Clinical trial results:
A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older

Summary

EudraCT number	2020-003643-29
Trial protocol	GB FR DE ES BE
Global end of trial date	18 June 2023

Results information

Result version number	v1 (current)
This version publication date	30 June 2024
First version publication date	30 June 2024

Trial information

Trial identification

Sponsor protocol code	VAC31518COV3009

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04614948
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Vaccines & Prevention B.V.
Sponsor organisation address	Archimedesweg 4-6, Leiden, Netherlands, 2333
Public contact	Clinical Registry Group, Janssen Vaccines & Prevention B.V., ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Vaccines & Prevention B.V., ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	18 June 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to demonstrate the efficacy of Ad26.COV2.S in the prevention of molecularly confirmed, moderate to severe/critical coronavirus disease-2019 (COVID-19), as compared to placebo, in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) seronegative adults.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 November 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 2981
Country: Number of subjects enrolled	Brazil: 500
Country: Number of subjects enrolled	Colombia: 2149
Country: Number of subjects enrolled	Germany: 100
Country: Number of subjects enrolled	Spain: 3132
Country: Number of subjects enrolled	France: 714
Country: Number of subjects enrolled	United Kingdom: 5905
Country: Number of subjects enrolled	Philippines: 1572
Country: Number of subjects enrolled	United States: 12579
Country: Number of subjects enrolled	South Africa: 2073
Worldwide total number of subjects	31705
EEA total number of subjects	6927

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	25993
From 65 to 84 years	5640
85 years and over	72

Subject disposition

Recruitment

Recruitment details:

Total of 31835 subjects were randomised, out of which 130 subjects were randomised but not vaccinated. Hence, 31705 subjects received vaccination in both double blind (DB) and open label (OL) phase. After completion of DB phases more subjects were enrolled therefore, the started count of DB+OL phase is exceeding the started count for DB phase.

Pre-assignment

Screening details:

Due to change in the planned analysis, combined data of DB and OL phase was collected and analysed after completion of the DB phase. Results of safety endpoints were also collected and analysed for combined DB and OL phase. Hence, safety data is reported only in adverse event section and not repeated in the endpoint section.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Combined Double-blind and Open-label Phase: All Subjects

Arm description:

Each subject was initially randomised to receive 1 dose of 0.5 millilitre (mL) adenovirus type 26 vector coronavirus-2 spike protein (Ad26.COV2.S) 5*10^10 viral particles (vp) vaccine intramuscularly on Day 1 and on Day 57 or 1 dose of placebo vaccine intramuscularly on Day 1 and on Day 57 during the DB phase (up to 7.2 months). Following authorization of COVID-19 vaccine(s) in their country, subjects could request to be unblinded to receive a different authorized/licensed COVID-19 vaccine outside of the study at any time during the study. Following Emergency Use Authorization of Ad26.COV2.S in the United States, all subjects were unblinded and entered OL phase, and those subjects that received placebo could receive a single dose of Ad26.COV2.S 5*10^10 vp vaccine. Later it was allowed to have a booster vaccination with a single dose of Ad26.COV2.S 5*10^10 vp vaccine for those subjects that received a single dose of Ad26.COV2.S vaccine in the study.

Arm type	Experimental
Investigational medicinal product name	Ad26.COV2.S
Investigational medicinal product code	
Other name	Ad26COVS, JNJ-78436735, VAC31518
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of Ad26.COV2.S 5*10^10 vp vaccine intramuscularly on Day 1 and Day 57. Subjects who received a single dose of Ad26.COV2.S vaccine in the study (either in DB or OL phase) were offered a booster dose of Ad26.COV2.S 5*10^10 vp vaccine.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL dose of Placebo matching to Ad26.COV2.S 5*10^10 vp vaccine intramuscularly on Day 1 and Day 57.

Number of subjects in period 1	Combined Double-blind and Open-label Phase: All Subjects
Started	31705
Ad26.COV2.S Double Blind Phase	15708 [1]
Placebo Double Blind Phase	15592 [2]
Completed	21018
Not completed	10687
Adverse event, serious fatal	131
Physician decision	178
Consent withdrawn by subject	5922
Adverse event, non-fatal	14
Initiated prohibited medication	92
Technical problems	17
Protocol deviation	9
Rolled over into different clinical trial	48
Pregnancy	2
Unspecified	477
Lost to follow-up	3796
Sponsor decision	1

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only reported subjects were planned in this milestone.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only reported subjects were planned in this milestone.

Baseline characteristics

Reporting groups

Reporting group title	Combined Double-blind and Open-label Phase: All Subjects

Reporting group description:

Each subject was initially randomised to receive 1 dose of 0.5 millilitre (mL) adenovirus type 26 vector coronavirus-2 spike protein (Ad26.COV2.S) 5*10^10 viral particles (vp) vaccine intramuscularly on Day 1 and on Day 57 or 1 dose of placebo vaccine intramuscularly on Day 1 and on Day 57 during the DB phase (up to 7.2 months). Following authorization of COVID-19 vaccine(s) in their country, subjects could request to be unblinded to receive a different authorized/licensed COVID-19 vaccine outside of the study at any time during the study. Following Emergency Use Authorization of Ad26.COV2.S in the United States, all subjects were unblinded and entered OL phase, and those subjects that received placebo could receive a single dose of Ad26.COV2.S 5*10^10 vp vaccine. Later it was allowed to have a booster vaccination with a single dose of Ad26.COV2.S 5*10^10 vp vaccine for those subjects that received a single dose of Ad26.COV2.S vaccine in the study.

Reporting group values	Combined Double-blind and Open-label Phase: All Subjects	Total	
Number of subjects	31705	31705	
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	25993	25993	
From 65 to 84 years	5640	5640	
elderlyOver85	72	72	
Missing	0	0	
Title for AgeContinuous Units: years			
arithmetic mean	51.5		
standard deviation	± 14.46	-	
Title for Gender Units: subjects			
Female	15032	15032	
Male	16669	16669	
Undifferentiated	4	4	
Missing	0	0	

End points

End points reporting groups

Reporting group title	Combined Double-blind and Open-label Phase: All Subjects

Reporting group description:

Each subject was initially randomised to receive 1 dose of 0.5 millilitre (mL) adenovirus type 26 vector coronavirus-2 spike protein (Ad26.COV2.S) 5*10^10 viral particles (vp) vaccine intramuscularly on Day 1 and on Day 57 or 1 dose of placebo vaccine intramuscularly on Day 1 and on Day 57 during the DB phase (up to 7.2 months). Following authorization of COVID-19 vaccine(s) in their country, subjects could request to be unblinded to receive a different authorized/licensed COVID-19 vaccine outside of the study at any time during the study. Following Emergency Use Authorization of Ad26.COV2.S in the United States, all subjects were unblinded and entered OL phase, and those subjects that received placebo could receive a single dose of Ad26.COV2.S 5*10^10 vp vaccine. Later it was allowed to have a booster vaccination with a single dose of Ad26.COV2.S 5*10^10 vp vaccine for those subjects that received a single dose of Ad26.COV2.S vaccine in the study.

Subject analysis set title	Double Blind Phase: Ad26.COV2.S
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received a single dose of 0.5 mL Ad26.COV2.S 5*10^10 vp vaccine intramuscularly on Day 1 and Day 57.

Subject analysis set title	Double Blind Phase: Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received a single dose of placebo matching to Ad26.COV2.S 5*10^10 vp vaccine intramuscularly on Day 1 and Day 57.

Primary: Double Blind Phase: Number of Subjects With Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 in Seronegative Subjects With Onset at Least 14 Days After the Second Vaccination

End point title	Double Blind Phase: Number of Subjects With Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 in Seronegative Subjects With Onset at Least 14 Days After the Second Vaccination[1]

End point description:

Molecularly confirmed moderate to severe/critical COVID-19: SARS-CoV-2 RT-PCR or molecular test result from any respiratory tract sample (nasal swab/sputum/throat swab/saliva sample) or other sample. Moderate: 1 sign/symptom: respiratory rate(RR) greater than or equal to (>=)20 breaths/min; symptoms: shortness of breath or 2 signs/symptoms: heart rate (HR) >=90 beats/min and symptoms: cough. Severe/critical: 1 signs/symptoms: RR>=30breaths/min, HR>=125beats/min, oxygen saturation<=93%, respiratory failure, evidence of shock, significant acute renal, hepatic, neurologic dysfunction, admission to ICU, death per FDA guidance. PP set: subjects in FAS, received 2 doses of DB vaccine, PCR negative at 1st vaccination (vacc.), seronegative at 1st vacc. and at 14 days after 2nd vacc. and no protocol deviations to impact efficacy of vaccine before unblinding. Subjects with positive PCR test between Days 1 and 70 and who discontinued prior to 14 days post-dose 2 were excluded.

End point type	Primary

End point timeframe:

From at least 14 days after second vaccination on Day 57 (Day 71) up to end of double blind phase (7.2 months)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analyzed for this endpoint.

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6024	5615		
Units: Subjects	14	52		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 Regardless of Serostatus With Onset At Least 1 Day After the First Day 1 Vaccination

End point title	Double Blind Phase: Number of Subjects With First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 Regardless of Serostatus With Onset At Least 1 Day After the First Day 1 Vaccination

End point description:

Molecularly confirmed moderate to severe/critical COVID-19: SARS-CoV-2 positive reverse transcription/polymerase chain reaction (RT-PCR) or molecular test result from any available respiratory tract sample (nasal swab/sputum/throat swab/saliva sample) or other sample. Moderate: 1 sign/symptom: respiratory rate >= 20 breaths/minute (min) and symptoms such as shortness of breath or 2 signs/symptoms: heart rate >= 90 beats min and symptoms such as cough. Severe/critical: 1 of the following signs and symptoms: respiratory rate >=30 breaths/min, heart rate >=125 beats/min, oxygen saturation (SpO2) less than or equal to (<=) 93% on room air at sea level respiratory failure, evidence of shock, significant acute renal, hepatic, or neurologic dysfunction, admission to Intensive Care Unit (ICU), death as per FDA guidance. Full analysis set (FAS): all randomised subjects with at least 1 documented study vaccine administration, regardless of protocol deviations and serostatus at enrollment.

End point type	Secondary

End point timeframe:

From at least 1 day after first vaccination on Day 1 (Day 2) up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	15708	15592		
Units: Subjects	115	259		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 Regardless of Serostatus With Onset at Least 14 Days After the Second Vaccination

End point title	Double Blind Phase: Number of Subjects With First Occurrence

	of Molecularly Confirmed Moderate to Severe/Critical COVID-19 Regardless of Serostatus With Onset at Least 14 Days After the Second Vaccination

End point description:

Molecularly confirmed moderate to severe/critical COVID-19: SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (nasal swab/sputum/throat swab/saliva sample) or other sample. Moderate: 1 sign/symptom: RR >=20 breaths/min and symptoms: shortness of breath or 2 signs/symptoms as HR >=90 beats/min and symptoms: cough. Severe/critical: 1 signs and symptoms: RR >=30 breaths/min, HR >=125 beats/min, SpO2 <=93% respiratory failure, evidence of shock, significant acute renal, hepatic, or neurologic dysfunction, admission to ICU, death as per FDA guidance. PP set: subjects in FAS who received 2 doses of DB vaccine, regardless of serostatus at time of 1st vacc. and at 14 days after 2nd vacc., were PCR negative at time of 1st vacc. and had no other major protocol deviations to possibly impact efficacy of vaccine before unblinding. Subjects with positive PCR test between Days 1 and 70 and who discontinued prior to 14 days post-dose 2 were excluded.

End point type	Secondary

End point timeframe:

From at least 14 days after second vaccination on Day 57 (Day 71) up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6813	6370		
Units: Subjects	14	53		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 in Seronegative Subjects With Onset at Least 1 Day After the First Day 1 Vaccination

End point title	Double Blind Phase: Number of Subjects With First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 in Seronegative Subjects With Onset at Least 1 Day After the First Day 1 Vaccination

End point description:

Molecularly confirmed moderate to severe/critical COVID-19: SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (nasal swab/sputum/throat swab/saliva sample) or other sample. Moderate: 1 sign/symptom such as respiratory rate >=20 breaths/min and symptoms such as shortness of breath or 2 signs/symptoms such as heart rate >= 90 beats/min and symptoms such as cough. Severe/critical: 1 of the following signs and symptoms: respiratory rate >=30 breaths/min, heart rate >=125 beats/min, SpO2 <=93% on room air at sea level respiratory failure, evidence of shock, significant acute renal, hepatic, or neurologic dysfunction, admission to ICU, death as per FDA guidance. Full analysis seronegative set included all randomised subjects with at least 1 documented study vaccine administration, regardless of protocol deviations and who were seronegative at baseline.

End point type	Secondary

End point timeframe:

From at least 1 day after first vaccination on Day 1 (Day 2) up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13951	13871		
Units: Subjects	112	256		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 With Onset at least 14 Days After the First Day 1 Vaccination

End point title	Double Blind Phase: Number of Subjects With First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 With Onset at least 14 Days After the First Day 1 Vaccination

End point description:

Molecularly confirmed moderate to severe/critical COVID-19: SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (nasal swab/sputum/throat swab/saliva sample) or other sample. Moderate: 1 sign/symptom: RR >=20 breaths/min and symptoms: shortness of breath or 2 signs/symptoms: HR >= 90 beats/min and symptoms: cough. Severe/critical: 1 signs and symptoms: RR >=30 breaths/min, HR >=125 beats/min, SpO2 <=93% respiratory failure, evidence of shock, significant acute renal, hepatic, or neurologic dysfunction, admission to ICU, death as per FDA guidance. Per-protocol first dose efficacy (PPFD) set: subjects in FAS who received at least 1st dose of vaccine in DB phase, PCR negative at 1st vacc., not seropositive at baseline and no major protocol deviations before unblinding to impact efficacy of vaccine. Subjects who had a positive PCR test between Days 1 and 14 and who discontinued prior to Day 15 were excluded.

End point type	Secondary

End point timeframe:

From at least 14 days after first vaccination on Day 1 (Day 15) up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13316	13286		
Units: Subjects	72	216		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With First Occurrence of

Molecularly Confirmed Moderate to Severe/Critical COVID-19 With Onset at Least 28 Days After the First Day 1 Vaccination

End point title	Double Blind Phase: Number of Subjects With First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 With Onset at Least 28 Days After the First Day 1 Vaccination

End point description:

Molecularly confirmed moderate to severe/critical COVID-19: SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (nasal swab/sputum/throat swab/saliva sample) or other sample. Moderate: 1 sign/symptom: RR >=20 breaths/min and symptoms: shortness of breath or 2 signs/symptoms: HR >= 90 beats/min and symptoms: cough. Severe/critical: 1 signs and symptoms: RR >=30 breaths/min, HR >=125 beats/min, SpO2 <=93% respiratory failure, evidence of shock, significant acute renal, hepatic, or neurologic dysfunction, admission to ICU, death as per FDA guidance. PPFD set: subjects in FAS who received at least 1st dose of vaccine in DB phase and who were PCR negative at the time of 1st vacc, who were not seropositive at baseline and had no protocol deviations before unblinding to impact the efficacy of vaccine. Subjects who had a positive PCR test between Day 1 and Day 28 and who discontinued prior to Day 29 were excluded.

End point type	Secondary

End point timeframe:

From at least 28 days after the first vaccination on Day 1 (Day 29) up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	12632	12402		
Units: Subjects	52	161		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With First Occurrence of COVID-19 Requiring Medical Intervention With Onset at Least 14 Days After the Second Vaccination

End point title	Double Blind Phase: Number of Subjects With First Occurrence of COVID-19 Requiring Medical Intervention With Onset at Least 14 Days After the Second Vaccination

End point description:

Number of subjects with first occurrence of COVID-19 requiring medical intervention (such as a composite endpoint of hospitalization, ICU admission, mechanical ventilation, and extracorporeal membrane oxygenation [ECMO]), linked to objective measures such as decreased oxygenation, X-ray or computed tomography [CT] findings and linked to any molecularly confirmed, COVID-19 with onset at least 14 days post second vaccination were reported. PP set: subjects in FAS who received 2 doses of DB study vaccine, were PCR negative at time of first vaccination, were seronegative at time of first vaccination and at 14 days after second vaccination and had no other major protocol deviations to possibly impact efficacy of vaccine before unblinding. Subjects who had a positive PCR test between Day 1 and Day 70 and subjects who discontinued prior to 14 days post-dose 2 were excluded.

End point type	Secondary

End point timeframe:

From at least 14 days after second vaccination on Day 57 (Day 71) up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6024	5615		
Units: Subjects	0	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Area Under the Curve (AUC) of SARS-CoV-2 Viral Load as Assessed by Quantitative RT-PCR in Subjects With Molecularly Confirmed Symptomatic COVID-19 With Onset at Least 14 Days After Second Vaccination

End point title	Double Blind Phase: Area Under the Curve (AUC) of SARS-CoV-2 Viral Load as Assessed by Quantitative RT-PCR in Subjects With Molecularly Confirmed Symptomatic COVID-19 With Onset at Least 14 Days After Second Vaccination

End point description:

AUC of SARS-CoV-2 viral load was assessed in confirmed COVID-19 cases using RT-PCR. Nasal swabs were used to detect and/or quantify SARS-CoV-2. Due to change in the planned analysis, data was collected and analysed for subjects with molecularly confirmed symptomatic COVID-19 regardless of severity that is mild, moderate or severe and was not collected and analysed separately for moderate to severe cases. PP set: subjects in FAS who received 2 doses of DB vaccine, PCR negative at 1st vaccination, seronegative at 1st vaccination and at 14 days after 2nd vaccination and no other protocol deviations to impact efficacy of vaccine before unblinding. Here, 'N' (number of subjects analysed) refers to the number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From Day 71 up to end of the COVID-19 episode (up to 90 days)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	11	47		
Units: Log10 copies*day per millilitre				
arithmetic mean (standard error)	847.68 (± 242.375)	1023.59 (± 156.298)		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With First Occurrence of

Molecularly confirmed COVID-19 Defined by the US FDA Harmonized Case Definition With Onset at Least 14 Days After the Second Vaccination

End point title	Double Blind Phase: Number of Subjects With First Occurrence of Molecularly confirmed COVID-19 Defined by the US FDA Harmonized Case Definition With Onset at Least 14 Days After the Second Vaccination

End point description:

Molecularly confirmed COVID-19 was defined as a SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (example, nasal swab sample, sputum sample, throat swab sample, saliva sample) or other sample; and COVID-19 symptoms consistent with those defined by the US FDA harmonized case definition at the time of finalization of the study protocol: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea. PP set: subjects in FAS who received 2 doses of DB vaccine, PCR negative at 1st vaccination, seronegative at 1st vaccination and at 14 days after 2nd vaccination and no other protocol deviations to impact efficacy of vaccine before unblinding. Subjects who had a positive PCR test between Day 1 and Day 70 and subjects who discontinued prior to 14 days post-dose 2 were excluded.

End point type	Secondary

End point timeframe:

From at least 14 days after second vaccination on Day 57 (Day 71) up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6024	5615		
Units: Subjects	12	52		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With First Occurrence of Molecularly Confirmed Mild COVID-19 With Onset at Least 14 Days After the Second Vaccination

End point title	Double Blind Phase: Number of Subjects With First Occurrence of Molecularly Confirmed Mild COVID-19 With Onset at Least 14 Days After the Second Vaccination

End point description:

Molecularly confirmed mild Covid-19: SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (example, nasal swab sample, sputum sample, throat swab sample, saliva sample) or other sample and any 1 signs and symptoms: fever (>=38 degree Celsius or >=100.4 degree Fahrenheit), sore throat, malaise (loss of appetite, generally unwell, fatigue, physical weakness), headache, muscle pain (myalgia), gastrointestinal symptoms, cough, chest congestion, runny nose, wheezing, skin rash, eye irritation/discharge, chills, new/changing olfactory/taste disorders, red/ bruised looking feet/toes, shaking chills or rigors. PP set: subjects in FAS who received 2 doses of DB vaccine, PCR negative at 1st vacc., seronegative at 1st vacc. and at 14 days after 2nd vacc. and no protocol deviations to impact efficacy of vaccine before unblinding. Subjects who had a positive PCR test between Days 1 and 70 and who discontinued prior to 14 days post-dose 2 were excluded.

End point type	Secondary

End point timeframe:

From at least 14 days after second vaccination on Day 57 (Day 71) up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6024	5615		
Units: Subjects	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With Burden of Disease (BOD) Based on First Occurrence of Molecularly Confirmed Symptomatic COVID-19 With Onset at Least 14 Days After the Second Vaccination

End point title	Double Blind Phase: Number of Subjects With Burden of Disease (BOD) Based on First Occurrence of Molecularly Confirmed Symptomatic COVID-19 With Onset at Least 14 Days After the Second Vaccination

End point description:

BOD was a weighted version of the mild, moderate, and severe/critical vaccine efficacies and was evaluated based on the first occurrence of molecularly confirmed COVID-19, including mild, moderate or severe/critical COVID-19 case. PP set: subjects in FAS (all randomised subjects with at least 1 documented study vaccine administration, regardless of the occurrence of protocol deviations and serostatus at enrollment) who received 2 doses of DB vaccine, PCR negative at 1st vaccination, seronegative at 1st vaccination and at 14 days after 2nd vaccination and no other protocol deviations to impact efficacy of vaccine before unblinding. Subjects who had a positive PCR test between Day 1 and Day 70 and subjects who discontinued prior to 14 days post-dose 2 were excluded.

End point type	Secondary

End point timeframe:

From at least 14 days after second vaccination on Day 57 (Day 71) up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6024	5615		
Units: Subjects	14	53		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With Serologic Conversion Between Day 71 up to Unblinding Visit Using an Enzyme-linked Immunosorbent

Assay (ELISA)

End point title	Double Blind Phase: Number of Subjects With Serologic Conversion Between Day 71 up to Unblinding Visit Using an Enzyme-linked Immunosorbent Assay (ELISA)

End point description:

Number of subjects with serologic conversion between Day 71 up to unblinding visit using an ELISA were reported. Due to change in planned analysis, data was collected and analysed between Day 71 up to unblinding visit instead of from baseline to unblinding visit. PP set: subjects in FAS (all randomised subjects with at least 1 documented study vaccine administration, regardless of the occurrence of protocol deviations and serostatus at enrollment) who received 2 doses of DB vaccine, PCR negative at 1st vaccination, seronegative at 1st vaccination and at 14 days after 2nd vaccination and no other protocol deviations to impact efficacy of vaccine before unblinding. Subjects who had a positive PCR test between Day 1 and Day 70 and subjects who discontinued prior to 14 days post-dose 2 were excluded.

End point type	Secondary

End point timeframe:

From Day 71 up to unblinding visit (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6024	5615		
Units: Subjects	32	45		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With Asymptomatic Infection Detected By Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) With Onset at Least 14 Days After the Second Vaccination

End point title	Double Blind Phase: Number of Subjects With Asymptomatic Infection Detected By Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) With Onset at Least 14 Days After the Second Vaccination

End point description:

Number of subjects with asymptomatic infection detected by RT-PCR with onset at least 14 days after the second vaccination (Day 71) were reported. PP set: subjects in FAS (all randomised subjects with at least 1 documented study vaccine administration, regardless of the occurrence of protocol deviations and serostatus at enrollment) who received 2 doses of DB vaccine, PCR negative at 1st vaccination, seronegative at 1st vaccination and at 14 days after 2nd vaccination and no other protocol deviations to impact efficacy of vaccine before unblinding. Subjects who had a positive PCR test between Day 1 and Day 70 and subjects who discontinued prior to 14 days post-dose 2 were excluded.

End point type	Secondary

End point timeframe:

From at least 14 days after second vaccination on Day 57 (Day 71) up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6024	5615		
Units: Subjects	40	56		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With First Occurrence of SARS-CoV-2 Infection (Serologically and/or Molecularly Confirmed) With Onset at Least 14 Days After the Second Vaccination

End point title	Double Blind Phase: Number of Subjects With First Occurrence of SARS-CoV-2 Infection (Serologically and/or Molecularly Confirmed) With Onset at Least 14 Days After the Second Vaccination

End point description:

Number of subjects with first occurrence of SARS-CoV-2 infection (serologically and/or molecularly confirmed) with onset at least 14 days after the second vaccination (Day 71) were reported. PP set: subjects in FAS (all randomised subjects with at least 1 documented study vaccine administration, regardless of the occurrence of protocol deviations and serostatus at enrollment) who received 2 doses of DB vaccine, PCR negative at 1st vaccination, seronegative at 1st vaccination and at 14 days after 2nd vaccination and no other protocol deviations to impact efficacy of vaccine before unblinding. Subjects who had a positive PCR test between Day 1 and Day 70 and subjects who discontinued prior to 14 days post-dose 2 were excluded.

End point type	Secondary

End point timeframe:

From at least 14 days after second vaccination on Day 57 (Day 71) up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	6024	5615		
Units: Subjects	60	113		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With Serious Adverse Events (SAEs)

End point title	Double Blind Phase: Number of Subjects With Serious Adverse Events (SAEs)

End point description:

An AE was any untoward medical occurrence in a clinical study subject administered a pharmaceutical

(investigational or non-investigational) product that does not necessarily have a causal relationship with the vaccine. SAE was any untoward medical occurrence that at any dose may result in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission of any infectious agent via a medicinal product. FAS post dose 1 population included FAS subjects excluding the subjects who received a COVID-19 vaccination outside of the study prior to first study vaccination.

End point type	Secondary

End point timeframe:

From Day 1 up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	15705	15588		
Units: Subjects	104	136		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With Adverse Events of Special Interest (AESIs)

End point title	Double Blind Phase: Number of Subjects With Adverse Events of Special Interest (AESIs)

End point description:

Number of subjects with AESIs were reported. AESIs were significant AEs that were judged to be of special interest because of clinical importance, known or suspected class effects, or based on nonclinical signals. Thrombosis with Thrombocytopenia Syndrome (TTS), a syndrome characterized by a combination of both a thrombotic event and thrombocytopenia, was considered to be an AESI in this study. A suspected TTS case was defined as: Thrombotic events: suspected deep vessel venous or arterial thrombotic events; Thrombocytopenia, defined as platelet count below 150,000/microlitre. FAS post dose 1 population included FAS subjects excluding the subjects who received a COVID-19 vaccination outside of the study prior to first study vaccination.

End point type	Secondary

End point timeframe:

From Day 1 up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	15705	15588		
Units: Subjects	2	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind: Number of Subjects With Medically-Attended Adverse Events (MAAEs)

End point title	Double Blind: Number of Subjects With Medically-Attended Adverse Events (MAAEs)

End point description:

An AE was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product that does not necessarily have a causal relationship with the vaccine. MAAEs were defined as AEs with medically-attended visits including hospital, emergency room, urgent care clinic, or other visits to or from medical personnel for any reason. FAS post dose 1 population included FAS subjects excluding the subjects who received a COVID-19 vaccination outside of the study prior to first study vaccination.

End point type	Secondary

End point timeframe:

From Day 1 up to 7.2 months

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	15705	15588		
Units: Subjects	1033	1003		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind: Number of Subjects With MAAEs Leading to Study Discontinuation

End point title	Double Blind: Number of Subjects With MAAEs Leading to Study Discontinuation

End point description:

An AE was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product that does not necessarily have a causal relationship with the vaccine. MAAEs were defined as AEs with medically-attended visits including hospital, emergency room, urgent care clinic, or other visits to or from medical personnel for any reason. FAS post dose 1 population included FAS subjects excluding the subjects who received a COVID-19 vaccination outside of the study prior to first study vaccination.

End point type	Secondary

End point timeframe:

From Day 1 up to end of double blind phase (7.2 months)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	15705	15588		
Units: Subjects	4	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With Solicited Local Adverse Events (AEs) During 7 Days Following Each Vaccination

End point title	Double Blind Phase: Number of Subjects With Solicited Local Adverse Events (AEs) During 7 Days Following Each Vaccination

End point description:

An AE was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product that does not necessarily have a causal relationship with the vaccine. Subjects who were enrolled in safety subset were asked to note in the e-Diary occurrences of injection site pain/tenderness, erythema, and swelling at the study vaccine injection site daily for 7 days post each vaccination (day of vaccination and the subsequent 7 days). Safety population was a subset of FAS for the analysis of solicited local adverse events. Here 'N' (number of subjects analysed) refers to the number of subjects evaluable for this endpoint and ‘n’ refers to all subjects evaluable at specified time points.

End point type	Secondary

End point timeframe:

7 days after first vaccination on Day 1 (up to Day 8), 7 days after second vaccination on Day 57 (up to Day 64)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3015	3052		
Units: Subjects				
Day 8 (n= 3015, 3052)	1676	653		
Day 64 (n= 1559, 1425)	896	252		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With Solicited Systemic AEs During 7 Days Following Each Vaccination

End point title	Double Blind Phase: Number of Subjects With Solicited Systemic AEs During 7 Days Following Each Vaccination

End point description:

Subjects who were enrolled in safety subset were instructed on how to record daily temperature using a thermometer provided for home use. Subjects recorded the temperature in the e-Diary in the evening of the day of vaccination, and then daily for the next 7 days approximately at the same time each day. If more than 1 measurement was made on any given day, the highest temperature of that day was recorded in the e-Diary. Fever was defined as endogenous elevation of body temperature >= 38.0 degree Celsius or >=100.4-degree Fahrenheit, as recorded in at least 1 measurement. Subjects also noted the signs and symptoms in the e-Diary on a daily basis for 7 days post each vaccination (day of vaccination and the subsequent 7 days), for the following events: fatigue, headache, nausea, myalgia. Safety population: subset of FAS for the analysis of solicited systemic adverse events. N= number of subjects evaluable for this endpoint, n=all subjects evaluable at specified time points.

End point type	Secondary

End point timeframe:

7 days after first vaccination on Day 1 (up to Day 8), 7 days after second vaccination on Day 57 (up to Day 64)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3015	3052		
Units: Subjects				
Day 8 (n= 3015, 3052)	1764	1138		
Day 64 (n= 1559, 1425)	821	442		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: Number of Subjects With Unsolicited Adverse Events (AEs) During 28 Days Post Each Vaccination

End point title	Double Blind Phase: Number of Subjects With Unsolicited Adverse Events (AEs) During 28 Days Post Each Vaccination

End point description:

An AE was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product that does not necessarily have a causal relationship with the vaccine. Unsolicited AEs were all AEs for which the subject is not specifically questioned in the subject diary. Safety population was a subset of FAS for the analysis of unsolicited adverse events. Here 'N' (number of subjects analysed) refers to the number of subjects evaluable for this endpoint and ‘n’ refers to all subjects evaluable at specified time points.

End point type	Secondary

End point timeframe:

28 days after first vaccination on Day 1 (up to Day 29), 28 days after second vaccination on Day 57 (up to Day 85)

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3015	3052		
Units: Subjects				
Day 29 (n= 3015, 3052)	454	332		
Day 85 (n= 1559, 1425)	159	120		

Statistical analyses

No statistical analyses for this end point

Secondary: Double Blind Phase: SARS-CoV-2 Binding Antibodies Assessed by ELISA

End point title	Double Blind Phase: SARS-CoV-2 Binding Antibodies Assessed by ELISA

End point description:

Binding antibodies to SARS-CoV-2 S protein as assessed by ELISA to measure humoral immune response was reported. The lower limit of quantification (LLOQ) was 50.3 ELISA units per millilitre (EU/mL). A sample was considered positive if the value was strictly greater than the LLOQ (>LLOQ). Per Protocol Immunogenicity (PPI) set: all randomised and vaccinated subjects (received both vaccines in DB phase, including those who were part of immunogenicity subset and for whom immunogenicity data were available, excluding subjects with major protocol deviations expected to impact immunogenicity outcomes. Here, N (number of subjects analysed) = subjects evaluated for this endpoint and 'n' = number of subjects evaluable at specified time points. 99999 signifies that geometric mean and 95% confidence interval could not be estimated as the analysed values were below the LLOQ (50.3 EU/mL).

End point type	Secondary

End point timeframe:

At Baseline (Day 1), Days 29, 57 and 71

End point values	Double Blind Phase: Ad26.COV2.S	Double Blind Phase: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	157	149		
Units: ELISA Unit/millilitre (EU/mL)				
geometric mean (confidence interval 95%)				
Day 1 (n= 157, 149)	99999 (99999 to 99999)	99999 (99999 to 99999)		
Day 29 (n= 140, 124)	367 (295 to 456)	99999 (99999 to 99999)		
Day 57 (n= 150, 111)	518 (422 to 635)	99999 (99999 to 99999)		
Day 71 (n= 78, 62)	2220 (1794 to 2748)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality/SAEs: DB phase: Day 1 till end of DB phase (up to 7.2 months), All subjects arm: Day 1 up to end of study (up to 2 years 6 months); Solicited AEs: 7 days after each DB vaccination (vacc.); Other AEs: Up to 28 days after each vacc.

Adverse event reporting additional description:

Safety subset (FAS subset) used for solicited/unsolicited AEs. 9999=no subject at risk and affected for non-SAEs in 'All Subjects' arm. DB arms: AEs: coded with MedDRA v24.0. Deaths during DB phase included subjects discontinued study due to death at primary analysis, including subjects that died after unblinding, i.e. after end of DB phase.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Double Blind (DB) Phase: Ad26.COV2.S

Reporting group description:

Subjects received a single dose of 0.5 mL Ad26.COV2.S 5*10^10 vp vaccine intramuscularly on Day 1 and Day 57.

Reporting group title	Combined Double-blind and Open-label Phase: All Subjects

Reporting group description:

Each subject was initially randomised to receive 1 dose of 0.5 millilitre (mL) Ad26.COV2.S 5*10^10 viral particles (vp) vaccine intramuscularly on Day 1 and on Day 57 or 1 dose of placebo vaccine intramuscularly on Day 1 and on Day 57 during the DB phase (up to 7.2 months). Following authorization of COVID-19 vaccine(s) in their country, subjects could request to be unblinded to receive a different authorized/licensed COVID-19 vaccine outside of the study at any time during the study. Following Emergency Use Authorization of Ad26.COV2.S in the United States, all subjects were unblinded and entered OL
phase, and those subjects that received placebo could receive a single dose of Ad26.COV2.S 5*10^10 vp vaccine. Later it was allowed to have a booster vaccination with a single dose of Ad26.COV2.S 5*10^10 vp vaccine for those subjects that received a single dose of Ad26.COV2.S vaccine in the study.

Reporting group title	Double Blind Phase: Placebo

Reporting group description:

Subjects received a single dose of placebo matching to Ad26.COV2.S 5*10^10 vp vaccine intramuscularly on Day 1 and Day 57.

Serious adverse events	Double Blind (DB) Phase: Ad26.COV2.S	Combined Double-blind and Open-label Phase: All Subjects	Double Blind Phase: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	104 / 15705 (0.66%)	1583 / 31705 (4.99%)	136 / 15588 (0.87%)
number of deaths (all causes)	6	131	13
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma Gastric			

subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Adenocarcinoma Pancreas			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Leukaemia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Myeloid Leukaemia			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Neoplasm of Testis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Cancer			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Transitional Cell Carcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Borderline Serous Tumour of Ovary			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			

subjects affected / exposed	0 / 15705 (0.00%)	22 / 31705 (0.07%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 23	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer Metastatic			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer Recurrent			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer Stage I			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer Stage Ii			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of Colon			
subjects affected / exposed	0 / 15705 (0.00%)	8 / 31705 (0.03%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal Neoplasm			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Neoplasm			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Astrocytoma			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal Cell Carcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer Stage Iv			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Gastrointestinal Carcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholesteatoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Lymphocytic Leukaemia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear Cell Renal Cell Carcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer			

subjects affected / exposed	0 / 15705 (0.00%)	8 / 31705 (0.03%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Colorectal Cancer			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Cancer			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Neoplasm			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fallopian Tube Cancer			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Follicular Lymphoma Stage Iii			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Follicular Thyroid Cancer			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial Carcinoma			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung Neoplasm Malignant			
subjects affected / exposed	0 / 15705 (0.00%)	6 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung Squamous Cell Carcinoma Stage Iii			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Cancer Metastatic			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung Adenocarcinoma Stage 0			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Adenocarcinoma			
subjects affected / exposed	1 / 15705 (0.01%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Lipoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratoacanthoma			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Lobular Breast Carcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive Ductal Breast Carcinoma			
subjects affected / exposed	1 / 15705 (0.01%)	7 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal Proliferative Breast Lesion			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular Carcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Carcinoma Cell Type Unspecified Stage Iv			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Neuroendocrine Carcinoma of the Skin			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm Prostate			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm Progression			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nasopharyngeal Cancer			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic Renal Cell Carcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic Malignant Melanoma			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metastases to Spine			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to Central Nervous System			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to Bone			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Meningioma			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Pleural Effusion			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma Stage I			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's Lymphoma			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Small Cell Lung Cancer Stage Iv			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Adenocarcinoma			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer Metastatic			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Prostate Cancer			
subjects affected / exposed	2 / 15705 (0.01%)	29 / 31705 (0.09%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 33	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma Cell Myeloma			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary Tumour Benign			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phyllodes Tumour			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paget's Disease of Nipple			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cancer			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteosarcoma			

subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Osteochondroma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Squamous Cell Carcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Neoplasm			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Carcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Adenocarcinoma Stage Iii			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of Lung			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Meningioma Benign			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Neoplasm			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Cell Lung Cancer			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schwannoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of Pharynx			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Neoplasm			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Cell Carcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenocarcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic Adenoma			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer Stage I			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer Recurrent			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Throat Cancer			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional Cell Carcinoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour of Ampulla of Vater			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma			
subjects affected / exposed	0 / 15705 (0.00%)	8 / 31705 (0.03%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of Skin			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of the Hypopharynx			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of the Tongue			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of the Vulva			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testis Cancer			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic Stenosis			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Aortic Aneurysm Rupture			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Aneurysm			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aneurysm Thrombosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aneurysm			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Dilatation			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Thrombosis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microscopic Polyangiitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Hypertension			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent Claudication			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iliac Artery Stenosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic Shock			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Hypotension			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Urgency			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Crisis			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential Hypertension			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			
subjects affected / exposed	0 / 15705 (0.00%)	9 / 31705 (0.03%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory Collapse			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			

subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penetrating Aortic Ulcer			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Arterial Occlusive Disease			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Stenosis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Aneurysm			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Occlusion			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous Thrombosis Limb			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous Thrombosis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose Vein			

subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systolic Hypertension			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superficial Vein Thrombosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Venous Disease			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Embolism			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Thrombosis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic Pregnancy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal Death			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational Diabetes			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational Hypertension			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hellp Syndrome			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placenta Praevia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-Eclampsia			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature Baby			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature Separation of Placenta			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion Spontaneous			
subjects affected / exposed	0 / 15705 (0.00%)	9 / 31705 (0.03%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Malaise			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental Death			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Capsular Contracture Associated with Implant			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Discomfort			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Pain			
subjects affected / exposed	0 / 15705 (0.00%)	8 / 31705 (0.03%)	2 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	1 / 15705 (0.01%)	19 / 31705 (0.06%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 19	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 19	0 / 0
Death Neonatal			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gait Disturbance			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia Pain			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection Site Swelling			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Organ Dysfunction Syndrome			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Non-Cardiac Chest Pain			

subjects affected / exposed	0 / 15705 (0.00%)	6 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	2 / 15705 (0.01%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden Death			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
Vascular Stent Stenosis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaccination Site Pain			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 15705 (0.01%)	0 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unevaluable event			
subjects affected / exposed	0 / 15705 (0.00%)	0 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Immune system disorders			
Allergy to Vaccine			

subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic Reaction			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food Allergy			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Miscarriage of Partner			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Homicide			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Bereavement			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Erectile Dysfunction			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal Uterine Bleeding			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Adnexal Torsion			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Prostatic Hyperplasia			
subjects affected / exposed	1 / 15705 (0.01%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Discomfort			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Enlargement			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Mass			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Dysplasia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colpocele			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystocele			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometriosis			

subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic Ovarian Cyst			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cyst			
subjects affected / exposed	0 / 15705 (0.00%)	7 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Disorder			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Hyperstimulation Syndrome			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Fluid Collection			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Prolapse			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Prolapse			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvar Dysplasia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heavy Menstrual Bleeding			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Respiratory Failure			
subjects affected / exposed	1 / 15705 (0.01%)	12 / 31705 (0.04%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 6	0 / 0
Asthma			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis Chronic			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal Septum Deviation			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	1 / 15705 (0.01%)	10 / 31705 (0.03%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Chylothorax			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea Exertional			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			

subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity Pneumonitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial Lung Disease			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Disorder			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal Mass			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal Dyspnoea			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive Sleep Apnoea Syndrome			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Distress			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	2 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
Pulmonary Mass			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Hypertension			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	1 / 15705 (0.01%)	35 / 31705 (0.11%)	4 / 15588 (0.03%)
occurrences causally related to treatment / all	1 / 1	1 / 36	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Congestion			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax Spontaneous			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural Effusion			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal Swelling			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal Haematoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising Pneumonia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Psychiatric disorders			
Drug Abuse			
subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Affective Disorder			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol Withdrawal Syndrome			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholism			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	1 / 15705 (0.01%)	4 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar Disorder			
subjects affected / exposed	2 / 15705 (0.01%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar I Disorder			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed Suicide			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Confusional State			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conversion Disorder			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	2 / 15705 (0.01%)	10 / 31705 (0.03%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Depression Suicidal			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Psychosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gender Dysphoria			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nicotine Dependence			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-Traumatic Stress Disorder			
subjects affected / exposed	1 / 15705 (0.01%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric Decompensation			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic Disorder			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizoaffective Disorder			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizoaffective Disorder Bipolar Type			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizophrenia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance-Induced Psychotic Disorder			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal Ideation			
subjects affected / exposed	1 / 15705 (0.01%)	7 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional Self-Injury			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device Failure			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Dislocation			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prosthetic Cardiac Valve Malfunction			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Gallbladder Disorder			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cirrhosis Alcoholic			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile Duct Stone			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary Cyst			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			

subjects affected / exposed	2 / 15705 (0.01%)	10 / 31705 (0.03%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 10	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Acute			
subjects affected / exposed	0 / 15705 (0.00%)	8 / 31705 (0.03%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	3 / 15705 (0.02%)	19 / 31705 (0.06%)	3 / 15588 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 19	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder Polyp			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Cirrhosis			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Hepatic Cyst			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocholecystis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal Vein Thrombosis			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder Rupture			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Biopsy Liver			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Murmur			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram St Segment Depression			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart Rate Irregular			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Necrosis Marker Increased			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep Study			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin Increased			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Acetabulum Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol Poisoning			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaesthetic Complication			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic Transfusion Reaction			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal Bite			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	1 / 15705 (0.01%)	8 / 31705 (0.03%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Avulsion Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone Graft Lysis			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Anastomotic Leak			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	1 / 15705 (0.01%)	7 / 31705 (0.02%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured Sacrum			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Frostbite			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	1 / 15705 (0.01%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Bones Fracture			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epicondylitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral Injury			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	6 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Injury			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns Third Degree			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain Contusion			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb Injury			

subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heat Exhaustion			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Injury			
subjects affected / exposed	0 / 15705 (0.00%)	6 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hand Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun Shot Wound			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ilium Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Intentional Overdose			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Injury			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Injury			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Rupture			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Sprain			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Complication			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poisoning			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Overdose			
subjects affected / exposed	1 / 15705 (0.01%)	4 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Patella Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoradionecrosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck Injury			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Rupture			
subjects affected / exposed	1 / 15705 (0.01%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	2 / 15705 (0.01%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Multiple Fractures			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Limb Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	2 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lisfranc Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	7 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial Rupture			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	0 / 15705 (0.00%)	7 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Complication			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-Traumatic Pain			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	1 / 15705 (0.01%)	12 / 31705 (0.04%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Seroma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull Fractured Base			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Snake Bite			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Fracture			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haematoma			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pneumothorax			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Limb Fracture			
subjects affected / exposed	1 / 15705 (0.01%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention Postoperative			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			

subjects affected / exposed	1 / 15705 (0.01%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Rupture			
subjects affected / exposed	0 / 15705 (0.00%)	9 / 31705 (0.03%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 11	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic Arthrosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic Intracranial Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Congenital Tracheomalacia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertrophic Cardiomyopathy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngocele			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brugada Syndrome			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina Pectoris			
subjects affected / exposed	2 / 15705 (0.01%)	14 / 31705 (0.04%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 14	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Coronary Syndrome			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Myocardial Infarction			
subjects affected / exposed	2 / 15705 (0.01%)	36 / 31705 (0.11%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 36	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 8	0 / 0
Angina Unstable			
subjects affected / exposed	1 / 15705 (0.01%)	7 / 31705 (0.02%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Valve Incompetence			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Valve Stenosis			

subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Arteriosclerosis Coronary Artery			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriospasm Coronary			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	1 / 15705 (0.01%)	27 / 31705 (0.09%)	2 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 28	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Atrial Flutter			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Tachycardia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block Complete			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block First Degree			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block Second Degree			
subjects affected / exposed	1 / 15705 (0.01%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Valve Disease			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bundle Branch Block Left			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 1
Cardiac Disorder			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	0 / 15705 (0.00%)	8 / 31705 (0.03%)	2 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac Failure Acute			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Congestive			
subjects affected / exposed	1 / 15705 (0.01%)	12 / 31705 (0.04%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Extrasystoles			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular Disorder			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Congestive Cardiomyopathy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cor Pulmonale			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	1 / 15705 (0.01%)	18 / 31705 (0.06%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 23	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Coronary Artery Occlusion			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Stenosis			

subjects affected / exposed	0 / 15705 (0.00%)	11 / 31705 (0.03%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 13	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-Respiratory Arrest			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Heart Valve Incompetence			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachycardia			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microvascular Coronary Artery Disease			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral Valve Disease			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral Valve Incompetence			
subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Fibrosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			

subjects affected / exposed	1 / 15705 (0.01%)	24 / 31705 (0.08%)	4 / 15588 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 24	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 10	0 / 0
Myocardial Ischaemia			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Palpitations			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial Effusion			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus Bradycardia			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus Node Dysfunction			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Cardiomyopathy			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Tachycardia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Fibrillation			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid Valve Incompetence			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Arrhythmia			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bell's Palsy			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain Injury			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Brain Oedema			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Arteriosclerosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Artery Stenosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cerebellar Infarction			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar Stroke			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Amyloid Angiopathy			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Haemorrhage			
subjects affected / exposed	1 / 15705 (0.01%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Cerebral Infarction			
subjects affected / exposed	0 / 15705 (0.00%)	8 / 31705 (0.03%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Thrombosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	3 / 15705 (0.02%)	12 / 31705 (0.04%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cervical Radiculopathy			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive Disorder			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketoacidotic Hyperglycaemic Coma			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			

subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cauda Equina Syndrome			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Paresis			
subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	2 / 15705 (0.01%)	12 / 31705 (0.04%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 2	2 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemorrhage Intracranial			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Haemorrhagic Stroke			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hashimoto's Encephalopathy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			

subjects affected / exposed	3 / 15705 (0.02%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Encephalopathy			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglossal Nerve Paresis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypoxic-Ischaemic Encephalopathy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Intracranial Aneurysm			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Intracranial Mass			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Cerebral Infarction			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre Syndrome			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar Stroke			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peroneal Nerve Palsy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Radiculopathy			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory Impairment			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic Encephalopathy			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Migraine			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis Transverse			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuromyopathy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normal Pressure Hydrocephalus			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nystagmus			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paresis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial Seizures			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of Consciousness			

subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sunct Syndrome			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tension Headache			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamic Infarction			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Global Amnesia			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	1 / 15705 (0.01%)	14 / 31705 (0.04%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 14	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-Traumatic Epilepsy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			

subjects affected / exposed	1 / 15705 (0.01%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Primary Headache Associated with Sexual Activity			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudostroke			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	1 / 15705 (0.01%)	8 / 31705 (0.03%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Claudication			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 15705 (0.00%)	11 / 31705 (0.03%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 15705 (0.00%)	10 / 31705 (0.03%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 11	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Anaemia Megaloblastic			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune Thrombocytopenia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelosuppression			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrogenic Anaemia			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic Vein Thrombosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 15705 (0.00%)	18 / 31705 (0.06%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 19	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia of Chronic Disease			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness Neurosensory			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	1 / 15705 (0.01%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness Transient			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			

subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiretinal Membrane			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Detachment			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal Ischaemia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scleritis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uveitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous Detachment			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Adhesions			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Abdominal Distension			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Hernia			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Hernia Obstructive			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain			
subjects affected / exposed	1 / 15705 (0.01%)	6 / 31705 (0.02%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Lower			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Wall Haematoma			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Fistula			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis Noninfective			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis Ischaemic			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis Ulcerative			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's Disease			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral Hernia			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 15705 (0.01%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular Perforation			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal Ulcer			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal Ulcer Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal Ulcer Perforation			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocele			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous Fistula			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiploic Appendagitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive Oesophagitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic Hernia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids Thrombosed			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus Hernia			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	2 / 15705 (0.01%)	16 / 31705 (0.05%)	2 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 19	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer			
subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer Perforation			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	8 / 31705 (0.03%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastrointestinal Ulcer Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 15705 (0.00%)	6 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Ulcer			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Prolapse			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Strangulation			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Ulcer			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-Abdominal Haematoma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestinal Obstruction			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Polyp			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Hernia			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric Panniculitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive Defaecation			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Obstruction			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Perforation			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Varices Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Oral Disorder			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			

subjects affected / exposed	0 / 15705 (0.00%)	7 / 31705 (0.02%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 7	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Necrotising			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic Ulcer			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic Ulcer Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal Hernia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngo-Oesophageal Diverticulum			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Haemorrhage			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal Mass			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary Gland Mass			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices Oesophageal			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus of Small Bowel			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	1 / 15705 (0.01%)	7 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Skin and subcutaneous tissue disorders			
Subcutaneous Emphysema			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson Syndrome			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Ulcer			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Foot			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alopecia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus Urinary			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Kidney Injury			
subjects affected / exposed	0 / 15705 (0.00%)	10 / 31705 (0.03%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 10	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Calculus Bladder			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Obstruction			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Haemorrhage			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Kidney Disease			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End Stage Renal Disease			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 15705 (0.01%)	15 / 31705 (0.05%)	3 / 15588 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 16	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Cyst			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Impairment			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Mass			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress Urinary Incontinence			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urate Nephropathy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	1 / 15705 (0.01%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Stenosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Bladder Polyp			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Obstruction			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune Thyroiditis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basedow's Disease			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parathyroid Disorder			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid Cyst			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroiditis Acute			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral Disc Degeneration			
subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infrapatellar Fat Pad Inflammation			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Deformity			
subjects affected / exposed	0 / 15705 (0.00%)	9 / 31705 (0.03%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 11	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diastasis Recti Abdominis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondropathy			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Protrusion			
subjects affected / exposed	2 / 15705 (0.01%)	16 / 31705 (0.05%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 18	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
subjects affected / exposed	1 / 15705 (0.01%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondrolysis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw Disorder			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in Extremity			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporosis			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	2 / 15705 (0.01%)	70 / 31705 (0.22%)	2 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 76	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck Pain			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular Weakness			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Contracture			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscopathy			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb Discomfort			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee Deformity			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral Lateral Recess Stenosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Disorder			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			

subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Stenosis			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Pain			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Osteoarthritis			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scoliosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 15705 (0.00%)	8 / 31705 (0.03%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 11	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periarthritis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendiceal Abscess			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Wall Abscess			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess Jaw			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess Limb			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Abscess			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	3 / 15705 (0.02%)	34 / 31705 (0.11%)	4 / 15588 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 35	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis Perforated			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arboviral Infection			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergilloma			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial Sepsis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Infective			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary Aspergillosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burn Infection			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis Infective			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter Gastroenteritis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter Site Infection			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	2 / 15705 (0.01%)	15 / 31705 (0.05%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 16	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bartholinitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Hepatitis B			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Colitis			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic Abscess			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated Appendicitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			

subjects affected / exposed	5 / 15705 (0.03%)	78 / 31705 (0.25%)	24 / 15588 (0.15%)
occurrences causally related to treatment / all	0 / 5	0 / 79	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 5	0 / 3
Diverticulitis			
subjects affected / exposed	0 / 15705 (0.00%)	7 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus Infection			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue Fever			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Foot Infection			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated Tuberculosis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Covid-19 Pneumonia			

subjects affected / exposed	3 / 15705 (0.02%)	45 / 31705 (0.14%)	13 / 15588 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 46	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 9	0 / 3
Diverticulitis Intestinal Perforated			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Bite			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Pyelonephritis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Urinary Tract Infection			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye Infection Intraocular			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer Helicobacter			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis Helminthic			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Escherichia Coli			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Norovirus			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Zoster			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiv Infection			
subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective Exacerbation of Bronchiectasis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Discitis			
subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney Infection			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised Infection			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Abscess			
subjects affected / exposed	1 / 15705 (0.01%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangitis			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis Viral			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningoencephalitis Herpetic			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Murine Typhus			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurosyphilis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic Herpes Zoster			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious Mononucleosis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas Infection			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasmodium Falciparum Infection			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal Sepsis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	3 / 15705 (0.02%)	45 / 31705 (0.14%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 46	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 6	0 / 0
Pneumonia Aspiration			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Bacterial			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Pneumococcal			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Pseudomonal			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Staphylococcal			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Viral			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Infection			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-Acute Covid-19 Syndrome			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Inflammatory Disease			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shunt Infection			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic Shock			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sinusitis			

subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spontaneous Bacterial Peritonitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal Bacteraemia			
subjects affected / exposed	1 / 15705 (0.01%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Submandibular Abscess			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected Covid-19			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic Candida			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubo-Ovarian Abscess			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Tuberculosis			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 15705 (0.01%)	6 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 15705 (0.01%)	22 / 31705 (0.07%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 29	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 5	0 / 0
Sialoadenitis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	1 / 15705 (0.01%)	14 / 31705 (0.04%)	2 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 17	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection Bacterial			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	1 / 15705 (0.01%)	10 / 31705 (0.03%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Vestibular Neuronitis			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Sepsis			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative abscess			
subjects affected / exposed	1 / 15705 (0.01%)	0 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Adult Failure to Thrive			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	2 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 15705 (0.00%)	6 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercholesterolaemia			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketoacidosis			
subjects affected / exposed	0 / 15705 (0.00%)	4 / 31705 (0.01%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	1 / 15588 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			

subjects affected / exposed	0 / 15705 (0.00%)	3 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dehydration			
subjects affected / exposed	1 / 15705 (0.01%)	8 / 31705 (0.03%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased Appetite			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 15705 (0.00%)	2 / 31705 (0.01%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 Diabetes Mellitus			
subjects affected / exposed	0 / 15705 (0.00%)	1 / 31705 (0.00%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 15705 (0.00%)	5 / 31705 (0.02%)	0 / 15588 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Double Blind (DB) Phase: Ad26.COV2.S	Combined Double-blind and Open-label Phase: All Subjects	Double Blind Phase: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2234 / 15705 (14.22%)	9999 / 31705 (31.54%)	1531 / 15588 (9.82%)
Nervous system disorders			
Headache(Solicited)			
alternative assessment type: Systematic			

subjects affected / exposed[1]	1432 / 3015 (47.50%)	9999 / 9999 (100.00%)	873 / 3052 (28.60%)
occurrences (all)	2059	9999	1167
Headache			
subjects affected / exposed[2]	138 / 3015 (4.58%)	9999 / 9999 (100.00%)	120 / 3052 (3.93%)
occurrences (all)	156	9999	130
General disorders and administration site conditions			
Pyrexia(Solicited)			
alternative assessment type: Systematic			
subjects affected / exposed[3]	177 / 3015 (5.87%)	9999 / 9999 (100.00%)	18 / 3052 (0.59%)
occurrences (all)	187	9999	18
Fatigue(Solicited)			
alternative assessment type: Systematic			
subjects affected / exposed[4]	1531 / 3015 (50.78%)	9999 / 9999 (100.00%)	897 / 3052 (29.39%)
occurrences (all)	2212	9999	1189
Vaccination site erythema (Solicited)			
alternative assessment type: Systematic			
subjects affected / exposed[5]	311 / 3015 (10.32%)	9999 / 9999 (100.00%)	170 / 3052 (5.57%)
occurrences (all)	399	9999	205
Vaccination site pain (Solicited)			
alternative assessment type: Systematic			
subjects affected / exposed[6]	1818 / 3015 (60.30%)	9999 / 9999 (100.00%)	664 / 3052 (21.76%)
occurrences (all)	2680	9999	832
Vaccination site pain			
subjects affected / exposed[7]	72 / 3015 (2.39%)	9999 / 9999 (100.00%)	23 / 3052 (0.75%)
occurrences (all)	77	9999	23
Fatigue			
subjects affected / exposed[8]	128 / 3015 (4.25%)	9999 / 9999 (100.00%)	119 / 3052 (3.90%)
occurrences (all)	146	9999	130
Vaccination site swelling (Solicited)			
alternative assessment type: Systematic			
subjects affected / exposed[9]	215 / 3015 (7.13%)	9999 / 9999 (100.00%)	65 / 3052 (2.13%)
occurrences (all)	260	9999	74
Gastrointestinal disorders			

Nausea(Solicited)			
alternative assessment type: Systematic			
subjects affected / exposed[10]	666 / 3015 (22.09%)	9999 / 9999 (100.00%)	387 / 3052 (12.68%)
occurrences (all)	816	9999	457
Musculoskeletal and connective tissue disorders			
Myalgia(Solicited)			
alternative assessment type: Systematic			
subjects affected / exposed[11]	1346 / 3015 (44.64%)	9999 / 9999 (100.00%)	572 / 3052 (18.74%)
occurrences (all)	1846	9999	718
Myalgia			
subjects affected / exposed[12]	99 / 3015 (3.28%)	9999 / 9999 (100.00%)	86 / 3052 (2.82%)
occurrences (all)	119	9999	95

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Only reported subjects were planned to be analysed for non-serious AEs in double blind arms. 9999 signifies that no subject at risk for non-serious AEs in 'All Subjects' arm.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Only reported subjects were planned to be analysed for non-serious AEs in double blind arms. 9999 signifies that no subject at risk for non-serious AEs in 'All Subjects' arm.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Only reported subjects were planned to be analysed for non-serious AEs in double blind arms. 9999 signifies that no subject at risk for non-serious AEs in 'All Subjects' arm.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Only reported subjects were planned to be analysed for non-serious AEs in double blind arms. 9999 signifies that no subject at risk for non-serious AEs in 'All Subjects' arm.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Only reported subjects were planned to be analysed for non-serious AEs in double blind arms. 9999 signifies that no subject at risk for non-serious AEs in 'All Subjects' arm.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Only reported subjects were planned to be analysed for non-serious AEs in double blind arms. 9999 signifies that no subject at risk for non-serious AEs in 'All Subjects' arm.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Only reported subjects were planned to be analysed for non-serious AEs in double blind arms. 9999 signifies that no subject at risk for non-serious AEs in 'All Subjects' arm.

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Only reported subjects were planned to be analysed for non-serious AEs in double blind arms. 9999 signifies that no subject at risk for non-serious AEs in 'All Subjects' arm.

[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Only reported subjects were planned to be analysed for non-serious AEs in double blind arms. 9999 signifies that no subject at risk for non-serious AEs in 'All Subjects' arm.

[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Only reported subjects were planned to be analysed for non-serious AEs in double blind

arms. 9999 signifies that no subject at risk for non-serious AEs in 'All Subjects' arm.

[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Only reported subjects were planned to be analysed for non-serious AEs in double blind arms. 9999 signifies that no subject at risk for non-serious AEs in 'All Subjects' arm.

[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Only reported subjects were planned to be analysed for non-serious AEs in double blind arms. 9999 signifies that no subject at risk for non-serious AEs in 'All Subjects' arm.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 September 2020	The overall reason for this amendment was to adjust the dose level of Ad26.COV2.S from 1*10^11 virus particle (vp) to 5*10^10 vp based on data from the first-in-human (FIH) study VAC31518COV1001.
27 November 2020	The overall reason for this amendment was to clarify that all subjects that had a reverse-transcriptase polymerase chain reaction (RT-PCR) positive finding for SARS-CoV-2 from any source, even if asymptomatic, were followed until there were two consecutive negative PCRs.
18 December 2020	The overall reason for this amendment was to outline the procedures to be followed in the event that an investigator receives a request to unblind study subjects who may become eligible to receive an authorised/licensed COVID-19 vaccine if/when these become available.
12 March 2021	The overall reason for this amendment was to outline the procedures to be followed after Ad26.COV2.S Emergency Use Authorization (EUA) in the United States (US) and approval of Protocol Amendment 4 by the local Health Authority and the Independent Ethics Committee/Institutional Review Board (IEC/IRB). A single dose of Ad26.COV2.S vaccine will be offered to enrolled subjects who initially received placebo, resulting in de facto unblinding of all subjects and investigators.
06 May 2021	The overall reason for this amendment was to include additional safety measures due to reports of adverse events following use of the Ad26.COV2.S vaccine under emergency use authorization in the US, suggesting an increased risk of thrombosis combined with thrombocytopenia.
15 October 2021	The overall reason for this amendment was to offer a 1-dose booster vaccination with Ad26.COV2.S at the 5*10^10 vp dose level to all ongoing subjects who received only a single vaccination with Ad26.COV2.S in the study.
27 April 2022	The overall reason for this amendment was vaccine Ad26.COV2.S had received EUA by the US Food and Drug Administration (FDA) and conditional marketing authorisation by the European Commission. Vaccine Ad26.COV2.S had also been authorized in several other countries/territories worldwide. The epidemic continued and new variants of concern emerged, and national recommendations introduced booster vaccinations.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Safety results for OL were included in the All Subjects arm and were not analysed separately. Hence, OL safety results are not repeated in endpoint section. FAS post dose-1 set was used to analyse safety in DB phase.

Notes: