastases to spine	3	3	3				
Metastases to spleen	2		2				
Metastases to the mediastinum	2		2				
Metastasis	31	7	31				
Metastatic bronchial carcinoma	2		2				
Metastatic gastric cancer	1	1	1				
Metastatic lymphoma	3		3				
Metastatic malignant melanoma	5		5				
Metastatic neoplasm	16		16				
Metastatic renal cell carcinoma	1		1				
Monoclonal gammopathy	23	4	14	6	9		
Mucinous adenocarcinoma of appendix	1	1	1				
Mucinous breast carcinoma	1		1				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Muscle neoplasm	2	1	2				
Myelodysplastic syndrome	63	9	63				
Myelofibrosis	7	1	7				
Myeloid leukaemia	5	1	5				1
Myelolipoma	1				1		
Myeloproliferative neoplasm	9	2	9				
Myxoid liposarcoma	1	1	1				
Myxoma	2	1	2				
Naevus haemorrhage	1		1				
Naevus lipomatosus cutaneous superficialis	1				1		
Nasal cavity cancer	1		1				
Nasopharyngeal cancer	1		1				
Nasopharyngeal cancer metastatic	1		1				
Nasopharyngeal tumour	1		1				
Natural killer-cell lymphoblastic lymphoma	1	1	1				
Neoplasm	167	18	85	19	82		1
Neoplasm malignant	271	59	271			2	6
Neoplasm of orbit	1		1				
Neoplasm of thymus	1		1				
Neoplasm progression	121	21	96	3	25		1
Neoplasm prostate	1	1	1				
Neoplasm recurrence	35	9	29	2	6		
Neoplasm skin	29	1	10	2	19		1
Neoplasm swelling	5		3		2		
Nephroblastoma	1		1				
Neurilemmoma benign	2		2				
Neuroblastoma	1	1	1				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Neuroendocrine carcinoma	6	4	6				
Neuroendocrine carcinoma metastatic	3	2	3				
Neuroendocrine carcinoma of the skin	2	1	2				
Neuroendocrine tumour	6	2	5		1		
Neuroendocrine tumour of the lung metastatic	2	1	2				
Neuroendocrine tumour of the rectum	1		1				
Neurofibroma	4		2	2	2		
Neuroma	5		3		2		
Nodular fasciitis	1				1		
Nodular lymphocyte predominant Hodgkin lymphoma	2		2				
Nodular melanoma	1		1				
Non-Hodgkin's lymphoma	36	5	36				
Non-Hodgkin's lymphoma recurrent	4	1	4				
Non-Hodgkin's lymphoma stage IV	2		2				
Non-Hodgkin's lymphoma unspecified histology indolent	1	1	1				
Non-small cell lung cancer	4	3	4				
Non-small cell lung cancer metastatic	1	1	1				
Non-small cell lung cancer stage III	2	2	2				
Non-small cell lung cancer stage IV	1	1	1				
Ocular lymphoma	1		1				
Ocular neoplasm	1	1	1				
Oesophageal adenocarcinoma	2	1	2				
Oesophageal cancer metastatic	2		2				
Oesophageal carcinoma	6		6				
Oesophageal neoplasm	1		1				
Oesophageal papilloma	1			1	1		
Oesophageal squamous cell carcinoma	1		1				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Oligodendroglioma	2		2				
Oncocytoma	1				1		
Oncologic complication	2		1		1		
Optic glioma	1		1				
Oral fibroma	1	1	1				
Oral haemangioma	1				1		
Oral neoplasm	1		1				
Oral papilloma	2	1	2				
Oropharyngeal neoplasm benign	1				1		
Osteochondroma	1		1				
Osteoma	1		1				
Osteosarcoma	2	1	2				
Ovarian cancer	17	3	17				
Ovarian cancer recurrent	1		1				
Ovarian cancer stage III	1		1				
Ovarian cancer stage IV	1		1				
Ovarian dysgerminoma stage unspecified	2		2				
Ovarian epithelial cancer	2		2				
Ovarian fibroma	2	1	1	1	1		
Ovarian germ cell cancer	1		1				
Ovarian germ cell teratoma benign	4	2	3		1		
Ovarian granulosa cell tumour	1		1				
Ovarian neoplasm	5	1	5				
Paget's disease of nipple							1
Paget's disease of the vulva	1		1				
Pancreatic carcinoma	47	11	47				
Pancreatic carcinoma metastatic	7	3	7				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pancreatic carcinoma recurrent	1	1	1				
Pancreatic carcinoma stage IV	1	1	1				
Pancreatic cystadenoma	3		2		1		
Pancreatic neoplasm	4		3		1		1
Papillary cystadenoma lymphomatosum	11	4	7	2	4		
Papillary renal cell carcinoma	1	1	1				
Papillary thyroid cancer	9	2	9				
Papilloma	7		2	3	5		
Paraganglion neoplasm	1		1				
Paraneoplastic syndrome	7	1	7				
Paraproteinaemia	3	1	1	1	2		
Parathyroid tumour	1		1				
Parathyroid tumour benign	3		3				
Pelvic neoplasm	2		2				
Penile wart	1		1				
Pericardial lipoma	1		1				
Pericardial mesothelioma malignant	1		1				
Peritoneal neoplasm	2		2				
Peritumoural oedema	1	1	1				
Phaeochromocytoma	5	1	5				
Pharyngeal neoplasm	7		7				
Phyllodes tumour	1				1		
Pituitary tumour	4		4				
Pituitary tumour benign	20	7	14		6		
Plasmablastic lymphoma	2	2	2				
Plasma cell leukaemia	2		2				
Plasma cell myeloma	55	14	55				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Plasma cell myeloma recurrent	5	1	5				
Plasma cell myeloma refractory	1		1				
Plasmacytoma	10	5	10				
Pleomorphic adenoma	4	1	3		1		
Pleural mesothelioma	2	1	2				
Pleural mesothelioma malignant	1		1				
Pleural neoplasm	3		2		1		
POEMS syndrome	6	1	6				
Polycythaemia vera	16	6	16				
Poorly differentiated thyroid carcinoma	1		1				
Post transplant lymphoproliferative disorder	2		2				
Primary gastrointestinal follicular lymphoma	1		1				
Primary mediastinal large B-cell lymphoma	2		2				
Primary myelofibrosis	2	1	2				
Prolactin-producing pituitary tumour	5	1	5				
Prolymphocytic leukaemia	1	1	1				
Prostate cancer	65	20	65				
Prostate cancer metastatic	3	1	3				
Prostate cancer recurrent	2		2				
Prostatic adenoma	4		1	1	3		
Pyogenic granuloma	4		2		2		
Rectal adenocarcinoma	3		3				
Rectal cancer	8	4	8				
Rectal cancer metastatic	2	1	2				
Rectosigmoid cancer	1	1	1				
Recurrent cancer	10	1	10				
Refractory anaemia with an excess of blasts	2	1	2				

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Neoplasms benign, malignant and unspecified (incl cyst

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		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Refractory cytopenia with unilineage dysplasia	1		1				
Renal cancer	22	7	22				2
Renal cancer metastatic	3		3				
Renal cancer recurrent	2	1	2				
Renal cell carcinoma	4	2	4				
Renal haemangioma	2	1	1	1	1		
Renal hamartoma	2		2				
Renal neoplasm	12	1	9	1	3		
Retroperitoneal neoplasm	1		1				
Rhabdoid tumour	1		1				
Rhabdomyosarcoma	3	2	3				
Richter's syndrome	1		1				
Rosai-Dorfman syndrome	6	2	5	1	1		
Salivary gland adenoma	3		2		1		
Salivary gland cancer	2	1	2				
Salivary gland neoplasm	9		8		1	2	2
Sarcoma	4	1	4				
Sarcoma of skin	1		1				
Schwannoma	7	2	5		2		
Scrotal cancer	1	1	1				
Seborrhoeic keratosis	11	1	3	1	8		
Second primary malignancy	5	1	5				
Seminoma	1		1				
Skin cancer	25	7	25			2	5
Skin papilloma	108	2	22	13	86		2
Skin squamous cell carcinoma metastatic	1		1				
Small cell carcinoma	1		1				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Small cell lung cancer	12	5	12				
Small cell lung cancer metastatic	1		1				
Small intestine carcinoma	2	1	2				
Soft tissue neoplasm	2		1		1		
Soft tissue sarcoma	3	1	3				
Solitary fibrous tumour	1		1				
Spinal meningioma benign	2		2				
Spindle cell sarcoma	1		1				
Splenic marginal zone lymphoma	2	2	2				
Squamous cell carcinoma	24	6	24				
Squamous cell carcinoma of lung	1	1	1				
Squamous cell carcinoma of skin	9	3	9				2
Squamous cell carcinoma of the oral cavity	1		1				
Squamous cell carcinoma of the tongue	1		1				
Superficial spreading melanoma stage unspecified	1	1	1				
Synovial sarcoma	1	1	1				
Systemic mastocytosis	3	1	3				
T-cell lymphoma	7	2	7				
T-cell lymphoma recurrent	2	1	2				
T-cell lymphoma stage IV	1	1	1				
T-cell type acute leukaemia	3	3	3				
TEMPI syndrome	1		1				
Teratoma	2			1	2		
Testicular neoplasm	2		2				
Testis cancer	17	3	17			1	1
Throat cancer	4	2	4				
Thymoma	8	2	8			1	1

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Thyroid adenoma	6		1	1	5		
Thyroid cancer	18	6	18				
Thyroid cancer recurrent	1		1				
Thyroid neoplasm	7	1	6	1	1	1	1
Tongue neoplasm malignant stage unspecified	2	2	2				
Tonsil cancer	5	1	5				
Tonsil cancer metastatic	1	1	1				
Transitional cell carcinoma	4	2	4				
Triple negative breast cancer	10	5	10				
Triple positive breast cancer	1		1				
Tumour associated fever	1		1				
Tumour flare	1		1				
Tumour haemorrhage	6		6				
Tumour inflammation	2		1		1		
Tumour necrosis	1		1				
Tumour pain	9	1	8	1	1		
Tumour perforation	2		2				
Tumour pseudoprogression	1		1				
Tumour rupture	3		3				
Tumour thrombosis	3		3				
Undifferentiated nasopharyngeal carcinoma	1		1				
Urethral adenoma	1				1		
Urinary tract neoplasm	2		2				
Uterine cancer	8	3	8				2
Uterine leiomyoma	148	24	69	24	79	1	3
Uterine neoplasm	1		1			1	1
Uveal melanoma	1		1				

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System Organ Class

Neoplasms benign, malignant and unspecified (incl cyst

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vaginal cancer recurrent	1		1				
Vaginal cancer stage 0	1		1				
Vulval cancer	3	1	3				1
Vulval cancer metastatic	1	1	1				
Vulvovaginal warts	1				1		
Waldenstrom's macroglobulinaemia	9	2	9				
Waldenstrom's macroglobulinaemia stage III	1		1				
Xanthogranuloma	1				1		
Yolk sac tumour site unspecified	1		1				
Total:	4901	952	4105	167	796	23	74

System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acalculia	3	1	3				
Accessory nerve disorder	2		1		1		
Acquired epileptic aphasia	2	2	2				
Acquired syringomyelia	2		2				
Acrodynia	1				1		
Action tremor	8		3		5		
Acute disseminated encephalomyelitis	175	21	175				
Acute flaccid myelitis	3		3				
Acute haemorrhagic leukoencephalitis	1	1	1				
Acute motor axonal neuropathy	13		13				1
Acute motor-sensory axonal neuropathy	12	2	12				
Acute polyneuropathy	85	9	85				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Adrenergic syndrome	2		1		1		
Advanced sleep phase	1				1		
Ageusia	4777	69	942	472	3835	1	28
Agitation neonatal	7		2	1	5		
Agnosia	12		7		5		
Agraphia	5	1	4		1		
Akathisia	44	2	15		29		
Akinesia	32		32				
Alcoholic seizure	1		1				
Alcohol induced persisting dementia	1		1				
Alexia	8		5		3		
Alien limb syndrome	1	1	1				
Allodynia	203	6	67	23	136		
Altered pitch perception	3				3		
Altered state of consciousness	1063	155	1063			1	6
Amimia	1	1	1				
Amnesia	1922	75	833	160	1089	1	7
Amnestic disorder	63	2	31	5	32		2
Amputation stump pain	2		1		1		
Amyloid related imaging abnormalities	1		1				
Amyotrophic lateral sclerosis	100	35	100				1
Anaesthesia	294	5	45	7	249		
Anaesthesia dolorosa	4	1	3	1	1		
Anosmia	3809	55	717	404	3092	2	25
Anosognosia	7		4		3		
Anterograde amnesia	18	1	18				
Anticholinergic syndrome	2		2				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Anti-myelin-associated glycoprotein associated polyneuropat	1	1	1				
Apallic syndrome	15	3	15				
Aphasia	2487	169	1212	307	1275	1	9
Apraxia	78	7	47	3	31		1
Aqueductal stenosis	4	1	4				
Arachnoid cyst	20		10	1	10		
Arachnoiditis	6		6				
Areflexia	171	10	98	15	73		
Ascending flaccid paralysis	5	1	5				
Asterixis	15	1	15				
Ataxia	460	42	290	25	170		2
Athetosis	1				1		
Atonic seizures	45	6	28	5	17		
Auditory nerve disorder	13	1	7	1	6		1
Aura	201	2	65	15	136	1	3
Autoimmune demyelinating disease	7		7				
Autoimmune encephalopathy	11	3	11				
Autoimmune neuropathy	20	4	20				
Autonomic nervous system imbalance	301	28	158	34	143		
Autonomic neuropathy	38	4	38				
Autonomic seizure	5	1	5				
Axonal and demyelinating polyneuropathy	25	5	25				
Axonal neuropathy	40	4	25	2	15		
Balance disorder	5789	256	2154	543	3635	8	32
Ballismus	12	1	9		3		
Band sensation	59		19	1	40		1
Basal ganglia haematoma	4		4				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Basal ganglia haemorrhage	41	6	41				1
Basal ganglia infarction	24	1	24				
Basal ganglia stroke	10		10				
Basilar artery aneurysm	1		1				
Basilar artery occlusion	14	1	14				
Basilar artery stenosis	6	1	6				
Basilar artery thrombosis	39	5	39				1
Basilar migraine	6		5		1		
Behavioural induced insufficient sleep syndrome	1				1		
Bell's palsy	3543	237	3543			1	16
Benign enlargement of the subarachnoid spaces	1		1				
Benign fasciculation syndrome	1	1	1				
Bickerstaff's encephalitis	13	2	13				
Blood brain barrier defect	7	1	7				
Brachial plexopathy	51	4	27	5	24		
Bradykinesia	225	7	105	10	120		1
Brain compression	16		16				
Brain hypoxia	22	2	22				
Brain injury	183	20	183				
Brain oedema	229	18	229				
Brain stem haematoma	1		1				
Brain stem haemorrhage	52	4	52				1
Brain stem infarction	117	8	117				
Brain stem ischaemia	14	1	14				1
Brain stem microhaemorrhage	1		1				
Brain stem stroke	27	1	27				2
Brain stem syndrome	30	5	30				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Brain stem thrombosis	10		10				
Brown-Sequard syndrome	9	1	9				
Brudzinski's sign	1				1		
Bulbar palsy	12	2	12				
Burning feet syndrome	36	1	17	3	19		
Burning sensation	7705	154	1890	911	5815	2	17
Burning sensation mucosal	60	1	7	3	53		
Capsular warning syndrome	1		1				
Cardiac autonomic neuropathy	2	2	2				
Carotid aneurysm rupture	4	1	4				
Carotid arteriosclerosis	59	4	46		13		1
Carotid artery aneurysm	16	6	16				
Carotid artery disease	17	4	17				
Carotid artery dissection	75	8	75				
Carotid artery dolichoectasia	1				1		
Carotid artery occlusion	64	7	64				2
Carotid artery perforation	1		1				
Carotid artery stenosis	71	16	71				2
Carotid artery thrombosis	46	4	46				
Carpal tunnel syndrome	273	14	116	20	157		5
Cataplexy	20	4	20				
Catathrenia	1			1	1		
Cauda equina syndrome	16	1	16				
Cavernous sinus syndrome	2		2				
Central auditory processing disorder	2	1	2				
Central nervous system immune reconstitution inflammatory	1		1				
Central nervous system inflammation	64	13	64				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Central nervous system lesion	123	18	81	8	42		1
Central nervous system lupus	1		1				
Central nervous system necrosis	1		1				
Central nervous system vasculitis	29	3	29				
Central pain syndrome	38	2	15	2	23		
Cerebellar artery occlusion	2		2				
Cerebellar artery thrombosis	10		10				
Cerebellar ataxia	30	1	19		11		
Cerebellar atrophy	9	2	9				1
Cerebellar embolism	3	1	3				
Cerebellar haematoma	8	2	8				
Cerebellar haemorrhage	63	2	63				
Cerebellar infarction	163	22	163				
Cerebellar ischaemia	23	1	23				
Cerebellar stroke	70	6	70				1
Cerebellar syndrome	37	4	37				
Cerebellar tonsillar ectopia	1		1				
Cerebral amyloid angiopathy	20	1	20				
Cerebral arteriosclerosis	24	2	21		3		
Cerebral arteritis	1		1				
Cerebral artery embolism	85	10	85				1
Cerebral artery occlusion	65	3	65				
Cerebral artery perforation	2		2				
Cerebral artery stenosis	30	4	30				
Cerebral artery thrombosis	60	1	60				
Cerebral atrophy	69	8	69			3	4
Cerebral calcification	3		1		2		1

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cerebral capillary telangiectasia	2		2				
Cerebral circulatory failure	2		2				
Cerebral congestion	17	1	11	1	6		
Cerebral cyst	10		4	2	6		
Cerebral disorder	174	7	83	18	91		2
Cerebral haematoma	101	6	101				
Cerebral haemorrhage	1275	112	1275			1	6
Cerebral haemorrhage foetal	5		5				
Cerebral haemorrhage neonatal	1		1				2
Cerebral hypoperfusion	5		5				
Cerebral infarction	1979	166	1979				6
Cerebral infarction foetal	1		1				
Cerebral ischaemia	303	25	303				4
Cerebral mass effect	7	1	7				
Cerebral microangiopathy	19	3	11	2	8		
Cerebral microembolism	1		1				
Cerebral microhaemorrhage	20	2	20				
Cerebral microinfarction	7	1	7				
Cerebral small vessel ischaemic disease	29	2	29				
Cerebral thrombosis	407	43	407				4
Cerebral vascular occlusion	4	1	4				
Cerebral vasoconstriction	13	1	13				
Cerebral vasodilatation	3	1	3				
Cerebral venous sinus thrombosis	580	61	580				3
Cerebral venous thrombosis	256	21	256				6
Cerebral ventricle dilatation	17	2	13		4		2
Cerebral ventricular rupture	16	2	16				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cerebrosclerosis	2	1	2				
Cerebrospinal fluid circulation disorder	5	1	3		2		
Cerebrospinal fluid leakage	28	7	28				
Cerebrospinal fluid retention	2	1	2				
Cerebrovascular accident	4878	483	4877	1	1	14	56
Cerebrovascular disorder	138	10	105	7	33		2
Cerebrovascular insufficiency	3		3				
Cerebrovascular stenosis	4	1	4				
Cervical cord compression	3		3				
Cervical plexus lesion	1	1	1				
Cervical radiculopathy	138	7	54	8	84		
Cervical spinal cord paralysis	3		3				
Cervicobrachial syndrome	193	13	73	22	120		
Cervicogenic headache	23	1	6	1	17		
Cervicogenic vertigo	6		1		5		
Change in seizure presentation	2		2				
Cholinergic syndrome	22	2	22				
Chorea	29	1	22	1	7		
Choreoathetosis	3				3		
Chronic inflammatory demyelinating polyradiculoneuropathy	107	36	107				
Chronic lymphocytic inflammation with pontine perivascular e	1		1				
Chronic paroxysmal hemicrania	1		1				
Ciliary ganglionitis	1	1	1				
Circadian rhythm sleep disorder	39		11	4	28		1
Claude's syndrome	4		4				
Clinically isolated syndrome	22	4	22				
Clonic convulsion	47	3	47				2

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Clonus	92	3	52	4	40		
Clumsiness	147	6	59	7	88		
Cluster headache	546	21	285	29	261	1	3
Cognitive disorder	1315	92	603	151	712		4
Cognitive linguistic deficit	6		3		3		
Cogwheel rigidity	4		1		3		
Cold dysaesthesia	3				3		
Cold-stimulus headache	59		29	1	30		
Coma	389	36	389			1	2
Coma hepatic	6	1	6				
Complex regional pain syndrome	130	13	74	10	56		1
Concentric sclerosis	2		2				
Consciousness fluctuating	25	4	25				
Conus medullaris syndrome	2		2				
Convulsion in childhood	4	1	4				
Convulsions local	26	4	26				
Convulsive threshold lowered	4		2		2		
Coordination abnormal	748	49	319	58	429		4
Cortical laminar necrosis	1		1				
Cramp-fasciculation syndrome	18	1	9		9		
Cranial nerve disorder	54	3	36	4	18		2
Cranial nerve palsies multiple	13	3	13				
Cranial nerve paralysis	34	5	34				
Cubital tunnel syndrome	21		9	2	12		
Cytotoxic lesions of corpus callosum	15	8	15				
Cytotoxic oedema	4		4				1
Decerebrate posture	3		3				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Decorticate posture	2		2				
Decreased vibratory sense	39	2	17	2	22		
Delayed ischaemic neurological deficit	1		1				
Dementia	341	59	341				2
Dementia Alzheimer's type	80	16	80				
Dementia of the Alzheimer's type, with delirium	3	1	3				
Dementia of the Alzheimer's type, with depressed mood	1	1	1				
Dementia with Lewy bodies	7	3	7				
Demyelinating polyneuropathy	85	16	85				
Demyelination	222	35	222			1	2
Depressed level of consciousness	1778	156	1778				6
Developmental coordination disorder	1		1				
Diabetic coma	9		9				
Diabetic complication neurological	1			1	1		
Diabetic hyperglycaemic coma							1
Diabetic hyperosmolar coma	3		3				
Diabetic ketoacidotic hyperglycaemic coma	1		1				
Diabetic neuropathy	14	1	5	3	9		1
Diplegia	267	48	267				1
Disturbance in attention	8543	441	2204	1602	6339	2	17
Dizziness	105613	1840	22370	11047	83243	83	514
Dizziness exertional	175	12	93	13	82		
Dizziness postural	1741	28	805	78	936		14
Dreamy state	15		4		11		
Drooling	155	11	81	9	74		1
Drop attacks	24	3	24				
Dropped head syndrome	9	2	6	1	3		

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Drug withdrawal convulsions	1	1	1				
Drug withdrawal headache	1		1				
Dural arteriovenous fistula	8	1	8				
Dysaesthesia	1371	57	443	120	928		2
Dysarthria	1961	130	1205	98	756		15
Dyscalculia	5	1	3		2		
Dysdiadochokinesis	8		8				
Dysgeusia	7422	38	1056	563	6366	1	10
Dysgraphia	131	5	51	14	80		
Dyskinesia	1033	37	434	60	599		
Dyskinesia neonatal	1				1		
Dyslalia	116	5	92	3	24		
Dyslexia	30	3	12	3	18		
Dysmetria	21	3	21				1
Dyspraxia	40		22	3	18		
Dysprosody	1		1				
Dysstasia	1961	68	816	190	1145	1	7
Dystonia	87	9	87				
Dystonic tremor	1				1		
Electric shock sensation	893	24	267	107	626		4
Embolic cerebellar infarction	7		7				
Embolic cerebral infarction	44	2	44				
Embolic stroke	148	11	148				2
Encephalitis autoimmune	79	13	79			1	1
Encephalitis post immunisation	9	4	9				
Encephalomalacia	9		9			1	1
Encephalopathy	220	62	220				2

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Enlarged foetal cisterna magna	1		1				
Epidural lipomatosis	1				1		
Epilepsy	1952	196	1952			1	11
Epileptic aura	20		9		11		
Epileptic encephalopathy	6	1	6				
Essential tremor	45	6	27	1	18		
Exaggerated startle response	6				6		
Exertional headache	38	1	15	8	23		
Extensor plantar response	27	2	17	1	10		
External compression headache	4		1	2	3		
Extrapyramidal disorder	37	4	25	1	12		
Facial nerve disorder	123	2	43	8	80		
Facial paralysis	5622	471	5622			5	26
Facial paresis	1979	110	1176	81	803	1	10
Facial spasm	187	1	71	10	116		
Faciobrachial dystonic seizure	2		2				
Febrile convulsion	330	43	170	32	160		1
Febrile infection-related epilepsy syndrome	2	1	2				
Femoral nerve palsy	1				1		
Fine motor delay	3				3		
Fine motor skill dysfunction	236	29	109	26	127	1	1
Focal dyscognitive seizures	25	6	25				
Foetal movement disorder	16		12		4		
Fontanelle bulging	1		1				
Fontanelle depressed	1		1				
Formication	1002	15	220	121	782		1
Freezing phenomenon	47	1	18	2	29		

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Frontotemporal dementia	7	4	7				
Fumbling	17		6	5	11		
Gait spastic	8	1	4	2	4		
Gelastic seizure	1		1				
Generalised onset non-motor seizure	5	1	5				
Generalised tonic-clonic seizure	709	49	709				5
Geniculate ganglionitis	1				1		
Gerstmann's syndrome	1		1				
Glabellar reflex abnormal	1				1		
Glial scar	2		2				
Gliosis	19	1	8	2	11		
Glossopharyngeal nerve disorder	4		4				
Glossopharyngeal nerve paralysis	2	1	2				
Glossopharyngeal neuralgia	7		5		2		
Grimacing	4	1	3	1	1		
Gross motor delay	8	1	8				
Guillain-Barre syndrome	1825	266	1825				8
Haemorrhage intracranial	117	12	117			1	1
Haemorrhagic cerebellar infarction	1		1				
Haemorrhagic cerebral infarction	26		26				
Haemorrhagic stroke	200	20	200				
Haemorrhagic transformation stroke	25		25				
Hand-eye coordination impaired	8		3		5		
Harlequin syndrome	1			1	1		
Hashimoto's encephalopathy	3	1	3				
Headache	331035	2606	43100	32555	287935	100	1010
Head discomfort	5318	90	1145	620	4173	2	6

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Head titubation	81	6	38	5	43		
Hemianaesthesia	102	20	102				2
Hemianopia	96	10	96				
Hemianopia heteronymous	2		2				
Hemianopia homonymous	62	9	62				
Hemiapraxia	4		2		2		
Hemiasomatognosia	1		1				
Hemiataxia	19	3	19				
Hemidysaesthesia	47	5	47				
Hemihyperaesthesia	24	3	24				
Hemihypoaesthesia	326	68	326				3
Hemiparaesthesia	475	50	475				5
Hemiparesis	1738	200	1738			6	10
Hemiplegia	830	90	830				2
Hemiplegic migraine	87	2	61	2	26		
Hepatic encephalopathy	15	2	15				1
Hippocampal atrophy	8	1	3		5		
Hippocampal sclerosis	3		3				
Hoffmann's sign	5		2		3		
Horner's syndrome	35	9	35				
Hydrocephalus	74	10	74				
Hyperaesthesia	1776	41	398	202	1378	1	7
Hyperammonaemic encephalopathy	2		2				
Hypercapnic coma	4		4				
Hypergeusia	9		3		6		
Hyperintensity in brain deep nuclei	4		2	1	2		
Hyperkinesia	7		3		4		

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hyperpathia	7				7		
Hyperreflexia	71	5	44	3	27		
Hyperresponsive to stimuli	29	1	6	1	23		
Hypersomnia	2235	38	563	355	1672	4	10
Hypertensive cerebrovascular disease	3	1	3				
Hypertensive encephalopathy	18		18				
Hypertensive hydrocephalus	1		1				
Hypertonia	181	11	68	24	113	1	2
Hypoaesthesia	34246	911	9682	3813	24564	10	77
Hypogeusia	369	8	48	56	321		
Hypoglossal nerve disorder	4		3		1		
Hypoglossal nerve paralysis	7		7				
Hypoglossal nerve paresis	4	2	4				
Hypoglycaemic coma	4		4				
Hypoglycaemic seizure	1		1				
Hypoglycaemic unconsciousness	5		5				
Hypokinesia	2046	71	713	237	1333	1	1
Hypokinetic dysarthria	1		1				
Hyponatraemic coma	1	1	1				
Hyponatraemic encephalopathy	1	1	1				
Hyporeflexia	155	11	85	13	70		
Hyporesponsive to stimuli	53	3	38		15		
Hyposmia	263	6	35	47	228		
Hypotonia	1739	96	387	306	1352		1
Hypotonic-hyporesponsive episode	459	109	226	180	233		1
Hypoxic-ischaemic encephalopathy	52	6	52				
Idiopathic generalised epilepsy	5	1	5				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Idiopathic intracranial hypertension	81	15	81				4
IIIrd nerve disorder	19	1	17		2		
IIIrd nerve paralysis	100	10	100				
IIIrd nerve paresis	27	2	27				
Immune-mediated encephalitis	8		8				
Immune-mediated neurological disorder	5	1	5				
Immune-mediated neuropathy	17	7	17				
Inability to crawl	3		3				
Incoherent	121	3	67	3	54		1
Infantile spasms	2	2	2				
Infant irritability	57		18	3	39		
Infant sedation	2		2				
Intellectual disability	31	7	31				
Intelligence increased	1				1		
Intensive care unit acquired weakness	4	3	3		1		
Intention tremor	16	2	10	2	6		
Intercostal neuralgia	74	2	21	7	53		2
Internal capsule infarction	6		6				
Intracranial aneurysm	108	11	108				1
Intracranial artery dissection	2		2				
Intracranial haematoma	9	2	9				
Intracranial haemorrhage neonatal	1	1	1				
Intracranial hypotension	13	4	10		3		
Intracranial mass	14	2	12	1	2		
Intracranial pressure increased	185	28	185			1	2
Intraventricular haemorrhage	38	3	38				1
Irregular sleep phase	9		3	1	6		

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Irregular sleep wake rhythm disorder	22	2	7	3	15		
Ischaemic cerebral infarction	156	11	156			1	1
Ischaemic neuropathy	3		3				
Ischaemic stroke	1531	124	1531				7
IVth nerve disorder	4		3		1		
IVth nerve paralysis	37	5	37				
IVth nerve paresis	7		7				
Judgement impaired	13		2	2	11		
Juvenile absence epilepsy	1	1	1				
Juvenile myoclonic epilepsy	2		2				
Kernig's sign	1		1				
Lacunar infarction	98	3	98				3
Lacunar stroke	40	4	40				
Language disorder	461	49	204	45	257	2	7
Large fibre neuropathy	1		1				
Laryngeal nerve palsy	1	1	1				
Laryngeal tremor	1				1		
Lateral medullary syndrome	19	2	19				
Lateropulsion	6		3	1	3		1
Lennox-Gastaut syndrome	1		1				
Lethargy	10011	70	2870	525	7141	5	35
Leukoencephalopathy	61	5	61				
Lewis-Sumner syndrome	3	1	3				
Lhermitte's sign	24	2	8	3	16		
Limbic encephalitis	35	5	35				
Locked-in syndrome	8	1	8				
Long thoracic nerve palsy	4	1	1		3		

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Loss of consciousness	8549	870	8546	2	3	8	59
Loss of proprioception	24		11	2	13		
Lower motor neurone lesion	9		5		4		
Lumbar radiculopathy	17		8		9		
Lumbosacral plexopathy	4		3		1		
Lumbosacral radiculopathy	18		9	1	9		
Lumbosacral radiculoplexus neuropathy	4	3	4				
Medication overuse headache	3		1		2		
Memory impairment	4007	223	1147	703	2860	3	16
Meningeal disorder	34		12	6	22		
Meningeal thickening	3		2		1		
Meningism	98	4	38	10	60		2
Meningitis noninfective	2		1		1		
Meningoradiculitis	17	1	15		2		
Meningorrhagia	11	1	11				
Menstrual headache	55		7	9	48		
Mental impairment	709	84	709				7
Meralgia paraesthetica	26	3	10	4	16		
Metabolic encephalopathy	10	1	10				
Micrographia	1		1				
Microsleep	6	2	3	1	3		
Microvascular cranial nerve palsy	3		3				
Migraine	14385	257	4652	1433	9733	6	59
Migraine-triggered seizure	5		5				
Migraine with aura	899	29	358	84	541	1	5
Migraine without aura	47		25	2	22		
Millard-Gubler syndrome	1	1	1				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Miller Fisher syndrome	89	12	89				
Mononeuritis	40	5	27	2	13		
Mononeuropathy	36	4	23	4	13		
Mononeuropathy multiplex	26	2	22		4		
Monoparesis	613	36	375	38	238	1	8
Monoplegia	994	124	994			5	13
Morton's neuralgia	10		3	1	7		
Morvan syndrome	2		2				
Motor developmental delay	2		1		1		
Motor dysfunction	929	51	434	92	495	1	2
Motor neurone disease	41	17	41				
Movement disorder	3478	146	1130	349	2348	2	9
Moyamoya disease	3		3				
Multifocal motor neuropathy	6	2	6				
Multiple sclerosis	722	140	722			8	30
Multiple sclerosis pseudo relapse	9	1	8		1	1	1
Multiple sclerosis relapse	601	136	601			5	40
Multiple system atrophy	3	1	3				
Muscle contractions involuntary	881	37	256	95	625		1
Muscle spasticity	201	16	92	18	109		1
Muscle tension dysphonia	2	1	1		1		
Muscle tone disorder	11	2	4		7		
Myasthenia gravis	296	77	296			3	4
Myasthenia gravis crisis	17	1	17				
Myasthenic syndrome	27	5	27				
Myelin oligodendrocyte glycoprotein antibody-associated dis	16	6	16				
Myelitis transverse	292	42	292				1

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Myelomalacia	3		3			1	1
Myelopathy	70	16	70				
Myoclonic epilepsy	22	2	22				
Myoclonus	362	24	192	25	170		
Myotonia	5		3		2		
Myxoedema coma	1		1				
Narcolepsy	100	15	100				
Neonatal epileptic seizure	1		1				
Neonatal seizure	7		7				
Nerve compression	243	4	97	22	146		7
Nerve degeneration	10	2	5	1	5		
Nervous system disorder	1425	83	635	195	790	3	6
Neuralgia	6456	310	2056	860	4400	1	11
Neuralgic amyotrophy	532	83	351	48	181		1
Neuritic plaques	1				1		
Neuritis	490	27	192	49	298		3
Neuritis cranial	24	1	24				
Neurodegenerative disorder	14	4	14				
Neuroleptic malignant syndrome	10		10				
Neurological decompensation	28	5	23	2	5		
Neurological symptom	586	35	317	55	269	3	6
Neurologic neglect syndrome	52	7	38	2	14		
Neuromuscular blockade	8		1	1	7		
Neuromuscular pain	30	2	12	2	18		
Neuromuscular toxicity	1	1	1				
Neuromyelitis optica spectrum disorder	82	17	82				
Neuromyopathy	46	11	46				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Neuromyotonia	3	1	2		1		
Neuronal neuropathy	4		4				
Neuropathy peripheral	2018	250	2017		1	13	30
Neuropathy vitamin B6 deficiency	1		1				
Neuropsychiatric lupus	1		1				
Neurosarcoidosis	12	4	12				
Neurotoxicity	8	1	8				
Neurovascular conflict	2	1	1		1		
New daily persistent headache	65	6	36	7	29		
Non-24-hour sleep-wake disorder	4		1		3		
Noninfectious myelitis	3		3				
Noninfective encephalitis	82	11	82			1	1
Normal pressure hydrocephalus	9	3	9				
Notalgia paraesthetica	4			1	4		
Numb chin syndrome	3		3				
Nystagmus	385	27	194	24	191		
Occipital neuralgia	137	4	54	6	83		
Oculocephalogyric reflex absent	1				1		
Oculofacial paralysis	9	1	9				
Olfactory dysfunction	9	1	4	3	5		
Olfactory nerve disorder	6			1	6		
On and off phenomenon	5			1	5		
Ophthalmic migraine	298	10	77	43	221		2
Ophthalmoplegic migraine	5			1	5		
Opisthotonus	10	1	10				
Optic neuritis	546	79	546				5
Optic perineuritis	3		3				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Oromandibular dystonia	8		3		5		
Orthostatic intolerance	119	10	52	16	67		
Orthostatic tremor	3			1	3		
Osmotic demyelination syndrome	2	1	2				
Pachymeningitis	12	1	12				
Palatal palsy	5		3	2	2		
Pancoast's syndrome	1		1				
Paraesthesia	50471	1043	11627	4758	38844	14	124
Paraesthesia mucosal	23		9	1	14		
Paralysis	1594	239	1594			2	9
Paralysis recurrent laryngeal nerve	14	4	14				
Paraneoplastic encephalomyelitis	2		2				
Paraparesis	143	27	143				
Paraplegia	91	17	91				
Paresis	531	36	288	45	243		1
Paresis cranial nerve	15		11		4		
Parkinsonian crisis	1		1				
Parkinsonian gait	11	2	3	1	8		
Parkinsonian rest tremor	5		1		4		
Parkinsonism	62	5	42	4	20		
Parkinson's disease	149	30	149			2	4
Parosmia	2316	25	409	329	1907		5
Paroxysmal choreoathetosis	1	1	1				
Paroxysmal sympathetic hyperactivity	2		2				
Partial seizures	171	22	171				
Partial seizures with secondary generalisation	12	1	12				
Patient elopement	14		5		9		

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Perinatal stroke	2		2				
Periodic limb movement disorder	4	1	3	1	1		
Peripheral motor neuropathy	38	5	28		10		2
Peripheral nerve lesion	49	7	24	9	25		
Peripheral nerve palsy	18	1	8	1	10		
Peripheral nerve paresis	24	2	18	1	6		
Peripheral paralysis	37	4	37				2
Peripheral sensorimotor neuropathy	27	2	22		5		1
Peripheral sensory neuropathy	133	12	84	11	49		
Periventricular leukomalacia	6	2	6				
Peroneal nerve palsy	137	14	77	11	60		
Persistent genital arousal disorder	5		2		3		
Persistent postural-perceptual dizziness	40	4	27	2	13		
Petit mal epilepsy	175	20	175				
Phantom limb syndrome	39	3	11	7	28		
Phrenic nerve irritation	1				1		
Phrenic nerve paralysis	7	1	7				
Pineal gland cyst	6		5	1	1		
Piriformis syndrome	19	1	7	2	12		
Pleocytosis	43	1	28	1	15		
Pleurothotonus	1		1				
Polyneuropathy	694	169	694			1	3
Polyneuropathy chronic	5		2	1	3		
Polyneuropathy idiopathic progressive	2		2				
Polyneuropathy in malignant disease	1		1				
Poor sucking reflex	1		1				
Post-anoxic myoclonus	1		1				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Post cardiac arrest syndrome	3		3				
Posterior cortical atrophy	2		2				
Posterior interosseous syndrome	6		3		3		
Posterior reversible encephalopathy syndrome	18	4	18				1
Posthaemorrhagic hydrocephalus	1		1				
Post herpetic neuralgia	346	35	147	32	199		1
Postictal headache	1		1				
Postictal paralysis	15		15				
Postictal state	43		24		19		
Post polio syndrome	1		1				
Postresuscitation encephalopathy	2	1	2				
Post stroke epilepsy	3	1	3				
Post stroke seizure	2	1	2				
Post-traumatic epilepsy	3		3				
Post-traumatic neuralgia	2				2		
Postural reflex impairment	1			1	1		
Postural tremor	6		5	1	1		
Precerebral artery occlusion	2	1	2				
Precerebral artery thrombosis	1		1				
Presbyastasis	2		1		1		
Presyncope	9123	113	2735	578	6388	1	29
Primary cough headache	7		3	1	4		
Primary headache associated with sexual activity	16		13		3		
Primary progressive multiple sclerosis	1		1				
Prodromal Alzheimer's disease	2	1	2				
Progressive bulbar palsy	3		3				
Progressive multiple sclerosis	2		2				

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Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Progressive supranuclear palsy	7	1	7				
Pronator teres syndrome	1		1				
Prosopagnosia	2		1		1		
Pseudobulbar palsy	1		1				
Pseudoparalysis	2		1		1		
Pseudoradicular syndrome	1		1				
Pseudostroke	7	2	7			1	1
Psychogenic seizure	108	14	87	2	21		
Psychomotor disadaptation syndrome	3	1	3				
Psychomotor hyperactivity	233	6	76	22	157		
Psychomotor skills impaired	47	2	25	1	22		
Pudendal canal syndrome	16	1	10		6		
Putamen haemorrhage	34	2	34				
Pyramidal tract syndrome	21	3	21				
Quadrantanopia	23	3	23				
Quadriparesis	125	21	125			1	1
Quadriplegia	72	10	72				
Radial nerve compression	1		1				
Radial nerve palsy	52	2	28	2	24		
Radicular pain	23		7	2	16		
Radiculitis brachial	71	6	43	5	28		
Radiculopathy	195	18	110	15	85		
Radiologically isolated syndrome	2		2				
Raymond-Cestan syndrome	1		1				
Reduced facial expression	73	4	31	1	42		
Reflexes abnormal	38	3	17	6	21		
Relapsing multiple sclerosis	9		9				

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Relapsing-remitting multiple sclerosis	30	10	30				
Repetitive speech	10		6	1	4		
Resting tremor	24		9	2	15		
Restless arm syndrome	24	1	6	2	18		
Restless legs syndrome	710	21	208	73	502	1	1
Retinal migraine	55		33		22		1
Retrograde amnesia	43	4	23	2	20		
Reversed hot-cold sensation	38		7	5	31		
Reversible cerebral vasoconstriction syndrome	20	2	20				
Reversible ischaemic neurological deficit	2		2				1
Right hemisphere deficit syndrome	2		2				
Ruptured cerebral aneurysm	54	2	54				
Sacral radiculopathy	1		1				
Sciatica	886	27	350	55	536		8
Sciatic nerve neuropathy	13		6	1	7		
Sciatic nerve palsy	6		3		3		
Secondary cerebellar degeneration	2		2				
Secondary progressive multiple sclerosis	4	1	4				
Sedation	200	9	52	36	148		3
Seizure	5152	660	5152			7	34
Seizure anoxic	6	1	6				
Seizure cluster	8		8				
Seizure like phenomena	55	5	55				
Senile dementia	9	2	9				
Sensorimotor disorder	93	10	61	10	32		
Sensory disturbance	2828	197	1013	378	1815	2	9
Sensory ganglionitis	1		1				

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Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Sensory loss	1195	36	502	176	693		5
Sensory overload	39	2	15	7	24		
Sensory processing disorder	14		8	1	6		
Sensory processing sensitivity	1	1	1				
Serotonin deficiency	1				1		
Serotonin syndrome	8	2	8				
Sigmoid sinus thrombosis	4	3	4				
Simple partial seizures	6		6				
Sinus headache	553	1	255	12	298	1	5
Sleep deficit	195	3	50	27	145		
Sleep paralysis	86	1	21	6	65		
Slow response to stimuli	96		39	3	57		
Slow speech	143	5	76	3	67		
Small fibre neuropathy	242	45	146	29	96		
Sneddon's syndrome	1		1				
Somnolence	17540	251	2855	2890	14685	6	36
Somnolence neonatal	1				1		
Spasmodic dysphonia	6		3	1	3		
Speech disorder	2520	101	1219	181	1301	2	9
Speech disorder developmental	19	2	8	1	11		
Sphenopalatine neuralgia	1	1	1				
Spinal claudication	4	1	3		1		
Spinal cord compression	19	3	19				1
Spinal cord disorder	57	9	57				
Spinal cord haemorrhage	7	1	7				
Spinal cord herniation	1		1				
Spinal cord infarction	25	4	25				

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Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Spinal cord ischaemia	18	4	18				
Spinal cord oedema	7	1	7				
Spinal epidural haematoma	4		4				
Spinal epidural haemorrhage	1		1				
Spinal meningeal cyst	6		4	2	2		
Spinal stroke	4	1	4				
Spinal subdural haemorrhage	1		1				
Spinal vascular disorder	3		3				
Spinocerebellar disorder	2		2				
Spondylitic myelopathy	1				1		
Status epilepticus	232	17	232				
Status migrainosus	32	6	22	2	10		3
Stiff leg syndrome	9		3		6		
Stiff person syndrome	11	3	11				1
Stroke in evolution	8		8				
Stupor	132	5	43	5	89		2
Subacute combined cord degeneration	3	1	3				
Subacute inflammatory demyelinating polyneuropathy	6	3	6				
Subarachnoid haemorrhage	416	29	416				
Subdural hygroma	6	1	6				
Sudden onset of sleep	64	11	64				
Superficial siderosis of central nervous system	1				1		
Superior sagittal sinus thrombosis	42	3	42				1
Supranuclear palsy	1		1				
Supraorbital neuralgia	1				1		
Sydenham's chorea	1		1				
Sympathicotonia	9		1		8		

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Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Sympathomimetic effect	1				1		
Synaesthesia	4		2		2		
Syncope	15629	1656	15629			23	147
Synkinesis	8	2	6	1	2		
Tardive dyskinesia	15	1	15				
Taste disorder	3076	33	488	435	2588	2	5
Temporal lobe epilepsy	15	2	15				
Tension headache	1483	26	582	97	901		14
Thalamic infarction	102	8	102				1
Thalamic stroke	1	1	1				
Thalamus haemorrhage	55	10	55				1
Thermoanaesthesia	4		2		2		
Thermohyperaesthesia	5		1		4		
Thermohypoaesthesia	17		10	1	7		
Thoracic outlet syndrome	31	2	11	5	20		
Thoracic radiculopathy	1			1	1		
Thoracic spinal cord paralysis	1		1				
Thrombotic cerebral infarction	37	1	37				
Thrombotic stroke	39	2	39				
Thunderclap headache	67	4	41	3	26		
Tinel's sign	6		2		4		
Tongue biting	115	5	70	7	45		
Tongue paralysis	74	6	74				1
Tonic clonic movements	91	5	91				
Tonic convulsion	122	8	122				
Tonic posturing	5	1	5				
Toxic encephalopathy	1		1				

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Toxic neuropathy	2		2				
Transient aphasia	29	1	23	1	6		
Transient epileptic amnesia	2	1	2				
Transient global amnesia	138	8	81	9	57		1
Transient ischaemic attack	1776	139	1776			1	11
Transverse sinus stenosis	4	1	4				
Transverse sinus thrombosis	52	12	52				2
Tremor	13045	320	4563	1184	8482	8	48
Tremor neonatal	3		2		1		
Trigeminal nerve disorder	135	4	55	4	80		
Trigeminal nerve paresis	11	1	11				
Trigeminal neuralgia	994	54	378	73	616		3
Trigeminal neuritis	34	1	15	2	19		
Trigeminal neuropathy	6	4	5		1		
Trigeminal palsy	21	1	21				
Tumefactive multiple sclerosis	5	2	5				
Tunnel vision	143	14	142		1	1	1
Typical aura without headache	25		15	3	10		
Uhthoff's phenomenon	13		3	6	10		
Ulnar nerve palsy	21	9	17	1	4		
Ulnar neuritis	17	2	17				
Ulnar tunnel syndrome	8	1	5	1	3		
Unresponsive to stimuli	479	33	479				
Upper motor neurone lesion	5		5				
Uraemic encephalopathy	1	1	1				
Useless hand syndrome	1	1	1				
Vagus nerve disorder	32	7	32				1

* I=Interval, C=Cumulative
* AE=Adverse Event
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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vagus nerve paralysis	7	2	7				
Vascular cognitive impairment	1		1				
Vascular dementia	23	1	23				
Vascular encephalopathy	22	3	22				
Vascular headache	33		18		15		
Vascular parkinsonism	2		2				
Vasogenic cerebral oedema	5		5				1
Vertebral artery aneurysm	3		3				
Vertebral artery occlusion	14	2	14				
Vertebral artery stenosis	10	4	10				
Vertebral artery thrombosis	12		12				
Vertebrobasilar artery dissection	58	5	58				1
Vertebrobasilar dolichoectasia	1		1				
Vertebrobasilar insufficiency	10	1	7	1	3		
Vertebrobasilar stroke	20	2	20				
Vertigo CNS origin	9	1	5		4		1
Vestibular migraine	79	8	54	1	25		1
Vestibular nystagmus	2		1		1		
Vibration syndrome	15	1	5	4	10		
Vibratory sense increased	26		3	1	23		
VIIIth nerve lesion	5	1	4		1		
Visual agnosia	4	2	4				
Visual pathway disorder	12		3	2	9		
Visual perseveration	15	2	7	1	8		
Visuospatial deficit	6	1	3	1	3		
VIth nerve disorder	16	2	13		3		
VIth nerve paralysis	149	19	149				3

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System Organ Class

Nervous system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
VIth nerve paresis	13	2	8		5		
Vocal cord paralysis	77	10	49	5	28		1
Vocal cord paresis	10	2	5		5		
Wallerian degeneration	1				1		
Wernicke's encephalopathy	2	1	2				
White matter lesion	72	5	45	3	27		
Writer's cramp	2	1	2				
Total:	791909	21572	228552	72401	563357	413	3041

System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal cord insertion	1		1				
Abnormal labour	2				2	1	2
Abortion	72	9	72			2	2
Abortion complete	4		4				
Abortion complicated	1		1				
Abortion early	20	1	20				2
Abortion incomplete	8		8				
Abortion late	11	1	11				
Abortion missed	126	9	126				
Abortion of ectopic pregnancy	4	1	4				
Abortion spontaneous	1976	133	1976			2	41
Abortion spontaneous complete	10		10				
Abortion spontaneous complicated	1		1				
Abortion spontaneous incomplete	2		2				

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abortion threatened	9		9				1
Afterbirth pain	1				1		
Amniorrhexis	11	1	7	1	4		
Amniorrhoea	11	2	8		3	1	1
Amniotic cavity disorder	2		1		1		
Anaphylactoid syndrome of pregnancy	1		1				
Anembryonic gestation	27		22	1	5		
Arrested labour	3		2		1		
Biochemical pregnancy	4		2		2		
Birth trauma							1
Breech delivery	1		1				
Breech presentation							5
Cephalhaematoma	2		2				
Cephalo-pelvic disproportion	3		1		2		
Cervical dilatation	1				1		
Cervical incompetence	7	1	7				
Cervix dystocia	1		1				
Complication of delivery	2		2				1
Complication of pregnancy	14	2	7	1	7		
Decidual cast	11		6	1	5		
Delayed delivery	1		1				
Delivery	1			1	1		
Eclampsia	3	1	3				1
Ectopic pregnancy	80	11	80				2
Face presentation	1		1				
False labour	1				1		1
First trimester pregnancy	1				1		

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Foetal cardiac disorder	14	4	14				
Foetal damage	1		1				
Foetal death	172	18	172			1	6
Foetal disorder	5		5				
Foetal distress syndrome	12		12				3
Foetal growth abnormality	11	1	11				
Foetal growth restriction	139	16	139			3	9
Foetal hypokinesia	74	5	74				8
Foetal macrosomia	3		2		1		
Foetal malnutrition	1		1				
Foetal malpresentation	1				1		
Foetal-maternal haemorrhage	4	1	4				
Foetal vascular malperfusion	13	2	13			1	1
Gestational diabetes	20	1	20			1	3
Gestational hypertension	10		6		4		2
Gestational trophoblastic detachment	3		3				
Habitual abortion	1	1	1				
Haemorrhage foetal	2	1	2				
Haemorrhage in pregnancy	85	8	85			1	3
HELLP syndrome	15		15				1
High risk pregnancy	5		3		2		
Hydrops foetalis	8		8				
Hyperemesis gravidarum	9	2	9				1
Hypothermia neonatal	1		1				
Hypoxic ischaemic encephalopathy neonatal	1		1				
Imminent abortion	3		3				
Increased foetal movements	1				1		

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Induced labour	8		1	1	7		
Intrapartum haemorrhage	3		3				1
Jaundice neonatal	21		9	3	12		2
Labour complication	5		1		4		
Labour pain	184	10	98	17	86		
Large for dates baby							2
Live birth	5		2		3		
Low birth weight baby	11	2	9	1	2		
Maternal condition affecting foetus	5	2	4		1		
Meconium in amniotic fluid	5	1	5				
Meconium stain	2		2				
Molar abortion	1		1				
Morning sickness	69	1	27	4	42		
Neonatal disorder	9			2	9		
Normal newborn	11			1	11		1
Obstructed labour	2		2				
Oligohydramnios	14		14			1	3
Pelvic girdle pain	19	4	9	2	10		
Perinatal brain damage	1		1				
Peripartum cardiomyopathy	2		2				
Peripartum haemorrhage	3		3				1
Placental calcification	3	1	3				
Placental disorder	25	2	18		7		
Placental infarction	5	1	4		1		
Placental insufficiency	21	9	21				
Placental necrosis	1		1				
Placenta praevia	4	1	4				1

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Placenta praevia haemorrhage	7	2	7				
Polyhydramnios	5		5				
Poor weight gain neonatal	4	1	1		3		1
Post abortion haemorrhage	4		4				
Postmature baby	1			1	1		
Postpartum disorder	2				2		
Postpartum haemorrhage	27	1	14		13	1	3
Postpartum state	2				2		
Precipitate labour	1			1	1		
Pre-eclampsia	40	5	33		7	3	12
Pregnancy	36	2	17		19		
Pregnancy after post coital contraception	4		4				
Pregnancy in habitual aborter	1				1		
Pregnancy of unknown location	1		1				
Pregnancy on contraceptive	8		8				
Pregnancy on oral contraceptive	16	2	16				
Pregnancy with contraceptive device	12	1	12				
Pregnancy with implant contraceptive	2		2				
Premature baby	212	23	165	5	47	4	15
Premature delivery	51	5	39	1	12	1	3
Premature labour	72	8	52	1	20	1	5
Premature rupture of membranes	44	7	38	1	6		3
Premature separation of placenta	28		28			2	5
Preterm premature rupture of membranes	29	2	24		5		2
Previous caesarean section	1	1	1				
Prolonged labour	4	1	2		2		3
Prolonged pregnancy	1				1		5

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pseudomenstruation neonatal	1				1		
Retained placenta or membranes	7		4		3		1
Retained products of conception	1		1				
Retroplacental haematoma	14	2	14				1
Risk of future pregnancy miscarriage	2		1		1		
Ruptured ectopic pregnancy	4	1	4				
Second trimester pregnancy							1
Shoulder dystocia	1		1				
Small for dates baby	12	3	9		3		1
Small size placenta	5	2	5				
Somatic symptom disorder of pregnancy	7		3		4		
Spontaneous rupture of membranes	1	1	1				
Stillbirth	66	9	66			1	3
Subchorionic haematoma	9	4	9				
Subchorionic haemorrhage	3		2	1	1		1
Term birth	1				1		
Third stage postpartum haemorrhage	1		1				
Third trimester pregnancy	1				1		
Threatened labour	17	3	16		1	1	1
Traumatic delivery	1		1				
Tubal rupture	1		1				
Twin pregnancy	4		1		3		
Umbilical cord abnormality	7		5		2	1	1
Umbilical cord around neck	1		1				
Umbilical cord compression	1		1				
Umbilical cord short	1		1				
Umbilical cord thrombosis	7	2	7				

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System Organ Class

Pregnancy, puerperium and perinatal conditions

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Unintended pregnancy	24		7	1	17		
Unwanted pregnancy	9	1	3		6		
Uterine atony	1		1				
Uterine contractions abnormal	49	1	18	5	31		
Uterine contractions during pregnancy	83	1	38	8	45		
Uterine hypertonus	37		9	5	28		
Uterine hypotonus	5		2	1	3		
Uterine irritability	1		1				
Vanishing twin syndrome							1
Vasa praevia							4
Weight decrease neonatal	3		2		1		
Total:	4493	357	3958	67	535	29	180

System Organ Class

Product issues

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Device breakage	9	1	7		2		
Device connection issue	25				25		
Device defective	1		1				
Device delivery system issue	1				1		
Device deposit issue	1			1	1		
Device dislocation	6		5	1	1		
Device expulsion	20	2	5	5	15		
Device failure	4		1		3		
Device infusion issue	1		1				
Device issue	14			2	14		

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System Organ Class

Product issues

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Device leakage	4	1	1	1	3		
Device loosening	2		2				
Device malfunction	7		1		6		
Device material issue	1			1	1		
Device occlusion	3		2		1		1
Device pacing issue	1		1				
Device physical property issue	7		1	2	6		
Device power source issue	1	1	1				1
Device stimulation issue	1				1		
Device temperature issue	1				1		
Drug delivery system malfunction	1				1		
Electromagnetic interference	9		3		6		
Embedded device	2		1		1		
Lead dislodgement	1		1				
Liquid product physical issue	156			42	156		
Needle issue	133	1	5	4	128	1	2
Oversensing	58		22	6	36		
Packaging design issue	1			1	1		
Patient-device incompatibility	6	1	2	2	4		
Physical product label issue	4			1	4	1	1
Product adhesion issue	1				1		
Product after taste	23		3	2	20		
Product availability issue						1	2
Product closure issue	3				3		
Product colour issue	64			1	64		
Product complaint	80		4	1	76	1	1
Product container issue	30			7	30		

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System Organ Class

Product issues

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Product container seal issue	8			1	8		
Product contamination	13				13		
Product contamination chemical	2		1		1		
Product contamination microbial	1		1				
Product contamination physical	78		2		76		
Product counterfeit	1				1		
Product delivery mechanism issue	1				1		
Product deposit	7				7		
Product design issue	1		1				
Product distribution issue	51			51	51		
Product expiration date issue	77			58	77		
Product formulation issue	5		1		4		
Product impurity	4				4		
Product label issue	142			115	142		
Product leakage	163			6	163		
Product lot number issue	17			2	17		
Product odour abnormal	8		2		6		
Product origin unknown	1		1				
Product packaging issue	9			5	9	1	1
Product packaging quantity issue	48			6	48		
Product physical consistency issue	1				1		
Product physical issue	26			1	26		
Product quality issue	183	1	7	8	176		1
Product reconstitution quality issue	10				10		
Product supply issue	32			1	32		
Product taste abnormal	19		2	1	17		
Product temperature excursion issue	21908		3	7464	21905		1

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System Organ Class

Product issues

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Suspected counterfeit product	47		1	4	46		
Suspected product contamination	3		1		2		
Suspected product quality issue	8		1		7		
Suspected product tampering	2				2		
Syringe issue	111			3	111		
Thrombosis in device	20		20				
Undersensing	9		4	1	5		
Total:	23698	8	118	7807	23580	5	11

System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aberrant motor behaviour	3		2		1		
Abnormal behaviour	240	17	103	18	137		1
Abnormal dreams	603	1	138	38	465		1
Abnormal sleep-related event	16		3	4	13		
Abulia	22		7	3	15		
Acrophobia	3				3		
Activation syndrome	1			1	1		
Acute psychosis	18	1	18				
Acute stress disorder	5974	2	63	115	5911		
Adjustment disorder	24	4	8	8	16		
Adjustment disorder with depressed mood	45	6	23	4	22		
Adjustment disorder with mixed anxiety and depressed mooc	1		1				
Adjustment disorder with mixed disturbance of emotion and c	1	1	1				
Aerophobia	1		1				

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Affective ambivalence	1				1		
Affective disorder	138	10	33	22	105		1
Affect lability	189	3	34	16	155		
Aggression	278	12	94	24	184		1
Agitated depression	9		5	1	4		
Agitation	1069	22	372	59	697		4
Agoraphobia	8	1	5	1	3		
Alcoholic hangover	3		1	1	2		
Alcoholic psychosis	1		1				
Alcoholism	13		13				
Alcohol problem	3	1	2		1		
Alcohol use disorder	1				1		
Alcohol withdrawal syndrome	1		1				
Alexithymia	3			2	3		
Alice in wonderland syndrome	3				3		
Anger	251	5	80	25	171		1
Anhedonia	32	1	11	4	21		
Anorexia nervosa	2				2		
Anorgasmia	11		7	2	4		
Anticipatory anxiety	6	1	2		4		1
Antisocial behaviour	4			2	4		
Antisocial personality disorder	1		1				
Anxiety	8097	223	2680	782	5417	6	37
Anxiety disorder	197	16	58	38	139		
Anxiety disorder due to a general medical condition	3			1	3		
Apathy	1229	52	246	253	983	1	3
Asocial behaviour	3			3	3		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Attention deficit hyperactivity disorder	46	2	14	6	32		
Attention-seeking behaviour	1		1				
Autism spectrum disorder	21	4	21				
Automatism	3		2		1		
Automatism epileptic	1		1				
Autophobia	1			1	1		
Autoscopy	49		21		28		
Aversion	14		4	1	10		
Behaviour disorder	94	2	41	7	53		
Behaviour disorder due to a general medical condition	1		1				
Belligerence	2		1		1		
Binge drinking	1				1		
Binge eating	14		1	2	13		
Bipolar disorder	31	4	31				
Bipolar I disorder	15	4	15				
Bipolar II disorder	1		1				
Blunted affect	4			3	4		
Body dysmorphic disorder	5		3	1	2		
Borderline personality disorder	5		1		4		
Boredom	23	1	2	16	21		
Bradyphrenia	358	9	116	35	242		2
Breath holding	8		5	1	3		
Breathing-related sleep disorder	9	2	3	3	6		
Brief psychotic disorder with marked stressors	2		2				
Brief psychotic disorder without marked stressors	1		1				
Brief psychotic disorder, with postpartum onset	1		1				
Bruxism	79	2	28	8	51		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Bulimia nervosa	1		1				
Burnout syndrome	48	2	20	9	28		
Cardiovascular somatic symptom disorder	5		1	1	4		
Catastrophic reaction	2		2				
Catatonia	19	3	9	2	10		
Change in sustained attention	2				2		
Chronic idiopathic pain syndrome	7	2	3		4		
Clang associations	1				1		
Claustrophobia	24	2	8	2	16		
Clinomania	2				2		
Communication disorder	114	8	60	5	54		
Completed suicide	31	2	31				
Complex tic	1		1				
Compulsions	4		2	1	2		
Compulsive handwashing	1				1		
Compulsive hoarding	1				1		
Compulsive lip biting	1				1		
Confabulation	1		1				
Confusional arousal	3		1	1	2		
Confusional state	6005	140	2567	317	3438		23
Constricted affect	9	1	6	1	3		
Conversion disorder	163	13	106	13	57		
Coprolalia	2		1		1		
Cyclothymic disorder	3		2		1		
Daydreaming	111	3	26	16	85		
Decreased eye contact	6		3		3		
Decreased interest	64	2	23	9	41		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Deja vu	9		5		4		
Delirium	657	44	657			1	3
Delirium febrile	27	3	27				
Delusion	137	7	65	7	72		
Delusional disorder, persecutory type	2		1		1		
Delusional disorder, unspecified type	6		2	2	4		
Delusional perception	19		12	1	7		
Delusion of grandeur	1		1				
Delusion of parasitosis	1		1				
Dependence	2		2				
Dependent personality disorder	2	1	2				
Depersonalisation/derealisation disorder	111	6	67	5	44		
Depressed mood	2526	57	618	424	1908	1	3
Depression	2646	146	968	411	1678	3	18
Depression suicidal	38	4	38			1	2
Depressive delusion	1		1				
Depressive symptom	62	2	22	8	40		1
Derailment	6		3		3		
Derealisation	145	3	47	21	98		
Dermatillomania	2				2		
Discouragement	37		1	1	36		
Disinhibition	11	2	6		5		
Disorganised speech	66	2	32	4	34		
Disorientation	2058	59	872	95	1186	1	9
Disruptive mood dysregulation disorder	1	1	1				
Dissociation	181	3	59	25	122		1
Dissociative amnesia	11		5	1	6		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dissociative disorder	35	2	18		17		1
Dissociative identity disorder	1				1		
Distractibility	46		18	1	28		
Disturbance in sexual arousal	24		7	7	17		
Disturbance in social behaviour	13	1	1	3	12		
Dopamine dysregulation syndrome	1			1	1		
Drug abuse	3		3				
Drug dependence	6	1	6			1	1
Dysania	1	1	1				
Dysphemia	173	9	91	9	82		
Dysphonia psychogenic	1		1				
Dysphoria	526	10	211	14	315		
Dyssomnia	9	1	2	2	7		
Eating disorder	657	9	195	52	462	1	3
Echolalia	1				1		
Echopraxia	1				1		
Emetophobia	1		1				
Emotional disorder	417	8	136	32	281	1	3
Emotional disorder of childhood	1		1				
Emotional distress	456	13	187	54	269		1
Emotional poverty	19		5	5	14		
Encopresis	2		2				
Enuresis	83	1	33	3	50		1
Epileptic psychosis	1		1				
Euphoric mood	240	1	51	8	189		
Excessive masturbation	1				1		
Excessive sexual fantasies	1				1		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Executive dysfunction	9	2	6		3		
Exploding head syndrome	12		4	2	8		1
Factitious disorder	6		4		2		
Fear	559	8	157	57	402	1	2
Fear of closed spaces	1		1				
Fear of death	180	9	64	22	116		
Fear of disease	27	2	6	6	21		1
Fear of eating	5		2	1	3		
Fear of falling	25		6	2	19		
Fear of injection	69		5	5	64		
Fear of pregnancy	5			2	5		
Fear-related avoidance of activities	6		2	1	4		
Feeling guilty	8		4	2	4		
Feeling of despair	204	3	37	29	167		1
Feelings of worthlessness	9		3	2	6		
Female orgasmic disorder	10		2	3	8		
Flashback	9		4	2	5		
Flat affect	47		16	3	31		
Flight of ideas	3		2		1		
Frustration tolerance decreased	134	2	23	12	111		1
Gastrointestinal somatic symptom disorder	4	2	3		1		
Gender dysphoria	1		1				
Generalised anxiety disorder	36	3	19		17		
Genito-pelvic pain/penetration disorder	4				4		
Grandiosity	1				1		
Grief reaction	10		2	1	8		
Habit cough	22		12		10		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Haemophobia	1			1	1		
Hallucination	1005	71	1005				5
Hallucination, auditory	126	14	126				2
Hallucination, gustatory	3	1	3				
Hallucination, olfactory	63	6	63				
Hallucinations, mixed	37	4	37				1
Hallucination, tactile	6		6				
Hallucination, visual	233	20	233				1
Head banging	51		39	1	12		
Helplessness	32	2	7	1	25		
Histrionic personality disorder	2			1	2		
Homicidal ideation	2				2		
Hostility	5		4		1		
Hydrophobia	2		1		1		
Hyperarousal	3			1	3		
Hypersexuality	3		1		2		
Hypersomnia-bulimia syndrome	3		2		1		
Hypervigilance	37		11	4	26		2
Hypnagogic hallucination	13	3	13			1	1
Hypnopompic hallucination	3		3				
Hypomania	10		3	1	7		
Hyposomnia	8		4		4		
Illness anxiety disorder	10	1	2		8		
Illogical thinking	4		2	1	2		
Illusion	187	9	47	19	140		
Immunisation stress-related response	77	1	14	35	63		
Impaired reasoning	20	2	5	4	15		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Impatience	25	1	3	4	22		
Imperception	12		5	2	7		
Impulse-control disorder	7		2		5		
Impulsive behaviour	5		1		4		
Inappropriate affect	54		21	2	33		1
Indifference	27	4	15	2	12		
Inferiority complex	3			2	3		
Initial insomnia	669	12	99	82	570		2
Insomnia	19192	281	4380	2193	14812	10	31
Intentional self-injury	25		25				
Intermittent explosive disorder	1				1		
Intrusive thoughts	18	1	11		7		
Irritability	2477	36	388	310	2089		2
Kinesiophobia	1		1				
Korsakoff's syndrome	1	1	1				
Lack of spontaneous speech	48	3	30	3	18		
Laziness	69	1	8	11	61		
Learning disability	7		1		6		
Learning disorder	9		3	5	6		
Libido decreased	186	7	42	32	144	1	1
Libido disorder	20	2	7	2	13		
Libido increased	54		3	12	51		
Limited symptom panic attack	1				1		
Listless	727	20	117	125	610	1	1
Logorrhoea	20		9	2	11		1
Loss of dreaming	3			2	3		
Loss of libido	162	9	32	36	130		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Major depression	64	8	64				
Male orgasmic disorder	1				1		
Mania	57	1	25	1	32		
Manic symptom	2				2		
Mental disorder	610	33	201	100	409		4
Mental disorder due to a general medical condition	2		2				
Mental fatigue	677	24	328	98	349		5
Mental status changes	66	3	25	1	41		
Merycism	4		1		3		
Middle insomnia	937	20	226	162	711		5
Mixed anxiety and depressive disorder	36	3	18	2	18		
Mixed delusion	1			1	1		
Mood altered	657	11	127	143	530		1
Mood disorder due to a general medical condition	4	1	4				
Mood swings	876	12	179	125	697		1
Morbid thoughts	10	1	4		6		1
Morose	11		3	1	8		
Mutism	95	4	55	5	40		
Mysophobia	1				1		
Nail picking	1				1		
Near death experience	223	17	223				
Negative thoughts	38	1	11	6	27		
Negativism	2				2		
Neglect of personal appearance	3		1	1	2		
Neologism	3				3		
Nervousness	1503	25	386	105	1117		5
Neuroleptic-induced deficit syndrome	1		1				

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Neurologic somatic symptom disorder	2		1		1		
Neuropsychiatric symptoms	1		1				
Neuropsychiatric syndrome	1				1		
Neurosis	16		6	3	10		
Nicotine dependence	3		1		2		
Nightmare	896	8	218	92	678		3
Nocturnal fear	2				2		
Nosophobia	3		2		1		
Obsessive-compulsive disorder	21		9	2	12		
Obsessive-compulsive personality disorder	2		1		1		
Obsessive-compulsive symptom	3		1	1	2		
Obsessive rumination	1		1				
Obsessive thoughts	9		5		4		
Onychophagia	1				1		
Oppositional defiant disorder	1		1				
Organic brain syndrome	17	2	12	2	5		
Orgasm abnormal	7		1	2	6		
Orgasmic sensation decreased	3		1		2		
Osmophobia	3		2	1	1		
Paediatric acute-onset neuropsychiatric syndrome	2	2	2				
Panic attack	1962	82	672	243	1290		9
Panic disorder	160	5	50	19	110		
Panic reaction	366	10	123	27	243		
Paralogism	1				1		
Paramnesia	7		5		2		
Paranoia	100	2	50	3	50		
Paranoid personality disorder	1				1		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Parasomnia	8		2	1	6		
Paroxysmal perceptual alteration	1				1		
Pathological doubt	2	1	1		1		
Performance fear	1		1				
Perinatal depression	5		4		1		
Persecutory delusion	10		6	1	4		
Perseveration	4	1	2		2		
Persistent depressive disorder	16		7	1	9		
Personality change	108	9	63	10	45		
Personality change due to a general medical condition	1				1		
Personality disorder	29		12	2	17		
Phantom vibration syndrome	1				1		
Phobia	24		2		22		
Phobia of driving							1
Phonophobia	93	2	34	4	59		1
Pica	2		1		1		
Polydipsia psychogenic	1			1	1		
Poor quality sleep	1570	23	411	227	1159		8
Poriomania	1				1		
Postictal psychosis	1	1	1				
Postpartum stress disorder	1		1				
Post stroke depression	3		1	2	2		
Post-traumatic amnestic disorder	3		2		1		
Post-traumatic stress disorder	59	2	32	5	27		
Posturing	2		1		1		
Poverty of speech	4	1	2	1	2		
Poverty of thought content	1				1		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Premature ejaculation	4		1		3		
Pressure of speech	4		2		2		
Procrastination	1				1		
Pseudodementia	2		2				
Pseudohallucination	5	1	2	1	3		
Psychiatric decompensation	16	2	9	1	7		
Psychiatric symptom	82	2	27	11	55		2
Psychogenic movement disorder	2		1		1		
Psychogenic pseudosyncope	3		2		1		
Psychogenic tremor	1				1		
Psychogenic visual disorder	1		1				
Psychological factor affecting medical condition	6		3		3		
Psychological trauma	24	1	6	3	18		
Psychomotor retardation	30	1	12	2	18		
Psychotic behaviour	5		4		1		
Psychotic disorder	168	14	113	7	55		
Psychotic disorder due to a general medical condition	3		3				
Psychotic symptom	13	3	13				
Purging	1		1				
Rapid eye movement sleep behaviour disorder	3	1	2		1		
Rapid eye movements sleep abnormal	1			1	1		
Reading disorder	84	1	19	8	65		
Regressive behaviour	1			1	1		
Restlessness	2636	63	604	311	2032		4
Schizoaffective disorder	2		2				
Schizoid personality disorder	1		1				
Schizophrenia	26	3	26				

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Schizotypal personality disorder	1			1	1		
School refusal	1				1		
Secondary tic	1				1		
Selective eating disorder	6		5		1		
Selective mutism	1	1	1				
Self-consciousness	5		2		3		
Self-destructive behaviour	2	1	2				
Self esteem decreased	31	2	7	3	24		1
Self-induced vomiting	1				1		
Self-injurious ideation	21		10	2	11		
Sense of a foreshortened future	6		4		2		
Sexual inhibition	2		1		1		
Sitophobia	3			2	3		
Sleep attacks	34	1	6	5	28		
Sleep disorder	5924	188	1417	912	4507	3	13
Sleep disorder due to a general medical condition	94	2	32	10	62		
Sleep disorder due to general medical condition, hypersomni	3			1	3		
Sleep disorder due to general medical condition, insomnia ty	129	2	58	8	71		
Sleep inertia	4		3		1		
Sleep-related eating disorder	1				1		
Sleep talking	19		4	1	15		
Sleep terror	60	2	26	2	34		1
Social anxiety disorder	13	1	4	2	9		
Social avoidant behaviour	35	3	12	9	23		
Social fear	3		2		1		
Social (pragmatic) communication disorder	2		1		1		
Soliloquy	15	1	5		10		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Somatic delusion	1			1	1		
Somatic hallucination	1		1				
Somatic symptom disorder	163	14	63	15	100		
Somnambulism	49		10	3	39		
Somniphobia	2				2		
Sopor	55		41	1	14		4
Speech sound disorder	13		6		7		
Staring	50	3	33	3	17		
Stereotypy	9		4	3	5		
Stockholm syndrome	1				1		
Stress	1233	35	361	206	872	5	20
Substance abuse	2		2				
Substance dependence	1		1				
Substance-induced psychotic disorder	6	3	6				
Suicidal behaviour	13		13				
Suicidal ideation	445	59	445			2	4
Suicide attempt	64	6	64				
Suicide threat	7	1	7				
Suspected suicide	1		1				
Suspiciousness	4		1	1	3		
Tachyphrenia	45	2	14	6	31		
Taciturnity	1				1		
Tearfulness	133		68	8	65		
Tension	498	7	111	68	387		1
Terminal insomnia	81	2	20	11	61		
Thanatophobia	4		1	1	3		
Thermophobia	4		1		3		

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System Organ Class

Psychiatric disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Thinking abnormal	418	10	109	46	309		
Thought blocking	12		4	3	8		
Thought insertion	1				1		
Tic	193	8	80	23	113		
Time perception altered	22	1	6	6	16		
Tobacco abuse	3			3	3		
Trance	8		1	1	7		
Transvestism	1				1		
Trichotillomania	3				3		
Verbigeration	1				1		
Violence-related symptom	3		1		2		
Vomiting psychogenic	1		1				
Waxy flexibility	1		1				
Total:	89111	2289	26481	9246	62630	41	273

System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acute kidney injury	966	124	966				3
Albuminuria	16		10	1	6		
Anti-glomerular basement membrane disease	9	3	9				
Anuria	107	9	107				1
Atonic urinary bladder	1		1				
Autoimmune nephritis	1		1				
Automatic bladder	1		1				
Azotaemia	31	4	31				

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Bence Jones proteinuria	2	1	2				
Bilirubinuria	5		4		1		
Bladder cyst	1		1				
Bladder dilatation	18	2	12		6		
Bladder discomfort	94	10	23	14	71		
Bladder disorder	127	8	62	8	65	1	2
Bladder diverticulum	2			1	2		
Bladder dysfunction	34	1	19	5	15		
Bladder fibrosis	1		1				
Bladder hypertrophy	6		3		3		
Bladder irritation	54	4	22	3	32		
Bladder mass	1		1				
Bladder necrosis	1		1				
Bladder obstruction	5		5				
Bladder pain	193	4	57	24	136	1	2
Bladder prolapse	3		2		1		
Bladder spasm	25	1	10		15		
Bladder sphincter atony	17	1	12		5		
Bladder tamponade	3	1	3				
Bladder ulcer	1		1				
Bullous oedema of the bladder	1				1		
C3 glomerulopathy	3		3				
Calculus bladder	12	2	6		6		1
Calculus urinary	20	2	7		13		1
Choluria	21		9	1	12		
Chromaturia	558	14	167	40	391	2	3
Chronic kidney disease	178	34	178			1	1

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Costovertebral angle tenderness	13		2	3	11		
Crush syndrome	2		2				
Crystalluria	1		1				
Cystitis glandularis	2		2				
Cystitis haemorrhagic	45	6	45				1
Cystitis interstitial	33	2	17	4	16		1
Cystitis-like symptom	16		1	4	15		
Cystitis noninfective	348	7	37	32	311	2	7
Diabetic nephropathy	16	4	12	1	4		1
Dysuria	941	27	308	88	633		6
End stage renal disease	25	7	25				
Fibrillary glomerulonephritis	2	2	2				
Focal segmental glomerulosclerosis	33	12	31		2		
Foetal renal impairment	1		1				
Follicular cystitis	1		1				
Genitourinary symptom	6		6				
Globulinuria	1	1	1				
Glomerulonephritis	102	19	102				
Glomerulonephritis acute	14	2	14				
Glomerulonephritis chronic	11	4	11				
Glomerulonephritis membranoproliferative	7		7				
Glomerulonephritis membranous	37	15	37				
Glomerulonephritis minimal lesion	74	13	74				1
Glomerulonephritis proliferative	3	1	3				
Glomerulonephritis rapidly progressive	45	13	45				
Glomerulonephropathy	2		2				
Glomerulosclerosis	4	2	4				

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Glycosuria	6		3		3		
Goodpasture's syndrome	8	1	8				
Haematinuria	1				1		
Haematuria	1032	56	454	75	578		3
Haemoglobinuria	9	1	9				
Haemorrhage urinary tract	101	8	101				1
Henoch-Schonlein purpura nephritis	7	3	7				
Hydronephrosis	26	2	26				2
Hypertensive nephropathy	4	2	4				
Hypertonic bladder	51	4	11	12	40		
Hyposthenuria	1			1	1		
Hypotonic urinary bladder	5	3	5				
IgA nephropathy	150	60	150				1
IgM nephropathy	1	1	1				
Immune-mediated cystitis	1		1				
Immune-mediated renal disorder	1	1	1				
Incontinence	306	13	145	19	161		1
Ketonuria	4		3		1		
Kidney congestion	6		4		2		
Kidney enlargement	15	1	8	2	7		
Kidney fibrosis	3		3				
Kidney hypermobility	1				1		
Kidney small	2		1		1		
Leukocyturia	46	3	27	3	19		
Loss of bladder sensation	12		10		2		
Lower urinary tract symptoms	12		4	1	8		
Lupus nephritis	17	4	17				

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Mesangioproliferative glomerulonephritis	3		3				
Microalbuminuria	6		2		4		
Micturition disorder	105	5	29	15	76	1	2
Micturition frequency decreased	9		2	1	7		
Micturition urgency	457	17	139	51	318		
Mixed incontinence	3				3		
Myeloma cast nephropathy	1		1				
Myoglobinuria	6		5	1	1		
Nephrectasia	1		1				
Nephritic syndrome	13		13				
Nephritis	131	23	131				2
Nephritis allergic	2	1	2				
Nephroangiosclerosis	2	1	2				
Nephrocalcinosis	2		2				
Nephrogenic diabetes insipidus	1		1				
Nephrolithiasis	254	28	254			7	24
Nephropathy	55	5	33	7	22		
Nephropathy toxic	2				2		
Nephrosclerosis	8	1	8				
Nephrotic syndrome	346	55	346				3
Neurogenic bladder	26	6	26				2
Nocturia	93	8	28	7	65		1
Oedematous kidney	2		2				1
Oliguria	93	3	44	6	49		2
Page kidney	1				1		
Paroxysmal nocturnal haemoglobinuria	9		9				
Pelvi-ureteric obstruction	1		1				

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Perinephric collection	1				1		1
Perinephric oedema	2		1	1	1		
Pollakiuria	1092	22	282	115	810	2	7
Polyuria	266	7	67	23	199		1
Postrenal failure	1		1				
Post streptococcal glomerulonephritis	1		1				
Prerenal failure	19	2	19				
Proteinuria	320	20	148	40	172	1	4
Pulmonary renal syndrome	4	2	4				
Pyelocaliectasis	7	3	7				1
Renal aneurysm	3		1		2		
Renal arteriosclerosis	1		1				
Renal arteritis	1	1	1				
Renal artery dissection	1		1				
Renal artery occlusion	1		1				
Renal artery stenosis	9	2	9				
Renal artery thrombosis	19	3	19				
Renal atrophy	9		9				
Renal colic	142	7	71	12	71		3
Renal cortical necrosis	2		2				
Renal cyst	93	7	35	10	58		
Renal cyst haemorrhage	2		2				
Renal disorder	358	28	172	38	186	1	9
Renal embolism	7		7				
Renal failure	757	77	757			1	6
Renal failure neonatal	1		1				
Renal haematoma	2	1	2				

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Renal haemorrhage	19		19				
Renal hypertension	3	1	2		1		
Renal hypertrophy	4		2		2		
Renal impairment	476	63	476			1	6
Renal infarct	77	7	77				1
Renal injury	28	8	28				
Renal ischaemia	12	2	12				
Renal-limited thrombotic microangiopathy	2		2				
Renal mass	6		3		3		
Renal necrosis	4	1	4				
Renal pain	2139	33	551	158	1588		2
Renal tubular atrophy	1		1				
Renal tubular disorder	4		4				
Renal tubular injury	3		3				
Renal tubular necrosis	21	1	21				
Renal vascular thrombosis	7		7				
Renal vasculitis	13	5	13				1
Renal vein compression	2	2	2				
Renal vein embolism	1		1				
Renal vein occlusion	3		3				
Renal vein thrombosis	24	4	24				
Scleroderma renal crisis	2		2				
Semenuria	1				1		
Single functional kidney	1	1	1				1
Strangury	10		5		5		3
Stress urinary incontinence	20		3	1	17		
Subacute kidney injury	1		1				

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tubulointerstitial nephritis	97	12	97				
Tubulointerstitial nephritis and uveitis syndrome	4	2	4				
Ureteral disorder	2		1	1	1		1
Ureteral wall thickening	1		1				
Ureteric dilatation	4		3		1		1
Ureteric obstruction	3		3				
Ureteric stenosis	3		3				
Ureterocele	1			1	1		
Ureterolithiasis	9	1	6	1	3		1
Urethral caruncle	2		1	1	1		
Urethral dilatation	1			1	1		
Urethral discharge	1			1	1		
Urethral disorder	8	1	4		4		
Urethral fistula	1		1				
Urethral haemorrhage	7		7				1
Urethral intrinsic sphincter deficiency	2		2				
Urethral obstruction	1		1				
Urethral pain	22		8	1	14		
Urethral polyp	1				1		
Urethral spasm	2		1		1		
Urethral stenosis	3		3				
Urethral syndrome	2				2		
Urethritis noninfective	7		1	2	6		1
Urge incontinence	22		7	5	15		
Urinary bladder atrophy	1		1				
Urinary bladder haematoma	1		1				
Urinary bladder haemorrhage	34	2	34				

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System Organ Class

Renal and urinary disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Urinary bladder polyp	3	1	1		2		
Urinary bladder rupture	2		2				
Urinary hesitation	30	1	12	3	18		2
Urinary incontinence	871	41	392	72	479		2
Urinary retention	404	50	404			1	3
Urinary straining	10		1		9		
Urinary tract discomfort	25	1	4		21		
Urinary tract disorder	69	4	13	14	56		1
Urinary tract inflammation	52	2	20	3	32		
Urinary tract obstruction	14	2	14			1	1
Urinary tract pain	34	1	10	5	24		
Urine abnormality	128	5	32	17	96		2
Urine flow decreased	33	3	17		16		1
Urine odour abnormal	152	2	31	12	121		
Urinoma	2		2				
Urogenital disorder	3				3		
Urogenital fistula	1		1				
Urogenital haemorrhage	3		3				
Urothelium erosion	1		1				
Vesicoureteric reflux	1		1				
Total:	15848	1119	8656	968	7192	23	139

System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal menstrual clots	19	4	4	15	15		

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* AE=Adverse Event
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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abnormal uterine bleeding	146	6	35	26	111		
Abnormal withdrawal bleeding	357		6	84	351		
Acquired hydrocele	1		1				
Acquired phimosis	3		1		2		
Adenomyosis	155	55	82	36	73		
Adnexal torsion	10	1	10				
Adnexa uteri cyst	2		1		1		
Adnexa uteri mass	2		2				
Adnexa uteri pain	894	34	189	200	705		1
Amenorrhoea	15262	638	1788	2207	13474	3	5
Anisomastia	8		1	1	7		
Artificial menopause	2			2	2		
Asherman's syndrome	1				1		
Aspermia	2				2		
Asthenospermia	2				2		
Atrophic vulvovaginitis	6		2		4		
Azoospermia	3		2		1		
Balanoposthitis	32		6	7	26		
Bartholin's cyst	11		6		5		
Benign prostatic hyperplasia	39	3	20	4	19		1
Bleeding anovulatory	9	2	3	4	6		
Breast atrophy	13		1	2	12		
Breast calcifications	7	1	2	3	5		1
Breast cyst	160	4	43	22	117		
Breast discharge	95	1	13	15	82		
Breast discolouration	9		3		6		
Breast discomfort	600	5	91	79	509		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Breast disorder	78		20	3	58		
Breast disorder female	25	3	8	2	17		
Breast disorder male	1				1		
Breast dysplasia	2		1		1		
Breast engorgement	218		13	30	205		
Breast enlargement	703	6	75	130	628		
Breast fibrosis	5	1	2	2	3		
Breast haematoma	29		10	2	19		
Breast haemorrhage	18	6	18				
Breast hyperplasia	6		4		2		
Breast induration	54		4	11	50		
Breast inflammation	263	6	51	25	212		1
Breast mass	591	8	196	47	395	1	4
Breast milk discolouration	21		7		14		
Breast milk odour abnormal	6				6		
Breast necrosis	3		3				
Breast oedema	152	5	28	27	124		
Breast pain	6017	88	1283	624	4734		16
Breast proliferative changes	1	1	1				
Breast swelling	1739	10	306	245	1433		
Breast tenderness	1149	7	139	245	1010		1
Breast ulceration	3		2		1		
Cervical cyst	4	1	1	1	3		
Cervical discharge	7		2	1	5		
Cervical dysplasia	21	4	11	5	10		
Cervical friability	4			2	4		
Cervical polyp	9	2	6	1	3		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cervix disorder	13	3	6	1	7		
Cervix enlargement	2		1	1	1		
Cervix erythema	1		1				
Cervix haematoma uterine	1		1				
Cervix haemorrhage uterine	14	2	14				
Cervix inflammation	3		1		2		
Cervix oedema	3				3		
Clitoral engorgement	2				2		
Coital bleeding	86	3	16	28	70		
Cystocele	2				2		
Dysmenorrhoea	19868	757	4471	3775	15397		17
Dyspareunia	56	7	17	20	39		
Ectropion of cervix	9	1	3		6		
Ejaculation delayed	2		1		1		
Ejaculation disorder	20		7		13		
Ejaculation failure	20		6		14		
Endometrial atrophy	5		3		2		
Endometrial disorder	29	2	15	6	14		
Endometrial dysplasia	1		1				
Endometrial hyperplasia	25	3	12	3	13		
Endometrial hypertrophy	3	1	1	1	2		
Endometrial hypoplasia	5	1	2	1	3		
Endometrial thickening	55	3	20	8	35		
Endometriosis	573	111	308	90	265	1	2
Epididymal cyst	4		4				
Epididymal disorder	2			1	2		
Epididymal enlargement	1		1				

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Epididymal tenderness	4		3		1		
Erectile dysfunction	581	73	581			4	11
Erection increased	29	1	6	3	23		
Fallopian tube disorder	7		2		5		
Female genital tract fistula	2		2				
Female reproductive tract disorder	20		3	10	17		
Female sexual arousal disorder	3	1	1	1	2		
Female sexual dysfunction	4		3		1		
Fibrocystic breast disease	16	2	7	1	9		
Foreskin oedema	2		1	1	1		
Galactorrhoea	94	1	18	20	76		1
Galactostasis	60		7	6	53		
Genital anaesthesia	4	1	3		1		
Genital blister	23	2	6	2	17		
Genital burning sensation	63		14	11	49		
Genital cyst	1		1				
Genital discharge	15			3	15		
Genital discolouration	2		1		1		
Genital discomfort	36	1	4	11	32		
Genital disorder	6			3	6		
Genital dysaesthesia	2		1	1	1		
Genital erosion	3		1		2		
Genital erythema	24		4	4	20		
Genital exfoliation	2				2		
Genital haemorrhage	185	55	185				
Genital hyperaesthesia	2		1		1		
Genital hypoaesthesia	16		6	6	10		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Genital lesion	12		1		11		
Genital macule	1		1				
Genital odour	4			2	4		
Genital pain	203	8	36	73	167		
Genital paraesthesia	20		4	4	16		
Genital prolapse	1	1	1				
Genital rash	58		10	9	48		3
Genitals enlarged	2		1		1		
Genital swelling	43	1	15	7	28		
Genital tract inflammation	25		6	1	19		
Genital ulceration	54	1	24	5	30		
Gynaecomastia	89	3	15	16	74		
Haematosalpinx	1		1				
Haematospermia	51		12	3	39		
Haemorrhagic breast cyst	2		2				
Haemorrhagic ovarian cyst	24	4	24				
Heavy menstrual bleeding	38304	1119	7495	6671	30809	1	17
Hydrometra	4		2	1	2		
Hydrosalpinx	7	2	7				
Hypomenorrhoea	3450	26	427	565	3023		2
Inadequate lubrication	1				1		
Infertility	100	12	47	18	53	1	1
Infertility female	49	5	20	15	29	1	1
Infertility male	4		3	1	1		
Intermenstrual bleeding	17050	299	1659	2923	15391		5
Labia enlarged	7		2	1	5		
Lactation disorder	138	2	17	8	121		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lactation puerperal increased	54	1	6	4	48		
Male reproductive tract disorder	1			1	1		
Male sexual dysfunction	2	1	1		1		
Mammary duct ectasia	8		1	2	7		
Mastoptosis	2		2				
Menometrorrhagia	1860	343	482	679	1378		
Menopausal disorder	13		5	2	8		
Menopausal symptoms	310	8	58	43	252		
Menopause delayed	6		2		4		
Menstrual discomfort	1542	4	66	118	1476		
Menstrual disorder	30048	250	2615	5358	27433	4	13
Menstruation delayed	18138	194	2609	2847	15529	1	12
Menstruation irregular	21588	787	3610	4250	17978	2	14
Metrorrhoea	4		2	1	2		
Nipple disorder	29		6		23		1
Nipple enlargement	7	1	2	4	5		
Nipple exudate bloody	11		2	1	9		
Nipple inflammation	23	1	6	2	17		
Nipple oedema	3			1	3		
Nipple pain	368	1	50	42	318		1
Nipple swelling	60		4	9	56		
Nocturnal emission	3				3		
Noninfective epididymitis	1				1		
Noninfective oophoritis	27	2	27				
Oedema genital	25	1	10	3	15		
Oligoasthenoteratozoospermia	1		1				
Oligomenorrhoea	5034	297	622	1021	4412		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Oligospermia	3		2		1		
Orchitis noninfective	23	2	8	1	15		
Organic erectile dysfunction	18		10	1	8		
Ovarian atrophy	1				1		
Ovarian cyst	383	35	140	73	243		1
Ovarian cyst ruptured	57	7	57				
Ovarian cyst torsion	2	1	2				1
Ovarian disorder	31	1	9	7	22		
Ovarian enlargement	17		3	3	14		
Ovarian failure	25	4	11	4	14		
Ovarian haematoma	2		1	1	1		
Ovarian haemorrhage	21	2	21				
Ovarian hyperfunction	1				1		
Ovarian hyperstimulation syndrome	1		1				
Ovarian mass	4		4			1	1
Ovarian necrosis	2		2				
Ovarian oedema	2			1	2		
Ovarian prolapse	2		2				
Ovarian rupture	2		2				
Ovarian vein thrombosis	19	3	19				
Ovulation disorder	144	3	31	31	113		
Ovulation pain	550	14	100	157	450		
Painful ejaculation	7	2	5		2		
Painful erection	10	1	4	2	6		
Pelvic adhesions	1				1		
Pelvic congestion	4		1		3		
Pelvic cyst	1				1		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pelvic discomfort	41		12	5	29	1	1
Pelvic floor muscle weakness	8		3		5		
Pelvic fluid collection	7	1	6	1	1		
Pelvic haematoma	3	1	2		1		
Pelvic haemorrhage	29	3	29				
Pelvic organ prolapse	3		1		2		
Pelvic pain	1487	66	363	247	1124		3
Penile artery occlusion	1	1	1				
Penile blister	10	1	4	2	6		
Penile burning sensation	4			1	4		
Penile curvature	1				1		
Penile dermatitis	11	1	2	2	9		
Penile discharge	5				5		
Penile discomfort	6		1	1	5		
Penile erosion	1		1				
Penile erythema	12		1	2	11		
Penile exfoliation	4				4		
Penile haematoma	4		1		3		
Penile haemorrhage	12		12				
Penile oedema	15		8		7		
Penile pain	40	1	9	6	31		
Penile size reduced	6				6		
Penile swelling	30		10	5	20		
Penile vascular disorder	3				3		
Penile vein thrombosis	14	2	14				
Penis disorder	44	1	9	9	35		
Perineal disorder	8	1	4	1	4		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Perineal erythema	1		1				
Perineal necrosis	1		1				
Perineal pain	19	4	10		9		
Perineal rash	2		1		1		
Perineal ulceration	2		2				
Peyronie's disease	19	5	9	4	10		
Plasma cell mastitis	3		2		1		
Polycystic ovaries	125	18	64	22	61		
Polymenorrhagia	24	1	6	8	18		
Polymenorrhoea	13424	220	1122	2532	12302		6
Poor milk ejection reflex	16			2	16		
Postmenopausal haemorrhage	3231	525	3231			4	11
Premature follicular ripening	1				1		
Premature menopause	96	16	42	18	54		
Premature ovulation	33	2	5	4	28		
Premenstrual dysphoric disorder	61	4	29	10	32		
Premenstrual pain	777	14	155	129	622		
Premenstrual syndrome	1723	209	449	437	1274		
Priapism	23	1	8	2	15		
Prostate tenderness	1				1		
Prostatic atrophy	1				1		
Prostatic calcification	2			1	2		
Prostatic cyst	2		1		1		
Prostatic disorder	19	1	5	2	14		
Prostatic haemorrhage	1		1				
Prostatic obstruction	1		1				
Prostatic pain	9		4	1	5		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Prostatism	1				1		
Prostatitis	113	2	54	5	59		
Prostatomegaly	24	3	9	2	15		
Pruritus genital	84	1	17	9	67		
Red breast syndrome	1				1		
Reproductive tract disorder	8		2	1	6		
Retracted nipple	3				3		
Retrograde menstruation	10		1		9		
Scrotal angiokeratoma	2				2		
Scrotal dermatitis	2				2		
Scrotal discomfort	6			2	6		
Scrotal disorder	5		1	2	4		
Scrotal erythema	13		5	2	8		
Scrotal exfoliation	4		2		2		
Scrotal haemorrhage	1				1		
Scrotal inflammation	3		1		2		
Scrotal irritation	1				1		
Scrotal oedema	11		6	1	5		
Scrotal pain	45		20	5	25		
Scrotal swelling	31		10	4	21		
Scrotal ulcer	2		2				
Scrotum erosion	1		1				
Semen discolouration	4	2	3		1		
Sexual dysfunction	56	2	17	13	39		
Shortened cervix	6	1	3	1	3		
Spermatic cord haemorrhage	1		1				
Spermatic cord obstruction	1				1		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Spermatocele	2		1		1		
Spermatogenesis abnormal	1			1	1		
Spontaneous ejaculation	2				2		
Spontaneous penile erection	17	1	2	1	15		
Superovulation	5		3		2		
Suppressed lactation	640	2	69	47	571		
Testicular appendage torsion	1				1		
Testicular atrophy	1		1				
Testicular cyst	3				3		
Testicular disorder	29	1	12	3	17		
Testicular haemorrhage	2		2				
Testicular hypertrophy	1				1		
Testicular infarction	3		3				
Testicular mass	1				1		
Testicular microlithiasis	1				1		
Testicular necrosis	2	1	2				
Testicular oedema	8		2	3	6		
Testicular pain	431	4	116	39	315		
Testicular retraction	2		2				
Testicular swelling	108	5	35	6	73		
Testicular torsion	10	1	10				
Testis discomfort	21		3	6	18		1
Thrombosis corpora cavernosa	1		1				
Uterine adhesions	2	1	2				
Uterine cervix hyperplasia	1		1				
Uterine cyst	22	3	7	6	15		
Uterine disorder	34	3	8	5	26		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Uterine enlargement	18	2	7	2	11		
Uterine haematoma	6		2		4		1
Uterine haemorrhage	423	170	423				2
Uterine inflammation	41	1	21	3	20		
Uterine ischaemia	1		1				
Uterine malposition	3			1	3		
Uterine mass	3		1		2	1	1
Uterine pain	549	79	142	166	407		
Uterine polyp	69	17	42	8	27		
Uterine prolapse	5		3	1	2		
Uterine spasm	272	2	59	35	213		
Uterine tenderness	12		2	4	10		
Vaginal cyst	10		5		5		
Vaginal discharge	614	10	91	85	523		1
Vaginal disorder	17	2	4	3	13		
Vaginal dysplasia	1	1	1				
Vaginal erosion	2		1		1		
Vaginal fistula							1
Vaginal haematoma	2		1		1		
Vaginal haemorrhage	5492	90	1424	372	4068		15
Vaginal lesion	8		2	1	6		
Vaginal mucosal blistering	6	2	6				
Vaginal odour	30		4	7	26		
Vaginal oedema	2		1		1		
Vaginal polyp	1		1				
Vaginal prolapse	1		1				
Vaginal stricture	1	1	1				

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vaginal ulceration	38	2	13	6	25		
Varicocele	17	3	13		4		
Varicose veins pelvic	8	2	2	3	6		
Varicose veins vaginal	3		2		1		
Varicose veins vulval	5				5		
Vulva cyst	5	3	4		1	1	1
Vulval disorder	22	2	7	3	15		
Vulval eczema	3		3				
Vulval haematoma	1		1				
Vulval haemorrhage	35	1	35				
Vulval oedema	9		2	1	7		
Vulval ulceration	85	12	36	11	49		
Vulvar dysplasia	1		1				
Vulvar erosion	1				1		
Vulvovaginal burning sensation	74	1	22	5	52		
Vulvovaginal discomfort	85	2	19	10	66		
Vulvovaginal disorder	2				2		
Vulvovaginal dryness	82	3	15	16	67		1
Vulvovaginal erythema	19		2	1	17		
Vulvovaginal exfoliation	1				1		
Vulvovaginal inflammation	26	1	8	3	18		
Vulvovaginal pain	258	6	68	31	190		
Vulvovaginal pruritus	90	1	21	11	69		
Vulvovaginal rash	8		4		4		
Vulvovaginal swelling	46	3	19	3	27		
Vulvovaginal ulceration	7	1	6		1		
Withdrawal bleed	50	1	10	6	40		

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System Organ Class

Reproductive system and breast disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Total:	222981	6935	39370	37536	183611	27	179

System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acquired diaphragmatic eventration	4		4				
Acute chest syndrome	4		4				
Acute interstitial pneumonitis	3	2	3				
Acute lung injury	6	2	6				
Acute pulmonary oedema	164	17	164				1
Acute respiratory distress syndrome	277	17	277				
Acute respiratory failure	358	40	358				3
Adenoidal disorder	22	1	1	1	21		
Adenoidal hypertrophy	2		2				
Agonal respiration	11	1	11				
Allergic bronchitis	6		3		3		
Allergic cough	34		11	3	23		
Allergic pharyngitis	4		3		1		
Allergic respiratory disease	8		3	2	5		
Allergic respiratory symptom	24	1	9	2	15		
Allergic sinusitis	14		3	2	11		
Alveolar lung disease	5		5				
Alveolar proteinosis	1				1		
Alveolitis	23	4	22	1	1		
Anoxia	7	1	7				
Aphonia	989	17	292	93	697	1	3

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Apnoea	207	35	207				
Apnoeic attack	9	1	9				
Asphyxia	172	13	172				
Aspiration	110	6	110				1
Asthma	3945	157	1700	377	2245	6	17
Asthma-chronic obstructive pulmonary disease overlap synd	3		1		2	1	1
Asthma exercise induced	32	2	9	7	23		
Asthma late onset	3		2		1		
Asthmatic crisis	251	14	251			2	14
Atelectasis	135	7	87	1	48		
Autoimmune lung disease	6	2	6				
Bendopnoea	1		1				
Bradypnoea	10		8		2		
Brief resolved unexplained event	4	3	4				1
Bronchial disorder	74	5	28	8	46		1
Bronchial dysplasia	2	1	2				
Bronchial haemorrhage	5	1	5				
Bronchial hyperreactivity	61	2	23	7	38		
Bronchial irritation	20		1	5	19		
Bronchial obstruction	21	1	21				
Bronchial oedema	4		4				
Bronchial secretion retention	20		8	2	12		
Bronchial wall thickening	14		6	1	8		
Bronchiectasis	61	12	61				1
Bronchitis chronic	35	2	13	6	22		
Bronchopleural fistula	1		1				1
Bronchopneumopathy	29	3	18	2	11		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Bronchopulmonary disease	3			1	3		
Bronchopulmonary dysplasia							1
Bronchospasm	846	18	485	24	361	1	4
Bronchostenosis	24	1	24			1	1
Catarrh	209	5	49	31	160		1
Central sleep apnoea syndrome	1		1				
Cheyne-Stokes respiration	7		7				
Childhood asthma	2				2		
Choking	253	18	253			1	3
Choking sensation	320	10	143	23	177		1
Chronic hyperplastic eosinophilic sinusitis	1		1				
Chronic obstructive pulmonary disease	433	37	285	38	148	2	7
Chronic respiratory disease	7		1		6		
Chronic respiratory failure	17	1	17				
Combined pulmonary fibrosis and emphysema	1		1				
Cough	30126	479	6802	2991	23324	21	119
Cough decreased	9			4	9		
Cough variant asthma	48		22	2	26		
Cyanosis central	4	1	4				
Cyanosis neonatal							1
Cystic lung disease	4		1		3		
Dependence on respirator	18	5	18				
Diaphragmalgia	133	3	31	21	102		
Diaphragmatic abnormal relaxation	1				1		
Diaphragmatic disorder	29	2	9	4	20		
Diaphragmatic paralysis	15	5	15				
Diaphragmatic rupture	1		1				

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Diaphragmatic spasm	17		7		10		
Diaphragm muscle weakness	3		2		1		
Diffuse alveolar damage	9	1	9				
Diffuse panbronchiolitis	1		1				
Dry lung syndrome	1		1				
Dry throat	923	7	193	61	730	1	4
Dysaesthesia pharynx	3				3		
Dysphonia	3150	61	918	275	2232	1	12
Dyspnoea	64509	2014	24383	5596	40126	33	225
Dyspnoea at rest	299	43	299			1	8
Dyspnoea exertional	3568	228	1510	429	2058	4	29
Dyspnoea paroxysmal nocturnal	28	3	16	1	12		
Ear, nose and throat disorder	4		2	1	2		
Egobronchophony	1				1		
Emphysema	130	7	61	7	69		
Eosinophilic bronchitis	2		2				
Eosinophilic pleural effusion	2		2				
Eosinophilic pneumonia	32		32				
Eosinophilic pneumonia acute	5	1	5				
Eosinophilic pneumonia chronic	4	1	4				
Epiglottic oedema	19		19				
Epistaxis	6087	76	1236	628	4851		12
Gasping syndrome	2		2				
Glottal incompetence	2	1	2				
Granulomatous pneumonitis	1		1				
Grunting	42	1	20		22		
Haemoptysis	657	22	355	37	302	1	2

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Haemothorax	13	2	13				
Hiccups	194	3	54	14	140		1
Hydrothorax	17		17				
Hyperactive pharyngeal reflex	7		2	1	5		
Hypercapnia	42	2	31	1	11		
Hyperoxia	3		1		2		
Hypersensitivity pneumonitis	27	3	27			1	1
Hyperventilation	1218	21	539	61	679		3
Hypocapnia	12	1	8		4		
Hypopnoea	411	7	224	18	187	1	1
Hypoventilation	102	7	102				5
Hypoxia	656	55	656				4
Idiopathic interstitial pneumonia	2		2				
Idiopathic pulmonary fibrosis	31	8	31				1
Immune-mediated lung disease	6		6				
Increased bronchial secretion	68		21	9	47		
Increased upper airway secretion	208	2	63	37	145		
Increased viscosity of bronchial secretion	20	1	10		10		
Increased viscosity of upper respiratory secretion	131	2	32	27	99		
Infantile apnoea	4	1	4				1
Interstitial lung disease	412	70	412			2	7
Intranasal hypoaesthesia	11		2	2	9		
Intranasal paraesthesia	21		2	1	19		
Irregular breathing	98	2	40	5	58		
Kussmaul respiration	1			1	1		
Laryngeal atrophy	1		1				
Laryngeal discomfort	168	5	53	8	115		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Laryngeal disorder	19		11	1	8		
Laryngeal dyspnoea	11	2	11				
Laryngeal erythema	4		2	1	2		
Laryngeal haematoma	3		1		2		
Laryngeal haemorrhage	2		2				
Laryngeal inflammation	50	3	8	10	42		1
Laryngeal mass	3			1	3		
Laryngeal obstruction	22	1	22				
Laryngeal oedema	525	27	524		1		8
Laryngeal pain	93	3	23	10	70	1	1
Laryngeal stenosis	17	1	17				
Laryngeal ulceration	1		1				
Laryngitis allergic	3		2		1		
Laryngospasm	174	11	102	20	72		2
Laryngotracheal oedema	1		1				
Larynx irritation	77	2	24	2	53		
Loeffler's syndrome	3		1		2		
Lower respiratory tract congestion	75	1	32	6	43		1
Lower respiratory tract inflammation	4		2		2		
Lung consolidation	33	1	26		7		
Lung cyst	4	1	2		2		
Lung diffusion disorder	11	1	4	2	7		
Lung disorder	883	47	416	81	467	3	6
Lung hernia	1				1		
Lung hyperinflation	22	1	12	2	10		
Lung infiltration	152	11	110	8	42		
Lung opacity	122	6	80	11	42		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lung perforation	1		1				
Meconium aspiration syndrome	2		2				1
Mediastinal cyst	1		1				
Mediastinal disorder	8	1	3		5		
Mediastinal effusion	1		1				
Mediastinal haematoma	1				1		
Mediastinal haemorrhage	3		3				
Mediastinal mass	7		6		1		
Mediastinal shift	1	1	1				
Middle lobe syndrome	2		1		1		
Mouth breathing	22		10	2	12		
Multifocal micronodular pneumocyte hyperplasia	1				1		
Nasal cavity mass	2			1	2		
Nasal congestion	4580	35	699	481	3881	2	15
Nasal crusting	28	1	3	3	25		
Nasal cyst	3				3		
Nasal discharge discolouration	21		3	2	18		
Nasal discomfort	385	3	66	33	319	1	1
Nasal disorder	59	1	17	5	42		
Nasal dryness	205	4	39	20	166		1
Nasal inflammation	61		13	9	48		
Nasal mucosa atrophy	1				1		
Nasal mucosal blistering	4		1	2	3		
Nasal mucosal discolouration	1				1		
Nasal mucosal disorder	28	1	6	4	22		
Nasal mucosal erosion	3		1	1	2		
Nasal mucosal hypertrophy	1				1		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Nasal mucosal ulcer	2		1		1		
Nasal mucosa telangiectasia	1		1				
Nasal necrosis	1		1				
Nasal obstruction	152	3	37	20	115		
Nasal odour	10		5	1	5		
Nasal oedema	166	5	52	12	114		
Nasal polyps	17	1	8	3	9		
Nasal pruritus	157		33	19	124		
Nasal septum deviation	11	1	3	2	8		
Nasal septum disorder	1			1	1		
Nasal turbinate abnormality	1				1		
Nasal turbinate hypertrophy	8	1	2		6		
Nasal ulcer	19		1	8	18		
Nasopharyngeal reflux	1				1		
Neonatal anoxia	2		2				
Neonatal asphyxia	6		6				1
Neonatal aspiration	1		1				
Neonatal dyspnoea	1				1	2	2
Neonatal hypoxia							1
Neonatal pneumothorax	2		2				1
Neonatal respiratory acidosis	1		1				
Neonatal respiratory distress	7		7				5
Neonatal respiratory distress syndrome	4	1	4				4
Neonatal respiratory failure	1		1				
Neonatal tachypnoea	1		1				2
Nocturnal dyspnoea	66	5	27	9	39		
Non-cardiogenic pulmonary oedema	1		1				

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
NSAID exacerbated respiratory disease	3		1	1	2		
Obliterative bronchiolitis	1		1				
Obstructive airways disorder	224	3	140	13	84		1
Obstructive sleep apnoea syndrome	24	2	10	4	14		
Organising pneumonia	98	10	98				
Oropharyngeal blistering	72	16	72				
Oropharyngeal cobble stone mucosa	3	1	2	1	1		
Oropharyngeal discomfort	3169	29	971	197	2198		1
Oropharyngeal oedema	30		17	1	13		
Oropharyngeal pain	21099	153	3577	2076	17522	11	79
Oropharyngeal plaque	21		9	3	12		
Oropharyngeal spasm	22		16		6		
Oropharyngeal swelling	55	1	16	5	39		
Orthopnoea	183	10	106	12	77		
Painful respiration	810	15	274	72	536		2
Paranasal cyst	7		4		3		
Paranasal sinus discomfort	361	3	65	15	296		
Paranasal sinus haemorrhage	6		2		4		
Paranasal sinus hypersecretion	38		5	2	33		
Paranasal sinus hyposecretion	2				2		
Paranasal sinus inflammation	49		9	10	40		1
Paranasal sinus mucosal hypertrophy	2			1	2		
Paraneoplastic pleural effusion	1	1	1				
Pharyngeal cyst	5		3	1	2		
Pharyngeal disorder	89		24	6	65		
Pharyngeal dyskinesia	1		1				
Pharyngeal enanthema	20		7	1	13		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pharyngeal erosion	1				1		
Pharyngeal erythema	234	3	66	23	168		
Pharyngeal haematoma	3	1	3				
Pharyngeal haemorrhage	25	4	25				
Pharyngeal hypoaesthesia	288	9	98	26	190		
Pharyngeal inflammation	159	4	43	12	116		
Pharyngeal lesion	3		1		2		
Pharyngeal leukoplakia	2	1	1		1		
Pharyngeal mass	50		20	3	30		
Pharyngeal oedema	435	15	226	26	209		3
Pharyngeal paraesthesia	557	1	182	30	375		5
Pharyngeal stenosis	22		22				
Pharyngeal swelling	3034	43	1131	278	1903		3
Pharyngeal ulceration	50	2	21	2	29		
Phonasthenia	1				1		
Pickwickian syndrome	2		2				
Platypnoea	3		1		2		
Pleural adhesion	4	2	3	1	1		
Pleural disorder	10		4	1	6		
Pleural effusion	1121	79	834	49	287	1	11
Pleural fibrosis	4	1	4				
Pleural mass	1		1				
Pleural rub	4		2		2		1
Pleural thickening	22	3	15	1	7		
Pleurisy	474	39	309	18	165		5
Pleuritic pain	408	4	143	28	265		1
Pneumomediastinum	19	3	19				

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pneumonitis	372	32	255	12	117	1	9
Pneumonitis aspiration	5		5				
Pneumothorax	172	18	172				2
Pneumothorax spontaneous	31	1	31				
Productive cough	1980	41	541	233	1439	2	10
Prolonged expiration	12	1	8	1	4		
Pulmonary air leakage	1				1		
Pulmonary alveolar haemorrhage	50	3	50				
Pulmonary arterial hypertension	37	5	37				1
Pulmonary artery dilatation	9	2	9				
Pulmonary artery occlusion	5		5				
Pulmonary artery stenosis	1	1	1				
Pulmonary artery thrombosis	47	8	47				1
Pulmonary calcification	6	2	2		4		
Pulmonary cavitation	4	1	4				
Pulmonary congestion	224	24	224			1	2
Pulmonary embolism	7872	632	7871		1	7	58
Pulmonary eosinophilia	4	3	4				
Pulmonary fibrosis	108	25	108			4	7
Pulmonary granuloma	11		8		3		
Pulmonary haematoma	1		1				
Pulmonary haemorrhage	48	4	48				
Pulmonary hilum mass	4		1	2	3		
Pulmonary hypertension	167	30	167				5
Pulmonary hypertensive crisis	2		2				
Pulmonary hypoperfusion	6	1	6				
Pulmonary infarction	324	18	324				

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pulmonary mass	132	10	65	7	67		4
Pulmonary microemboli	16	4	16				
Pulmonary necrosis	2		2				
Pulmonary oedema	613	67	613			1	3
Pulmonary pain	1273	29	334	176	939	1	4
Pulmonary pneumatocele	2		1	1	1		
Pulmonary sarcoidosis	37	12	36		1		
Pulmonary sensitisation	4		2		2		
Pulmonary thrombosis	362	31	362			2	8
Pulmonary toxicity	10	2	10				
Pulmonary vascular disorder	4		1	1	3		
Pulmonary vasculitis	6		6				
Pulmonary vein stenosis	1	1	1				
Pulmonary veno-occlusive disease	1		1				
Pulmonary venous thrombosis	8	2	8				
Rales	187	5	102	12	85	1	5
Reflux laryngitis	12		5	3	7		
Respiration abnormal	742	19	313	64	429		
Respiratory acidosis	49		35	2	14		
Respiratory alkalosis	49		29	2	20		
Respiratory arrest	414	41	414				1
Respiratory depression	44	3	44				
Respiratory depth decreased	14		3	3	11		
Respiratory depth increased	1				1		
Respiratory disorder	1323	60	648	101	675		1
Respiratory disorder neonatal	1		1				2
Respiratory distress	2506	277	2506			17	31

* I=Interval, C=Cumulative
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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Respiratory failure	1027	153	1027			2	9
Respiratory fatigue	85	1	42	2	43		
Respiratory fremitus	1		1				
Respiratory gas exchange disorder	5		3		2		
Respiratory muscle weakness	18	1	15		3		
Respiratory paralysis	5		5				
Respiratory symptom	273	5	95	19	178		
Respiratory tract congestion	168	1	34	7	134		3
Respiratory tract haemorrhage	17	4	17				
Respiratory tract inflammation	25	1	5	4	20		
Respiratory tract irritation	115		24	15	91		1
Respiratory tract oedema	87	4	87				
Restrictive pulmonary disease	8	1	6	1	2		
Reversible airways obstruction	4		4				
Rheumatoid arthritis-associated interstitial lung disease	2		2				
Rheumatoid lung	1		1				
Rhinalgia	301	2	65	35	236	1	1
Rhinitis allergic	238	2	42	17	196		
Rhinitis atrophic	1				1		
Rhinitis perennial	4				4		
Rhinorrhoea	10590	72	1324	969	9266	5	32
Rhonchi	71		26	4	45		1
Sinonasal obstruction	43		14	7	29		
Sinus congestion	376	5	91	31	285		4
Sinus disorder	320	9	71	26	249	1	2
Sinus pain	713	7	234	82	479		1
Sinus polyp	6		1		5		

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* AE=Adverse Event
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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Sleep apnoea syndrome	202	23	77	30	125	1	3
Small airways disease	4				4		
Sneezing	2511	12	426	210	2085	5	13
Snoring	89	1	27	8	62		
Sputum decreased	1				1		
Sputum discoloured	100	1	34	9	66	2	5
Sputum increased	84	1	27	11	57		
Sputum retention	45		18	5	27		
Status asthmaticus	13	2	13				
Stertor	19		11	1	8		
Stridor	289	4	193	3	96		
Suffocation feeling	353	15	149	30	204		
Systemic sclerosis pulmonary	1		1				
Tachypnoea	956	17	521	25	435		
Thoracic haemorrhage	3		3				
Throat clearing	92	4	26	5	66		
Throat irritation	3910	44	929	300	2981	1	8
Throat lesion	19		2	4	17		
Throat tightness	3625	44	1672	113	1953	2	26
Tonsillar cyst	2		1		1		
Tonsillar disorder	55		10	4	45		
Tonsillar erythema	34	1	12		22		
Tonsillar exudate	3			1	3		
Tonsillar haemorrhage	5		5				
Tonsillar hypertrophy	459	9	114	56	345	1	1
Tonsillar inflammation	105	2	15	6	90		
Tonsillar ulcer	7		3	1	4		

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Tonsillolith	13		3	1	10		
Tracheal calcification	1				1		
Tracheal compression	3		3				
Tracheal dilatation	1				1		
Tracheal disorder	10		3		7		
Tracheal inflammation	19	1	6	1	13		
Tracheal oedema	9		9				
Tracheal pain	35		7	7	28		
Tracheal stenosis	19	2	19				
Tracheomalacia	1		1				
Transient tachypnoea of the newborn	1		1				1
Upper-airway cough syndrome	143	4	36	6	107	1	4
Upper airway obstruction	36	1	36				1
Upper respiratory tract congestion	152		27	7	125		1
Upper respiratory tract inflammation	42		9	1	33		
Upper respiratory tract irritation	11	1	3	2	8		
Use of accessory respiratory muscles	76	3	47	1	29		
Vasomotor rhinitis	7	1	1	1	6		
Velopharyngeal incompetence	1		1				
Ventilation perfusion mismatch	1	1	1				
Vocal cord atrophy	2		1	1	1		
Vocal cord cyst	1		1				
Vocal cord disorder	52	2	15	6	37		
Vocal cord dysfunction	22	2	9	4	13		
Vocal cord fixation	1			1	1		
Vocal cord inflammation	19		5	6	14		
Vocal cord polyp	2	2	2				

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System Organ Class

Respiratory, thoracic and mediastinal disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vocal cord thickening	5	1	2		3		
Vocal fold immobility	1			1	1		
Wheezing	2393	55	1281	85	1112	3	9
Yawning	210		56	19	154		
Total:	214911	6193	79267	17402	135644	164	944

System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Acantholysis	1		1				
Acanthosis	2		1		1		
Acanthosis nigricans	1				1		
Achromotrichia acquired	3		2		1		
Acne	1481	19	221	239	1260		3
Acne conglobata	5		4	1	1		
Acne cystic	71		20	5	51		
Acne fulminans	2	1	2				
Acquired blaschkoid dermatitis	1	1	1				
Acquired C1 inhibitor deficiency	1	1	1				
Acquired epidermolysis bullosa	4		4				
Acquired perforating dermatosis	1		1				
Actinic cheilitis	2				2		
Actinic keratosis	10	1	2		8		1
Acute cutaneous lupus erythematosus	7	1	7				
Acute febrile neutrophilic dermatosis	40	3	40				
Acute generalised exanthematous pustulosis	50	5	50				

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Adiposis dolorosa	2		1		1		
Alopecia	5249	134	844	769	4405	2	8
Alopecia areata	629	36	167	92	462		
Alopecia scarring	2	1	1		1		
Alopecia totalis	44	5	16	13	28		
Alopecia universalis	39	6	15	7	24		
Androgenetic alopecia	23		7	5	16		
Anetoderma	2			2	2		
Angiodermatitis	2		2				
Angioedema	2852	284	2851		1	3	16
Angiokeratoma	1				1		
Angiolymphoid hyperplasia with eosinophilia	2				2		
Anhidrosis	18		8	2	10		
Aquagenic pruritus	1				1		
Aquagenic wrinkling of palms	3			1	3		
Argyria	1				1		
Aseptic pustule	5			4	5		
Asteatosis	1				1		
Atrophie blanche	1	1	1				
Autoimmune blistering disease	5	1	5				
Autoimmune dermatitis	5		1		4		
Blister	2943	55	780	375	2163	2	6
Blister rupture	17	1	1	1	16		
Blood blister	153		47	11	106	1	1
Brachioradial pruritus	2				2		
Bromhidrosis	3			1	3		
Brow ptosis	4		1		3		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Bullous haemorrhagic dermatosis	18	3	18				
Butterfly rash	47	1	16	3	31		1
Cafe au lait spots	1				1		
Capillaritis	22	1	4	3	18		
Cellulite	8		1	1	7		
Chloasma	10	1	1		9		
Chronic cutaneous lupus erythematosus	32	7	32				2
Chronic pigmented purpura	23	3	6		17		
Chronic spontaneous urticaria	89	13	39	15	50		
Circumoral oedema	34		11	1	23		1
Circumoral swelling	78	1	22	8	56		
Cold sweat	4691	64	1518	431	3173		7
Cold urticaria	83	1	24	14	59		
Confluent and reticulate papillomatosis	3				3		
Cullen's sign	1		1				
Cutaneous contour deformity	3				3		
Cutaneous lupus erythematosus	17	7	17			1	1
Cutaneous sarcoidosis	21	3	21				
Cutaneous symptom	75	1	20	5	55		
Cutaneous vasculitis	289	40	287		2		
Cutis laxa	1				1		
Cutis verticis gyrata	1	1	1				
Dandruff	51	1	4	12	47		
Decubitus ulcer	63	1	35	4	28		
Dermal cyst	64		14	6	50		1
Dermatitis	1051	29	294	113	757		1
Dermatitis acneiform	160	3	24	16	136		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dermatitis allergic	1367	19	426	119	941	1	5
Dermatitis atopic	397	22	131	54	266		1
Dermatitis bullous	331	25	331				6
Dermatitis contact	211	4	52	19	159	1	1
Dermatitis diaper	11		5		6		
Dermatitis exfoliative	19		19				
Dermatitis exfoliative generalised	99	34	99				
Dermatitis herpetiformis	20		8	1	12		
Dermatitis psoriasiform	78		24	8	54		
Dermatomyositis	139	43	139				
Dermatosis	53	1	11	9	42		2
Diabetic cheiroarthropathy	1			1	1		
Diabetic foot	7	1	6		1	1	1
Diabetic ulcer	1				1		
Diabetic wound	1		1				
Diffuse alopecia	149	4	31	31	118		
Diffuse cutaneous mastocytosis	2		1		1		
Digital pulpitis	2		2				
Drug eruption	435	5	157	19	278		
Drug reaction with eosinophilia and systemic symptoms	52	13	52				1
Dry skin	1310	27	303	136	1007	1	11
Dyshidrotic eczema	139	4	38	19	101		
Ecchymosis	617	15	182	45	435		3
Eczema	3328	87	702	490	2626	3	7
Eczema asteatotic	33	1	8	2	25		
Eczema infantile	6		2		4		
Eczema nummular	76	3	24	7	52		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Eczema vesicular	10		4		6		
Eczema weeping	26		7	3	19		
Eosinophilic cellulitis	15		8	1	7		
Eosinophilic panniculitis	1			1	1		
Eosinophilic pustular folliculitis	4			1	4		
Ephelides	6				6		1
Epidermal necrosis	9	1	9				
Epidermolysis	3		3				
Erythema	24121	229	4725	1966	19396	5	63
Erythema ab igne	1				1		
Erythema annulare	28	4	7		21		
Erythema elevatum diutinum	2				2		
Erythema marginatum	2				2		
Erythema multiforme	599	100	599				3
Erythema nodosum	383	11	144	31	239		
Erythematotelangiectatic rosacea	2		1		1		
Erythrodermic atopic dermatitis	1			1	1		
Erythrodermic psoriasis	19	1	10	2	9		1
Erythrosis	20		1	7	19		
Excessive granulation tissue	4	1	4				
Exfoliative rash	103	1	39	13	64		
Fingerprint loss	4	1	2		2		
Fixed eruption	28		7	2	21		
Flagellate dermatitis	2			1	2		
Follicular eczema	1		1				
Follicular mucinosis	2		1		1		
Fracture blisters	1				1		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Fungating wound	1		1				
Generalised bullous fixed drug eruption	5	2	5				
Granuloma annulare	94	5	25	23	69		
Granuloma skin	12	1	2	3	10		
Granulomatous dermatitis	2	1	1		1		
Guttate psoriasis	94	5	40	7	54	1	1
Haematidrosis	1				1		
Haemorrhage subcutaneous	291	31	291				
Haemorrhage subepidermal	4		1	2	3		
Haemorrhagic urticaria	5		5				
Haemosiderin stain	3	1	1		2		
Hair colour changes	51		5	6	46		
Hair disorder	51		7	9	44		
Hair growth abnormal	83	1	12	20	71		
Hair growth rate abnormal	3	1	2		1		
Hair texture abnormal	68	2	10	7	58		
Hand dermatitis	127	4	25	30	102		
Hangnail	1				1		
Heliotrope rash	1		1				
Henoch-Schonlein purpura	188	18	123	9	65		
Herpes gestationis	4	1	3		1		
Hidradenitis	82	9	32	12	50	1	7
Hirsutism	19	1	4	5	15		
Hyperhidrosis	19161	276	4744	1919	14417	4	57
Hyperkeratosis	51	6	18	8	33		2
Hypersensitivity vasculitis	56	2	56				
Hypertrichosis	35	1	4	13	31		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Hypertrophic scar	4		1	1	3		1
Hypohidrosis	19	1	7	3	12		
Hypotrichosis	16		2	1	14		
Ichthyosis acquired	6		5		1		
Idiopathic angioedema	6		6				
Idiopathic urticaria	17	2	10	4	7		
Immune-mediated dermatitis	2		1		1		
Ingrowing nail	7	1	2	1	5	1	2
Ingrown hair	4		1		3		
Interstitial granulomatous dermatitis	7	2	3	3	4		
Intertrigo	11		1	1	10	1	1
Ischaemic skin ulcer	3		2	1	1		
Itching scar	27		4	3	23		
Jessner's lymphocytic infiltration	3		3				
Keloid scar	11		2	1	9		
Keratoderma blenorrhagica	1		1				
Keratolysis exfoliativa acquired	3		1		2		
Keratosis pilaris	19		5	2	14		
Koebner phenomenon	6		1	1	5		
Koilonychia	1				1		
Lentigo	1				1		
Leukoderma	2		1		1		
Leukonychia	2	1	1	1	1		
Leukoplakia	7	1	3		4		
Lichenification	4		1		3		
Lichen nitidus	1	1	1				
Lichenoid keratosis	71	8	30	10	41		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lichen planopilaris	22	1	9	6	13		
Lichen planus	317	16	87	62	230		
Lichen planus pemphigoides	1	1	1				
Lichen sclerosus	115	7	41	11	74		
Lichen striatus	4				4		
Linear IgA disease	3	1	3				
Lipoatrophy	6		3	1	3		
Lipodystrophy acquired	4	3	4				
Lipohypertrophy	2		2				
Livedo reticularis	256	14	100	21	156		1
Lividity	63	4	32	3	31		
Lupus miliaris disseminatus faciei	1		1				
Lymphomatoid papulosis	8	2	4		4		
Macule	157	2	24	18	133		
Madarosis	80	2	25	13	55		
Mechanical urticaria	193	11	51	22	142		2
Mechanic's hand	1		1				
Melanoderma	3		1		2		
Milia	5		2	1	3		
Miliaria	263	2	76	11	187		
Morbihan disease	1				1		
Mucocutaneous disorder	4			2	4		
Mucocutaneous haemorrhage	3		3				
Mucocutaneous rash	2		1		1		
Mucocutaneous ulceration	1		1				
Mucous membrane pemphigoid	3	1	3				
Myxoid cyst	2			1	2		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Nail bed bleeding	12		2	2	10		
Nail bed disorder	5		2	1	3		
Nail bed inflammation	8		1		7		
Nail bed tenderness	2		1		1		
Nail cuticle fissure	1				1		
Nail discolouration	117	3	25	13	92		
Nail discomfort	7			1	7		
Nail disorder	63	1	12	13	51		
Nail dystrophy	5			2	5		
Nail fold inflammation	1				1		
Nail growth abnormal	15	1	4	4	11		
Nail hypertrophy	1				1		
Nail necrosis	1		1				
Nail pigmentation	8	1	5	1	3		
Nail pitting	2			1	2		
Nail psoriasis	19	2	5	4	14		
Nail ridging	14	1	5	1	9		
Necrobiosis lipoidica diabeticorum	1		1				
Necrolytic migratory erythema	1		1				
Necrotic angiodermatitis	2		1	1	1		
Needle track marks	12		2		10		
Neurodermatitis	455	21	53	91	402		1
Neuropathic pruritus	3		3				
Neutrophilic dermatosis	11		6		5		
Night sweats	3892	95	1065	338	2827	1	12
Nikolsky's sign	3		3				
Nodular rash	15		3		12		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Oculomucocutaneous syndrome	43	1	43				
Oedema blister	5		1		4		
Oil acne	2		2				
Onychalgia	27	1	9	3	18		
Onychoclasis	58	3	9	14	49		1
Onycholysis	28		11	3	17		
Onychomadesis	30	1	8	3	22		
Pain of skin	2273	36	577	292	1696	1	5
Palmar erythema	119	1	28	10	91		
Palmar-plantar erythrodysaesthesia syndrome	48	3	12	6	36		
Palmoplantar keratoderma	5	2	3	1	2		
Palmoplantar pustulosis	37	5	16	10	21		
Palpable purpura	16	2	11	2	5		
Panniculitis	59	8	59				
Papule	737	9	125	69	612	1	1
Papulopustular rosacea	11	1	4	1	7		
Paradoxical psoriasis	1		1				
Parakeratosis	7		1		6		
Paraneoplastic dermatomyositis	1		1				
Parapsoriasis	52	9	22	8	30		
Partial lipodystrophy	1				1		
Pathergy reaction	4		2		2		
Peau d'orange	3				3		
Pemphigoid	318	96	318			1	3
Pemphigus	121	42	121				
Penile ulceration	5		1		4		
Perioral dermatitis	43		8	12	35		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pernio-like erythema	64	12	20	20	44		
Petechiae	2214	65	681	198	1533	1	8
Photodermatosis	13			8	13		
Photosensitivity reaction	713	12	185	98	528		3
Pigmentation disorder	212	4	35	29	177		
Piloerection	212	1	50	15	162		
Pityriasis	49		16	2	33		
Pityriasis alba	3				3		
Pityriasis lichenoides et varioliformis acuta	23	4	12	4	11		
Pityriasis rosea	722	10	120	61	602		
Pityriasis rubra pilaris	28	5	12	7	16		
Plantar erythema	16		5		11		
Poikiloderma	1				1		
Polymorphic eruption of pregnancy	1		1				
Polymorphic light eruption	17		5		12		
Post inflammatory pigmentation change	8	1	3	1	5		
Precancerous skin lesion	1		1				
Progressive facial hemiatrophy	2	1	2				
Progressive macular hypomelanosis	2		1		1		
Prurigo	95		18	2	77		
Pruritus	40659	399	7729	3621	32930	4	86
Pruritus allergic	64	1	17	5	47		
Pseudofolliculitis	7		2	1	5		
Pseudoporphyria	1		1				
Psoriasis	1718	88	538	257	1180	3	25
Purpura	825	20	305	45	520		2
Purpura fulminans	1		1				

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Purpura senile	4		3		1		
Pustular psoriasis	59	10	37	8	22		
Pyoderma gangrenosum	26	7	26				
Rash	47712	621	8300	5216	39412	8	87
Rash erythematous	5291	52	1341	428	3950	1	9
Rash follicular	13	2	5	7	8		
Rash macular	3569	43	743	391	2826		7
Rash maculo-papular	1061	15	272	91	789		3
Rash maculovesicular	12		2	2	10		
Rash morbilliform	281	3	58	41	223		1
Rash neonatal	4		2		2		
Rash papular	1807	17	356	113	1451		4
Rash papulosquamous	13	1	3	2	10		
Rash pruritic	8456	84	1481	849	6975		21
Rash rubelliform	23	3	12	6	11		
Rash scarlatiniform	12		3	1	9		
Rash vesicular	965	21	218	98	747		3
Reactive perforating collagenosis	2	1	1		1		
Rebound atopic dermatitis	1				1		
Rebound eczema	1				1		
Rebound psoriasis	3				3		
Reticular erythematous mucinosis	1				1		
Rosacea	246	7	56	43	190		
Sarcoid-like reaction	4		2		2		
Scab	250	2	47	21	203	1	3
Scar discomfort	19		2	3	17		
Scar pain	93	3	20	10	73		

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Scleroderma associated digital ulcer	1		1				
Scleroedema	1		1				
Sebaceous gland disorder	3				3		
Sebaceous glands overactivity	1				1		
Sebaceous hyperplasia	1			1	1		
Seborrhoea	57	1	12	10	45		
Seborrhoeic alopecia	1	1	1				
Seborrhoeic dermatitis	73	3	17	13	56		
Segmented hyalinising vasculitis	14	5	14				
Senile pruritus	2	2	2				
Sensitive skin	9888	26	570	266	9318	1	4
Septal panniculitis	2	1	2				
Severe cutaneous adverse reaction	3	3	3				
Shagreen skin	1				1		
Skin atrophy	45	1	6	10	39		1
Skin burning sensation	2181	39	499	250	1682		4
Skin degenerative disorder	2	1	1		1		
Skin depigmentation	93	1	18	11	75		
Skin discharge	11		3	1	8		
Skin discolouration	1977	47	482	205	1495		5
Skin discomfort	247	11	33	46	214		
Skin disorder	2615	85	668	596	1947	1	6
Skin erosion	97	4	40	9	57		
Skin exfoliation	1125	22	285	128	840	1	2
Skin fibrosis	1				1		
Skin fissures	156	5	38	24	118		2
Skin fragility	8	2	2	2	6		2

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Skin haemorrhage	436	15	98	99	338		
Skin hyperpigmentation	78	1	9	7	69		
Skin hyperplasia	1				1		
Skin hypertrophy	80	3	23	11	57		
Skin hypopigmentation	17		2	4	15		
Skin indentation	28	2	6	6	22		
Skin induration	85	4	14	8	71		
Skin irritation	719	10	158	89	561	1	3
Skin laxity	12		3	2	9		
Skin lesion	793	39	227	92	566	1	7
Skin lesion inflammation	7		4		3		
Skin maceration	1				1		
Skin mass	370	9	93	30	277		4
Skin necrosis	43	2	43				
Skin odour abnormal	224	6	32	34	192		
Skin oedema	62	1	15	2	47		
Skin plaque	154	5	39	27	115	1	3
Skin reaction	1183	15	215	104	968		1
Skin sensitisation	189	1	35	17	154		
Skin striae	26		8	5	18		
Skin swelling	484	4	109	52	375	1	3
Skin texture abnormal	35	1	3	9	32		
Skin tightness	225	2	53	15	172		1
Skin ulcer	228	19	127	22	101	2	4
Skin ulcer haemorrhage	3		1	1	2		
Skin warm	982	6	271	53	711	3	5
Skin weeping	87	2	41	9	46		1

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Skin wrinkling	63	1	20	5	43		
Solar dermatitis	37	1	7	10	30		
Solar lentigo	19	1	6	5	13		
Solar urticaria	19	1	3	5	16		
Spider naevus	4		1		3		
Splinter haemorrhages	10	2	5	1	5		
Stasis dermatitis	16	3	7	2	9		
Stevens-Johnson syndrome	90	11	90				
Sticky skin	17		3	1	14		
Subacute cutaneous lupus erythematosus	10		10			1	1
Subcorneal pustular dermatosis	3		2		1		
Subcutaneous emphysema	9		5	1	4		
Superficial inflammatory dermatosis	21	1	9	2	12		
Sweat discolouration	5		1		4		
Sweat gland disorder	3		1	1	2		
Symmetrical drug-related intertriginous and flexural exanther	15	3	11		4		
Systemic lupus erythematosus rash	19	1	15	1	4		
Target skin lesion	10		10				
Telangiectasia	69	2	22	4	47		
Topical steroid withdrawal reaction	1			1	1		
Toxic epidermal necrolysis	31	5	31				
Toxic skin eruption	151	12	151				
Transient acantholytic dermatosis	14	1	6		8		
Trichodynia	21	1	3		18		
Trichorrhexis	46		3	7	43		
Umbilical erythema	2		1		1		
Umbilical haematoma	1		1				

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System Organ Class

Skin and subcutaneous tissue disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Umbilical haemorrhage	1		1				
Urticaria	23879	321	5263	2304	18616	2	54
Urticaria aquagenic	7	1	1	2	6		
Urticaria cholinergic	21		5	3	16		
Urticaria chronic	348	28	155	55	193		
Urticaria contact	5		1		4		
Urticarial dermatitis	9		2	1	7		
Urticarial vasculitis	60	7	60				
Urticaria papular	40		11	1	29		
Urticaria physical	9			2	9		
Urticaria pigmentosa	2				2		
Urticaria pressure	12	2	6		6		
Urticaria thermal	24		7	4	17		
Urticaria vesiculosa	5		2		3		
Urticaria vibratory	1				1		
Vancomycin infusion reaction	2		1		1		
Vascular purpura	81	7	55	3	26		1
Vascular skin disorder	7		1	3	6		
Vasculitic rash	73	2	33	1	40		
Vasculitic ulcer	3	1	3				
Vitiligo	262	13	52	61	210		
Xanthelasma	4			2	4		
Xeroderma	3		1		2		
Yellow nail syndrome	1				1		
Yellow skin	156	3	43	15	113		
Total:	254390	4544	57627	24811	196763	66	628

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System Organ Class

Social circumstances

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aborted pregnancy	7	1	5	1	2		
Adolescence	1				1		
Alcohol use	6		2		4		
Anal sex	1		1				
Anxious parent	1				1		
Bedridden	1498	47	378	243	1120		1
Bed sharing	1		1				
Blood product transfusion dependent	2		2				
Body modification	6				6		
Breast feeding	31		2	1	29		
Breast prosthesis user	4				4		
Caffeine consumption	2				2		
Cardiac assistance device user	2	1	1		1		
Caregiver	3	1	2		1		
Contraindication to medical treatment	2				2		
Contraindication to vaccination	10	1	1		9		
Convalescent	2			2	2		
Corrective lens user	2	1	1		1		2
Dependence on oxygen therapy	17		17				
Device dependence	2		2				
Disability	89	11	52	9	37		1
Disease risk factor	3		1		2		
Drug abuser	1		1				
Economic problem	3		2		1		
Edentulous	1				1		
Educational problem	20		3	6	17		
Excessive exercise	3		1		2		

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System Organ Class

Social circumstances

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Exercise adequate	1				1		
Exercise lack of	21	1	10	2	11		
Ex-tobacco user	2				2		
Family stress	4		2		2		
Fasting	11		2		9		
Feeding tube user	4	1	3	1	1		
Flooding	1		1				
Hair dye user	2		1		1		
Hearing aid user	2				2		
Hearing disability	33	1	12	1	21		
Homosexuality	3		1		2		
Housebound	18	1	9	3	9		
Illiteracy	10	1	5	3	5		
Immobile	183	35	183				1
Immobilisation prolonged	4	2	4				
Impaired ability to use machinery	5				5		
Impaired driving ability	389	16	156	47	233	1	2
Impaired quality of life	696	38	269	116	427		2
Impaired work ability	2918	158	1105	510	1813		2
Inadequate diet	3		2		1		
Infant	1		1				
Job change	1				1		
Job dissatisfaction	37		9	6	28		
Joint prosthesis user	2		1		1		
Limb prosthesis user	2				2		
Living alone	2				2		
Living in residential institution	1				1		

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System Organ Class

Social circumstances

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Loss of employment	15	1	3	3	12		
Loss of personal independence in daily activities	4313	185	1641	544	2672	5	13
Marital problem	2			1	2		
Menarche	49		5	4	44		
Menopause	204	19	76	31	128		
Mental disability	10	1	3	1	7		
Miscarriage of partner	1				1		
Multigravida	1				1		
Multiparous	2				2		
Non-consummation	6			3	6		
Non-tobacco user	4				4		
Occupational problem environmental	1				1		
Orthosis user	1				1		
Overwork	11	1	1	3	10		
Paralytic disability	2		1	1	1		
Partner stress	5			2	5		
Patient dissatisfaction with device	1			1	1		
Patient dissatisfaction with treatment	1				1		1
Patient uncooperative	3	1	2		1		
Personal relationship issue	2			2	2		
Physical assault	2				2		
Physical disability	96	9	47	12	49		
Poor personal hygiene	2		1		1		
Postmenopause	10		5	1	5		
Puberty	1				1		
Refusal of treatment by patient	5		2		3		
Refusal of vaccination	2				2		

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System Organ Class

Social circumstances

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Respite care	1	1	1				
Retirement	5	1	2		3		
Sexual abstinence	1			1	1		
Sick leave	368	37	113	74	255		
Sick relative	6		3		3		
Sight disability	43	2	16	2	27		
Sitting disability	135	3	48	16	87		
Social problem	18		2	8	16		
Stress at work	18	1	3	3	15		
Substance use	4				4		
Tanning	2				2		
Threat of redundancy	2				2		
Tobacco user	4				4		
Truancy	1				1		
Underimmunisation	2			1	2		
Unemployment	2			1	2		
Unhealthy lifestyle	1			1	1		
Urinary assistance device user	1				1		
Vegan	1				1		
Voluntary redundancy	1				1		
Walking aid user	91	9	33	20	58		2
Walking disability	261	22	128	17	133		
Water pollution	5		3	1	2		
Wheelchair user	51	12	29	6	22		
Wig wearer	5	1	1		4		
Total:	11857	623	4420	1711	7437	6	27

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System Organ Class

SOC Not Yet Coded

Preferred Term	*Total # of Spontaneous AE*	Spontaneous	
		Nonserious	
		I	C
	1		1
Total:	1		1

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* AE=Adverse Event
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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdominal cavity drainage	1		1				
Abdominal operation	4		3		1		
Abdominoplasty	1		1				
Abortion induced	45	2	39	1	6		1
Abscess drainage	11		5		6		
Abscess management	1			1	1		
Acupuncture	1			1	1		
Adenotonsillectomy	1				1		
Adrenocortical steroid therapy	5		1		4		
Airway secretion clearance therapy	1		1				
Allergy prophylaxis	1				1		
Allogenic stem cell transplantation	1		1				
Amputation	9	1	7		2		
Anaemia prophylaxis	1			1	1		
Anaesthesia procedure	1				1		
Anal fissure excision	1		1				
Analgesic intervention supportive therapy	3				3		
Analgesic therapy	32			2	32		
Anaphylaxis prophylaxis	1		1				
Aneurysm repair	2		2				
Angioplasty	5	2	4		1		
Ankle operation	1		1				
Antiallergic therapy	3				3		
Antibiotic therapy	2				2		
Anticoagulant therapy	4		2		2		
Antidepressant therapy	1				1		
Antiemetic supportive care	1				1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Antiinflammatory therapy	1				1		
Antiviral prophylaxis	1				1		
Antiviral treatment	1				1		
Aortic aneurysm repair	1		1				
Aortic surgery	1				1		
Aortic valve replacement	5	3	5				
Appendicectomy	19	6	18		1		1
Arm amputation	4	2	3		1		
Arterial bypass operation	1		1				
Arterial stent insertion	2	1	1		1		
Arterial therapeutic procedure	1			1	1		
Arteriovenous fistula operation	1				1		
Arthrodesis	4		1		3		
Arthroscopic surgery	1	1	1				
Artificial insemination	1				1		
Asthma prophylaxis	3		1		2		
Axillary lymphadenectomy	20		3	2	17		
Bed rest	123	5	26	42	97		
Bile duct stent insertion						1	1
Bladder catheterisation	11	2	7		4		
Bladder catheter permanent	1		1				
Bladder catheter replacement	1			1	1		
Bladder neck operation	1	1	1				
Bladder sphincterectomy	1	1	1				
Bone marrow transplant	4	2	4				
Botulinum toxin injection	1				1		
Brain operation	2	2	2				

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Brain tumour operation	1	1	1				
Breast conserving surgery	3	2	3				
Breast cyst drainage	1		1				
Breast operation	3		3			1	1
Breast prosthesis removal	1		1				
Breast reconstruction	2		2				
Burn dressing	1		1				
Bursa removal	1				1		
Caesarean section	24	9	19		5	1	1
Cardiac ablation	8	5	7		1		
Cardiac operation	16	4	15		1		1
Cardiac pacemaker insertion	27	9	22	2	5		
Cardiac pacemaker replacement	1		1				
Cardiac resynchronisation therapy	3	1	2		1		
Cardioversion	18	5	13	1	5		
Carotid artery stent insertion	1		1				
Carpal tunnel decompression	2	1	2				
Cartilage graft	1	1	1				
Cataract operation	4	1	3		1		
Catheter management	1			1	1		
Catheter placement	1				1		
Catheter removal	1			1	1		
Cautery to nose	3			2	3		
Central nervous system stimulation	6		2	2	4		
Cerebrospinal fluid drainage	1				1		
Cerebrovascular operation	1		1				
Cervical diathermy	1				1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cervical polypectomy	1		1				
Chemotherapy	6	2	3		3		
Chest wall operation	1	1	1				
Chiropractic	1		1				
Cholecystectomy	22	2	14		8	1	2
Clamping of blood vessel	1				1		
Colon operation							1
Colostomy	2		1		1		
Colostomy closure						1	1
Compression garment application	1				1		
Contraception	2		1		1		
Contraceptive diaphragm	1				1		
Contraceptive implant	2		1		1		
Cooling therapy	1				1		
Corneal operation	1		1				
Corneal transplant	2	1	2				
Coronary angioplasty	2		1	1	1		
Coronary arterial stent insertion	4		4				
Coronary artery bypass	8	1	6		2	1	3
COVID-19 immunisation	889	22	164	150	725		4
COVID-19 prophylaxis	1				1		
COVID-19 treatment	2	1	1		1		
Cranial nerve decompression	1		1				
Craniectomy	3		3				
Craniotomy	2	1	2				
Cryotherapy							1
Cyst removal	1		1				

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Dental care	2				2		
Dental implantation	6	1	2	3	4		
Dental local anaesthesia	1				1		
Dental operation	3	1	3				
Depilation	1				1		
Dermabrasion	9		6		3		
Dermal filler injection	3		1		2		
Diabetes mellitus management	2	1	1	1	1		
Diabetic diet	1		1				
Dialysis	10	6	9		1	1	2
Diverticulectomy	1		1				
Drainage	16		1	2	15		
Dry skin prophylaxis	1				1		
Dupuytren's contracture operation	1			1	1		
Ear irrigation	1		1				
Ear operation	2	1	2				
Ear tube insertion	1		1				
Ectopic pregnancy termination	1				1		
Electroconvulsive therapy	1		1				
Electrolyte substitution therapy	2				2		
Emergency care	9	2	5	3	4		
Empyema drainage	1				1		
Endocervical curettage	1				1		
Endodontic procedure	4	1	1		3		1
Endometrial ablation	1	1	1				
Endometrial scratching	1				1		
Endometriosis ablation	1	1	1				

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Endotracheal intubation	10	2	8	1	2		
Endovenous ablation	1		1				
Enteral nutrition	1			1	1		
Epidural blood patch	1				1		
Epidural injection							1
Excessive dietary supplement intake	1				1		
Exeresis						1	1
Eyeglasses therapy	1				1		
Eye irrigation	2				2		
Eye laser surgery	1	1	1				
Eyelid operation	1		1				
Eye operation	3		3				4
Face lift	1		1				
Facet joint block	1			1	1		
Fallopian tube operation	1	1	1				
Fasciectomy	1		1				
Finger amputation	3	2	3				
Finger repair operation	1				1		
Fluid intake restriction	5		3		2		
Fluid replacement	1		1				
Foot amputation	1	1	1				
Foot operation	1	1	1			1	2
Fracture reduction	1		1				
Frontal sinus operation	2				2		
Gallbladder operation	2		1		1		1
Gastric bypass							1
Gastrointestinal surgery	1		1				

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Gastrointestinal tube insertion	1	1	1				
Gastrointestinal tube removal	1				1		
Gastropexy	1				1		
Gastrorrhaphy	1				1		
Gastrostomy	4	2	3	1	1		
General anaesthesia	1		1				
Genitourinary operation	1	1	1				
Haematoma evacuation	1		1				
Haemodialysis	4	2	3		1		
Haemostasis	1			1	1		
Hand amputation	1		1				
Hearing aid therapy	1	1	1				
Heart transplant	1	1	1				
Heart valve operation	3	1	3				
Heart valve replacement	2	2	2				
Heat therapy	1				1		
Hepatectomy	1	1	1				
Hernia repair	3		2		1		2
Hip arthroplasty	11	3	8		3	2	4
Hip surgery	3	1	3			1	3
Hormonal contraception	1				1		
Hormone replacement therapy	1		1				1
Hormone therapy	9	2	3		6		
Hospitalisation	20	3	19		1	1	4
Hysterectomy	10	3	8		2	1	1
Hysterosalpingo-oophorectomy	2	1	2				
Ileectomy	1		1				

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Ileostomy	2		1		1		
Ileostomy closure						1	1
Immune tolerance induction	2				2		
Immunisation	50181	1092	20139	2689	30042	29	224
Immunoglobulin therapy	1		1				
Implantable defibrillator insertion	4		4				
Influenza immunisation	1		1				
Infusion	2			1	2		
Inguinal hernia repair	1		1				
Injection	20		8		12		
Insulin therapy	1				1		
Intensive care	9	2	9				
Interchange of vaccine products	46581	2546	16616	5822	29965	644	933
Internal fixation of fracture	1				1		
Internal fixation of spine	1		1				
Intervertebral disc operation	3	2	3				1
Intestinal anastomosis	1				1		
Intestinal operation	1	1	1			1	2
Intestinal resection	1			1	1	2	5
Intra-cerebral aneurysm operation	1		1				
Intracerebral haematoma evacuation	1	1	1				
Intrauterine contraception	11				11		
Intra-uterine contraceptive device insertion	4				4		
Intra-uterine contraceptive device removal	2			1	2		
Intravesical immunotherapy	1		1				
Iridotomy	1				1		
Jaw lesion excision	1		1				

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Jaw operation	1		1				1
Joint arthroplasty	1		1				1
Joint fluid drainage	4			2	4		
Joint injection	4		3		1		
Joint stabilisation	11	1	4	4	7		
Keratoplasty	1		1				
Knee arthroplasty	13	4	12	1	1	2	11
Knee operation	4	1	4			1	4
Labour induction	4		3		1		
Lactation inhibition therapy	2				2		
Laparoscopic surgery	1	1	1				
Large intestinal polypectomy	2				2		
Leg amputation	21	8	21				
Lens extraction	1				1		
Lesion excision	1			1	1		
Ligament operation	1		1				
Limb amputation	3	1	3				
Limb immobilisation	75	9	29	5	46		1
Limb operation	11	1	9		2		
Limb reconstructive surgery							1
Lip cosmetic procedure	1				1		
Liver transplant	2	1	2				
Local anaesthesia	12		4	1	8		
Localised alternating hot and cold therapy	1		1				
Lung assist device therapy	2		1		1		
Lung operation	1		1				
Lung transplant	1	1	1				

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Lymphadenectomy	8		2		6		
Lymphoid tissue operation	1	1	1				
Macrophage activation	2		2				
Magnetic therapy	1		1				
Mammoplasty	2	1	2				
Manual lymphatic drainage	2				2		
Mass excision	17		4		13		
Mastectomy	8	1	6	2	2		
Mechanical ventilation	4		3	1	1		
Medical device removal	2		1	1	1		
Medical diet	7		3	1	4		
Medical induction of coma	22	1	19	1	3		
Medical procedure	2		1		1		
Medication dilution	1				1		
Menstrual cycle management	342	1	14	8	328		
Migraine prophylaxis	2		1		1		
Mineral supplementation	5			2	5		
Mitral valve repair	3	1	3				
Mitral valve replacement	1		1				
Multiple drug therapy	1			1	1		
Multiple sclerosis relapse prophylaxis	3		1		2		
Myomectomy	2		1		1		
Nail operation	3		2		1	1	1
Nasal cavity packing	3				3		
Nasal septal operation	1		1				
Neck lift	1		1				
Nephrectomy	1	1	1				

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Nerve block	18	1	8	2	10		2
Neurolysis	4	2	2	1	2		
Nipple resection	1		1				
Nothing by mouth order	14				14		
Oesophagectomy	1				1		
Oestrogen replacement therapy	1				1		
Oophorectomy	2				2		
Oral contraception	14		2		12		
Oral surgery	1	1	1				
Orchidectomy	1		1				
Orthodontic procedure	1				1		
Orthopaedic procedure	1				1		
Ovarian operation	1		1				
Ovarian repair	1	1	1				
Ovulation induction	4		2	1	2		
Oxygen therapy	8	1	4		4		1
Pacemaker generated rhythm	4	3	3	1	1		
Palliative care	5		4		1		
Pancreatic operation	1		1				
Parathyroidectomy	1		1				1
Parenteral nutrition	3	1	2		1		
Parotidectomy	1	1	1				
Patient isolation	3		1		2		
Pelvic floor stimulation	1				1		
Percutaneous coronary intervention	1		1				
Pericardial drainage	10		7		3		
Pericardial operation	1		1				

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pericardiotomy	1	1	1				
Peripheral artery surgery	1		1				
Peripheral nerve destruction	3			1	3		
Peripheral nerve neurostimulation	2		1		1		
Phlebectomy	3		3				
Phlebotomy	3		2		1		1
Physical fitness training	1				1		
Physiotherapy	2				2		
Plasmapheresis	2	2	2				
Platelet transfusion	1				1	1	1
Pleural decortication	1		1				
Pneumonectomy	1	1	1				
Polypectomy	2		1		1		
Positive airway pressure therapy	1		1				
Positive end-expiratory pressure	1		1				
Posterior fossa decompression	1		1				
Postoperative analgesia	1				1		
Prepuce dorsal slit	1		1				
Probiotic therapy	1				1		
Proctocolectomy	1	1	1				
Product substitution	1				1		
Product used for unknown indication	1	1	1				
Promotion of wound healing	2				2		
Prophylaxis of nausea and vomiting	7		4		3		
Prostatic operation	3	3	3				
Prosthetic vessel implantation	1		1				
Psychotherapy	1			1	1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Pulmonary endarterectomy							1
Radical hysterectomy	1		1				
Radical prostatectomy	1	1	1				
Radiotherapy	3		1		2		
Radiotherapy to ear	1	1	1				
Red blood cell transfusion	1				1		
Rehabilitation therapy	7		2	2	5		1
Renal artery stent placement	1		1				
Renal surgery	3		2		1	1	1
Renal transplant	4	1	3	1	1		
Renal tumour excision	1		1				
Resuscitation	49	6	46	1	3		
Retinal cryoablation	1		1				
Retinal operation	2		2				
Retinopexy	2		2				
Rotator cuff repair	1		1				
Routine health maintenance	1		1				
Salpingectomy	5	1	3	1	2		
Salpingo-oophorectomy bilateral	1		1				
Sclerotherapy	3		1	1	2		
Shoulder arthroplasty							5
Shoulder operation	2		2			1	3
Sigmoidectomy	2	1	2				
Sinus operation	4			1	4	1	3
Skin cosmetic procedure	1				1		
Skin graft	3		2		1		
Skin lesion removal	1			1	1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Skin neoplasm excision						1	2
Skin operation	1		1				
Sleep disorder therapy	1				1		
Small intestinal resection	3	1	3				
Smallpox immunisation	1				1		
Specialist consultation	17				17		
Spinal cord operation	1		1				
Spinal decompression	1				1		
Spinal fusion surgery	2		1		1		2
Spinal laminectomy	3	1	2		1		
Spinal operation	6	3	4		2	1	3
Spinal support	1			1	1		
Splenic artery embolisation	2		2				
Stent placement	17	5	14		3	2	2
Sterilisation	1		1				
Stress management	1	1	1				
Supine position	5		2	1	3		
Supportive care	5	1	1	3	4		
Surgery	38	13	31	3	7	1	2
Suture insertion	5	2	3	1	2		
Tenodesis	2		2				
Testicular operation	2		1	1	1		
Therapeutic embolisation	1		1				
Therapeutic hypothermia	1		1				
Therapeutic procedure	1				1		2
Therapeutic skin care topical	1		1				
Therapy cessation	2				2		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Therapy change	9		2	1	7		
Therapy interrupted	3		1		2	1	4
Thoracic cavity drainage	1		1				1
Thoracic operation	1	1	1				
Thrombectomy	10	2	9		1		
Thromboembolectomy	2	1	2				
Thrombolysis	21		17	1	4		
Thymectomy	1		1				
Thyroidectomy	3		2		1		
Thyroid hormone replacement therapy	1				1		
Thyroid operation	2	1	1		1		
Tissue sealing	1				1		
Toe amputation	5	5	5				
Tonsillectomy	1		1				
Tooth extraction	31	1	7	3	24		3
Tooth restoration	1		1				
Tracheostomy	3	1	2		1		
Tracheostomy tube removal	1				1		
Transcatheter aortic valve implantation	1	1	1				
Transfusion	11		10		1		
Transplant	1		1				
Transurethral bladder resection	1				1		
Transurethral prostatectomy	2		2				
Treatment delayed	1				1		
Trigeminal nerve injection	1				1		
Tumour ablation	1		1				
Uterine dilation and curettage	18	1	11		7		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Uterine dilation and evacuation	1				1		
Uterine operation	2	1	2				
Vaccine coadministration	2			2	2		
Vaginal removal of intrauterine foreign body	1			1	1		
Vagotomy	1		1				
Vascular anastomosis	1		1				
Vascular compression therapy	1				1		
Vascular graft	4	1	3		1		
Vascular operation	1		1				
Vascular stent insertion	1	1	1				
Vasodilation procedure	1				1		
Vehicle solution use	1				1		
Venous operation	2		1		1		
Ventricular drainage	1		1				
Ventriculo-cardiac shunt	1	1	1				
Ventriculo-peritoneal shunt	1	1	1				
Vestibuloplasty	1				1		
Vitamin supplementation	1				1		
Vitrectomy	1	1	1				
Vulvectomy	2	1	2				
Weight loss diet	2		1		1		
Wheat-free diet	1		1				
Wisdom teeth removal	2				2		
Withdrawal of life support	1		1				
Wound closure	1				1		
Wound drainage	1		1				
Wound treatment	1			1	1		

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System Organ Class

Surgical and medical procedures

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Wrist surgery	2		2				
Total:	99663	3907	37876	8806	61787	705	1273

System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Accelerated hypertension	11		3		8		
Achenbach syndrome	17		3	1	14		
Acute aortic syndrome	5	1	5				
Air embolism	2		2				
Aneurysm	117	5	80	5	37		
Aneurysm arteriovenous	1		1				
Aneurysm ruptured	47	1	47				
Aneurysm thrombosis	1	1	1				
Angiodysplasia	2	1	2				
Angiopathy	202	9	83	30	119		2
Aortic aneurysm	75	12	61	5	14		
Aortic aneurysm rupture	37	2	37				
Aortic arteriosclerosis	62	5	51		11		2
Aortic dilatation	36	4	19	7	17		
Aortic disorder	16	2	11	1	5		
Aortic dissection	149	11	149			1	1
Aortic dissection rupture	9	1	9				
Aortic elongation	4		1		3		
Aortic embolus	6		6				
Aortic intramural haematoma	5	1	5				

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Aortic occlusion	7		7				
Aortic perforation	1		1				1
Aortic rupture	11	1	11				
Aortic stenosis	46	9	46				
Aortic thrombosis	40	3	40				
Aortic wall hypertrophy	1	1	1				
Aortitis	32	6	32				
Arterial disorder	42	3	20		22		
Arterial haemorrhage	16		16				
Arterial insufficiency	2		2				
Arterial intramural haematoma	2		2				
Arterial occlusive disease	138	6	111	3	27	1	6
Arterial rupture	16		16				
Arterial spasm	5	1	4		1		
Arterial stenosis	29	1	29				
Arterial stiffness	1				1		
Arterial thrombosis	95	11	82	3	13		1
Arterial wall hypertrophy	1		1				
Arteriosclerosis	240	5	149	11	91		1
Arteriovenous fistula	15	3	14		1		
Arteritis	36	4	24	2	12		
Artery dissection	35	1	35				
Atheroembolism	3		3				
Atherosclerotic plaque rupture	7		7				
Axillary vein thrombosis	41	6	36	2	5		1
Behcet's syndrome	53	6	53				3
Bleeding varicose vein	8		4	1	4		

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Blood pressure fluctuation	1343	71	448	184	895	4	9
Blood pressure inadequately controlled	49		16	3	33		1
Bloody discharge	100	2	35	11	65		
Blue toe syndrome	77	4	33	4	44		
Brachial artery entrapment syndrome	4	3	3		1		
Brachiocephalic artery occlusion	1		1				
Brachiocephalic artery stenosis	1		1				
Brachiocephalic vein occlusion	1		1				
Brachiocephalic vein thrombosis	11	1	11				
Calcium embolism	2		2				
Capillary disorder	48	2	12	2	36		
Capillary fragility	140	1	33	12	107		
Capillary leak syndrome	68	5	68				1
Carotidynia	11			3	11		
Circulatory collapse	1674	187	1674			11	24
Circulatory failure neonatal	1		1				
Claudication of jaw muscles	11		3	1	8		
Collateral circulation	3				3		
Cryoglobulinaemia	16	1	16				
CT hypotension complex	2		2				
Cyanosis	1193	59	581	99	612		3
Deep vein thrombosis	5076	364	5074	1	2	6	39
Dependent rubor	8		1		7		
Diabetic vascular disorder	1		1				
Dialysis hypotension	1		1				
Diastolic hypertension	23	1	15	2	8		
Diastolic hypotension	5		4		1		

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Diffuse vasculitis	11		8		3		
Distributive shock	6	3	6				
Dry gangrene	3		3				
Embolism	407	50	407			1	3
Embolism arterial	45	4	45				
Embolism venous	79	17	79				1
Endocrine hypertension	1		1				
Endothelial dysfunction	22	5	10	4	12		
Erythrocyanosis	1			1	1		
Erythromelalgia	27	1	13	1	14		
Essential hypertension	38	3	29	1	9		1
Exsanguination	3	1	3				
Extravasation blood	25	1	6	7	19		
Extremity necrosis	25	4	21		4		
False lumen dilatation of aortic dissection	1		1				
Femoral artery embolism	6		6				
Fibromuscular dysplasia	7		4	1	3		
Flushing	4020	38	1010	159	3010	2	16
Giant cell arteritis	333	49	270	14	63		
Granulomatosis with polyangiitis	55	15	55				
Haematocoele	2			1	2		
Haematoma	3225	42	684	312	2541		5
Haemodynamic instability	57	6	45	1	12		
Haemodynamic rebound	1		1				
Haemorrhage	2809	220	2809			4	26
Haemorrhage neonatal	3		3				
Haemorrhagic infarction	22	1	22				

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Haemorrhagic vasculitis	2		2			1	1
Hot flush	8380	94	1509	716	6871	2	19
Hyperaemia	167	1	37	7	130		5
Hypertension	16522	555	6826	1070	9696	12	79
Hypertensive angiopathy	2		2				
Hypertensive crisis	1682	112	1681		1		14
Hypertensive emergency	60	6	60				1
Hypertensive urgency	54	8	54				1
Hypoperfusion	25	2	16		9		
Hypotension	6240	140	2548	379	3692	4	29
Hypotensive crisis	25	2	25				
Hypovolaemic shock	98	6	98				
Iliac artery arteriosclerosis	1		1				
Iliac artery disease	1	1	1				
Iliac artery occlusion	10	1	9		1		
Iliac artery rupture	1		1				
Iliac artery stenosis	5		5				
Infarction	194	29	194				
Inferior vena cava dilatation	13	2	10		3		
Inferior vena caval occlusion	4		4				
Inferior vena cava stenosis	1		1				
Inferior vena cava syndrome	2		2				
Intermittent claudication	75	5	38	4	37		
Internal haemorrhage	262	22	262				3
Ischaemia	232	16	181	12	51		5
Ischaemic limb pain	6		4		2		
Jugular vein distension	29	2	14	1	15		

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Jugular vein embolism	1		1				
Jugular vein haemorrhage	1		1				
Jugular vein occlusion	4		3		1		
Jugular vein thrombosis	98	12	93		5		2
Kawasaki's disease	34	7	34				
Labile blood pressure	106	10	52	8	54		
Labile hypertension	39	2	8	6	31		
Leriche syndrome	3		3				
Lower limb artery perforation	1		1				
Lupus vasculitis	3		2		1		
Lymphangiectasia	4		1		3		
Lymphangiopathy	6		3	3	3		
Lymphatic fistula	3		3				
Lymphocele	12		2		10		
Lymphoedema	898	23	252	64	646		7
Lymphorrhoea	9		6	1	3		
Lymphostasis	13		3		10		
Macroangiopathy	7	2	4		3		
MAGIC syndrome	2		2				
Malignant hypertension	22	3	22				
May-Thurner syndrome	9		7		2		
Microangiopathy	48	4	29	3	19		
Microembolism	25	3	25				1
Microscopic polyangiitis	37	6	30	1	7		
Necrosis ischaemic	1		1				
Necrosis of artery	1		1				
Neonatal hypotension	1		1				

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Neovascularisation	6		3	1	3		
Neurogenic shock	46	1	46				
Non-dipping	2				2		
Obstructive shock	5		5				
Orthostatic hypertension	12		9	1	3		
Orthostatic hypotension	333	18	137	19	196		1
Paget-Schroetter syndrome	6		5	1	1		
Pallor	3644	88	1303	246	2341	1	13
Paradoxical embolism	8	1	7		1		
Paradoxical pressor response	1				1		
Paraneoplastic thrombosis	1		1				
Pelvic venous thrombosis	115	9	115				
Peripheral arterial occlusive disease	79	10	62		17		
Peripheral artery aneurysm	10	1	8		2		1
Peripheral artery aneurysm rupture	2		2				
Peripheral artery dissection	2		2				
Peripheral artery haematoma	1		1				
Peripheral artery occlusion	51	7	51				1
Peripheral artery stenosis	10	1	10				
Peripheral artery thrombosis	166	14	147	2	19	1	1
Peripheral circulatory failure	123	3	52	5	71		1
Peripheral coldness	3022	48	861	263	2161	1	8
Peripheral embolism	76	6	66	1	10		
Peripheral ischaemia	228	19	158	7	70		
Peripheral vascular disorder	755	24	147	76	608	1	7
Peripheral vein occlusion	1		1				
Peripheral vein stenosis	2		2				

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Peripheral vein thrombosis	1			1	1		
Peripheral vein thrombus extension	3		3				
Peripheral venous disease	273	11	108	28	165		
Periphlebitis	11	2	3		8		
Phlebitis	725	31	345	49	380		4
Phlebitis deep	13	1	10		3		1
Phlebitis superficial	128	5	55	9	73		
Phlebolith	3		1		2		
Plethoric face	1				1		
Polyarteritis nodosa	19	5	19				
Poor peripheral circulation	309	23	105	46	204		1
Poor venous access	8	2	4		4	3	8
Postpartum venous thrombosis	2		2				
Post thrombotic syndrome	21	3	11	3	10		
Prehypertension	5		1		4		
Pseudovasculitis	2				2		
Raynaud's phenomenon	551	34	189	66	362		3
Reperfusion injury	1		1				
Rheumatoid vasculitis	2	1	2				
Secondary hypertension	12	1	5		7		
Segmental arterial mediolysis	1	1	1				
Shock	505	30	505				1
Shock haemorrhagic	43	6	43				
Shock symptom	41	4	41				
Spider vein	76	4	19	8	57		1
Subclavian artery aneurysm	1		1				
Subclavian artery dissection	1		1				

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Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Subclavian artery embolism	1		1				
Subclavian artery occlusion	4		4				
Subclavian artery stenosis	2		2				
Subclavian artery thrombosis	11		11				
Subclavian vein occlusion	3		3				
Subclavian vein stenosis	1		1				
Subclavian vein thrombosis	117	17	117				
Superficial vein prominence	39	3	14	3	25		
Superficial vein thrombosis	1058	40	638	40	420		5
Superior vena cava occlusion	1		1				
Superior vena cava syndrome	11	1	9		2		
Susac's syndrome	9	4	9				
Systolic hypertension	37	2	19	2	18		
Takayasu's arteritis	10	2	10				
Thromboangiitis obliterans	8	1	6		2		
Thrombophlebitis	937	55	592	38	345	1	2
Thrombophlebitis migrans	3		3				
Thrombosed varicose vein	18	2	9	2	9		
Thrombosis	5200	516	5200			8	45
Varicophlebitis	51	2	20	4	31		
Varicose ulceration	8	1	6	1	2		
Varicose vein	603	20	154	86	449		1
Varicose vein ruptured	9		6		3		
Vascular calcification	10		5	2	5		
Vascular compression	6		2	1	4		
Vascular dissection	2		2				
Vascular fragility	6	2	3		3		

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System Organ Class

Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Vascular insufficiency	9	1	4		5		
Vascular occlusion	70	10	38	15	32		2
Vascular pain	534	13	126	68	408		
Vascular rupture	71	3	24	18	47		1
Vascular shunt	2			1	2		
Vascular stenosis	11	1	6	2	5		
Vascular wall hypertrophy	2		2				
Vasculitis	894	89	516	62	378		1
Vasculitis necrotising	23	1	18	1	5		1
Vasoconstriction	47	2	23		24		
Vasodilatation	393	9	116	36	277		
Vasospasm	46	2	20	4	26		
Vein collapse	15	2	7		8		1
Vein discolouration	54		10	4	44		
Vein disorder	287	4	70	18	217		
Vein rupture	53	9	53				1
Vein wall hypertrophy	3		1	1	2		
Vena cava embolism	2		2				
Vena cava thrombosis	43	1	43				
Venoocclusive disease	1		1				
Venous aneurysm	5		5				
Venous haemorrhage	13	2	13				1
Venous hypertension	2		1		1		
Venous occlusion	65	8	46	5	19		
Venous perforation	2		2				
Venous recanalisation	1		1				
Venous stenosis	1		1				

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Vascular disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Venous thrombosis	558	43	413	20	145	1	5
Venous thrombosis in pregnancy	2		2				
Venous thrombosis limb	813	61	673	9	140		6
Vessel perforation	2				2		
Visceral congestion	3		3				
White coat hypertension	7		3		4		
Withdrawal hypertension	7		2		5		
Total:	81983	3703	42843	4445	39140	66	438

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