



Clinical trial results: SELECT - Semaglutide effects on cardiovascular outcomes in people with overweight or obesity

Summary

EudraCT number	2017-003380-35
Trial protocol	BG DK FI IE PT GB LV NL CZ HU BE AT SE HR NO IT RO
Global end of trial date	29 June 2023

Results information

Result version number	v2 (current)
This version publication date	12 December 2024
First version publication date	11 July 2024
Version creation reason	<ul style="list-style-type: none">• Correction of full data set The update corresponding to the time frame in the study.

Trial information

Trial identification

Sponsor protocol code	EX9536-4388
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03574597
WHO universal trial number (UTN)	U1111-1200-5564

Notes:

Sponsors

Sponsor organisation name	Novo Nordisk A/S
Sponsor organisation address	Novo Alle, Bagsvaerd, Denmark, 2880
Public contact	Clinical Reporting Office (2834), Novo Nordisk A/S, clinicaltrials@novonordisk.com
Scientific contact	Clinical Reporting Office (2834), Novo Nordisk A/S, clinicaltrials@novonordisk.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 July 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	29 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that semaglutide subcutaneously 2.4 milligram (mg) once-weekly lowers the incidence of major adverse cardiovascular events (MACE) versus semaglutide placebo, both added to standard of care in subjects with established cardiovascular (CV) disease and overweight or obesity.

Protection of trial subjects:

This trial was conducted in accordance with the principles of the Declaration of Helsinki, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice, including the archiving of essential documents, and US Food and Drug Administration (FDA) 21 US Code of Federal Regulations (CFR) 312.50 and 312.56.

Background therapy:

Not applicable

Evidence for comparator: -

Actual start date of recruitment	24 October 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Algeria: 47
Country: Number of subjects enrolled	Argentina: 359
Country: Number of subjects enrolled	Colombia: 187
Country: Number of subjects enrolled	Malaysia: 187
Country: Number of subjects enrolled	United Kingdom: 933
Country: Number of subjects enrolled	United States: 3652
Country: Number of subjects enrolled	Austria: 120
Country: Number of subjects enrolled	Belgium: 128
Country: Number of subjects enrolled	Bulgaria: 356
Country: Number of subjects enrolled	Croatia: 141
Country: Number of subjects enrolled	Czechia: 344
Country: Number of subjects enrolled	Denmark: 198
Country: Number of subjects enrolled	Finland: 168
Country: Number of subjects enrolled	France: 169
Country: Number of subjects enrolled	Germany: 885
Country: Number of subjects enrolled	Greece: 354
Country: Number of subjects enrolled	Hungary: 135
Country: Number of subjects enrolled	Ireland: 71

Country: Number of subjects enrolled	Italy: 293
Country: Number of subjects enrolled	Latvia: 177
Country: Number of subjects enrolled	Netherlands: 342
Country: Number of subjects enrolled	Norway: 227
Country: Number of subjects enrolled	Poland: 640
Country: Number of subjects enrolled	Portugal: 137
Country: Number of subjects enrolled	Romania: 321
Country: Number of subjects enrolled	Spain: 186
Country: Number of subjects enrolled	Sweden: 183
Country: Number of subjects enrolled	Türkiye: 217
Country: Number of subjects enrolled	Ukraine: 482
Country: Number of subjects enrolled	Taiwan: 155
Country: Number of subjects enrolled	Australia: 327
Country: Number of subjects enrolled	Brazil: 606
Country: Number of subjects enrolled	Canada: 749
Country: Number of subjects enrolled	India: 492
Country: Number of subjects enrolled	Israel: 310
Country: Number of subjects enrolled	Japan: 357
Country: Number of subjects enrolled	Mexico: 341
Country: Number of subjects enrolled	Russian Federation: 1491
Country: Number of subjects enrolled	Serbia: 184
Country: Number of subjects enrolled	South Africa: 797
Country: Number of subjects enrolled	Thailand: 156
Worldwide total number of subjects	17604
EEA total number of subjects	5575

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)	10876
From 65 to 84 years	6680
85 years and over	48

Subject disposition

Recruitment

Recruitment details:

The subjects were screened at 811 sites in 41 countries. Out of 811 sites, subjects were randomised at 804 sites.

Pre-assignment

Screening details:

Subjects were randomized in a 1:1 ratio to receive treatment with either semaglutide or placebo as an adjunct to standard-of-care.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

The trial products containing the active drug (semaglutide) and the placebo drug were visually identical and packed in a manner that maintained blinding.

Arms

Are arms mutually exclusive?	Yes
Arm title	Semaglutide

Arm description:

Subjects received semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 16 (0.25 mg, 0.5 mg, 1.0 mg and 1.7 mg) followed by maintenance dose of 2.4 mg once weekly up to the end of treatment period.

Arm type	Experimental
Investigational medicinal product name	Semaglutide B 3.0 milligram per milliliter (mg/mL)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received semaglutide injection once weekly at the same day of the week. Injections were to be administered by subcutaneous injection in the thigh, abdomen or upper arm at any time of day irrespective of meals.

Arm title	Placebo
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Arm description:

Subjects received placebo (matched to semaglutide) subcutaneously once weekly up to the end of treatment period.

Arm type	Placebo
Investigational medicinal product name	Semaglutide placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received semaglutide injection once weekly at the same day of the week. Injections were to be administered by subcutaneous injection in the thigh, abdomen or upper arm at any time of day irrespective of meals.

Number of subjects in period 1	Semaglutide	Placebo
Started	8803	8801
Full analysis set (FAS)	8803	8801
Completed	8544	8517
Not completed	259	284
Consent withdrawn by subject	67	96
Lost to follow-up	192	188

Baseline characteristics

Reporting groups

Reporting group title	Semaglutide
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Reporting group description:

Subjects received semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 16 (0.25 mg, 0.5 mg, 1.0 mg and 1.7 mg) followed by maintenance dose of 2.4 mg once weekly up to the end of treatment period.

Reporting group title	Placebo
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Reporting group description:

Subjects received placebo (matched to semaglutide) subcutaneously once weekly up to the end of treatment period.

Reporting group values	Semaglutide	Placebo	Total
Number of subjects	8803	8801	17604
Age Categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	61.6 ± 8.9	61.6 ± 8.8	-
Gender Categorical Units: Subjects Female Male	2448 6355	2424 6377	4872 12732

End points

End points reporting groups

Reporting group title	Semaglutide
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Reporting group description:

Subjects received semaglutide subcutaneously once weekly in a fixed-dose escalation manner, with dose increases every 4 weeks for up to week 16 (0.25 mg, 0.5 mg, 1.0 mg and 1.7 mg) followed by maintenance dose of 2.4 mg once weekly up to the end of treatment period.

Reporting group title	Placebo
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Reporting group description:

Subjects received placebo (matched to semaglutide) subcutaneously once weekly up to the end of treatment period.

Primary: Time from randomisation to first occurrence of a composite endpoint consisting of: cardiovascular (CV) death, non-fatal myocardial infarction (MI), or non-fatal stroke

End point title	Time from randomisation to first occurrence of a composite endpoint consisting of: cardiovascular (CV) death, non-fatal myocardial infarction (MI), or non-fatal stroke
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End point description:

Number of subjects with first occurrence of endpoint consisted of CV death (undetermined cause of death presumed CV death), non-fatal MI, or non-fatal stroke are presented. The endpoint was evaluated based on data from in-trial observation period. In-trial observation period defined as the period from date of randomisation to one of the following dates, whichever comes first: date of follow-up visit, date when subject withdrew consent, date of last contact with subject for subjects who were lost to follow-up (subject did not complete the trial and did not withdraw consent), date of death. FAS included all randomised subjects. All subjects were analysed according to the treatment to which they were assigned at randomisation.

End point type	Primary
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End point timeframe:

From randomisation to first occurrence of a composite endpoint

End point values	Semaglutide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8803	8801		
Units: Subjects	569	701		

Statistical analyses

Statistical analysis title	Semaglutide vs Placebo
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Statistical analysis description:

Data from the in-trial period. The endpoint was analysed using a Cox proportional hazards model with treatment as categorical fixed factor. Subjects without events of interest were censored at the end of their in-trial period.

Comparison groups	Semaglutide v Placebo
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Number of subjects included in analysis	17604
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.89

Secondary: Time from randomisation to first occurrence of a composite heart failure (HF) endpoint consisting of: HF hospitalisation, urgent HF visit or CV death

End point title	Time from randomisation to first occurrence of a composite heart failure (HF) endpoint consisting of: HF hospitalisation, urgent HF visit or CV death
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End point description:

Number of subjects with first occurrence of a composite HF endpoint consisted of HF hospitalisation, urgent HF visit or CV death are presented. The endpoint was evaluated based on data from in-trial observation period. In-trial observation period defined as the period from date of randomisation to one of the following dates, whichever comes first: date of follow-up visit, date when subject withdrew consent, date of last contact with subject for subjects who were lost to follow-up (subject did not complete the trial and did not withdraw consent), date of death. FAS included all randomised. All subjects were analysed according to the treatment to which they were assigned at randomisation.

End point type	Secondary
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End point timeframe:

From randomisation to first occurrence of a composite endpoint

End point values	Semaglutide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8803	8801		
Units: Subjects	300	361		

Statistical analyses

No statistical analyses for this end point

Secondary: Time from randomisation to all-cause death

End point title	Time from randomisation to all-cause death
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End point description:

Number of subjects with all-cause death are presented. The endpoint was evaluated based on data from in-trial observation period. In-trial observation period defined as the period from date of randomisation to one of the following dates, whichever comes first: date of follow-up visit, date when subject withdrew consent, date of last contact with subject for subjects who were lost to follow-up (subject did not complete the trial and did not withdraw consent), date of death. FAS included all randomised subjects.

All subjects were analysed according to the treatment to which they were assigned at randomisation.

End point type	Secondary
End point timeframe:	
Time from randomisation to event	

End point values	Semaglutide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8803	8801		
Units: Subjects	375	458		

Statistical analyses

No statistical analyses for this end point

Secondary: Time from randomisation to CV death

End point title	Time from randomisation to CV death
End point description:	
Number of subjects with CV death are presented. The endpoint was evaluated based on data from in-trial observation period. In-trial observation period defined as the period from date of randomisation to one of the following dates, whichever comes first: date of follow-up visit, date when subject withdrew consent, date of last contact with subject for subjects who were lost to follow-up (subject did not complete the trial and did not withdraw consent), date of death. FAS included all randomised subjects. All subjects were analysed according to the treatment to which they were assigned at randomisation.	
End point type	Secondary
End point timeframe:	
Time from randomisation to event	

End point values	Semaglutide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8803	8801		
Units: Subjects	223	262		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From randomisation (week 0) up to 240 weeks

Adverse event reporting additional description:

AEs are reported based on data from in-trial observation period. Not all the AEs were collected systematically and more details on the approach followed for collecting the AEs is mentioned in the section 9.2 of protocol. AEs were not separately collected for each dose level. Hence, AEs are presented in randomized arm (semaglutide vs placebo).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26
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Reporting groups

Reporting group title	Semaglutide
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Reporting group description:

Subjects received semaglutide subcutaneously once weekly in a dose escalation manner for up to week 16: 0.24 mg from week 0 to week 4, 0.5 mg from week 4 to week 8, 1.0 mg from week 8 to week 12, 1.7 mg from week 12 to week 16 and 2.4 mg from week 16 up to week 247 during the maintenance period followed by a 5-week follow-up period.

Reporting group title	Placebo
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Reporting group description:

Subjects received placebo (matched to semaglutide) subcutaneously once weekly during dose escalation and maintenance periods up to week 247 followed by a 5-week follow-up period.

Serious adverse events	Semaglutide	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	2941 / 8803 (33.41%)	3204 / 8801 (36.40%)	
number of deaths (all causes)	371	460	
number of deaths resulting from adverse events	19	16	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma metastatic			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Adenocarcinoma gastric			

subjects affected / exposed	6 / 8803 (0.07%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	2 / 6	1 / 5
deaths causally related to treatment / all	1 / 1	0 / 2
Acute myeloid leukaemia		
subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Acute lymphocytic leukaemia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	15 / 8803 (0.17%)	15 / 8801 (0.17%)
occurrences causally related to treatment / all	3 / 16	3 / 15
deaths causally related to treatment / all	0 / 2	1 / 2
Adenocarcinoma pancreas		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	1 / 1
Adrenocortical carcinoma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Adrenal neoplasm		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal adenoma		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of salivary gland		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
B-cell small lymphocytic lymphoma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign duodenal neoplasm		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Benign gastrointestinal neoplasm		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign lung neoplasm		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign mediastinal neoplasm		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of cervix uteri		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of skin		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of thyroid gland		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basal cell carcinoma		
subjects affected / exposed	18 / 8803 (0.20%)	27 / 8801 (0.31%)
occurrences causally related to treatment / all	0 / 21	0 / 36
deaths causally related to treatment / all	0 / 0	0 / 0
Benign salivary gland neoplasm		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder adenocarcinoma stage unspecified		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	3 / 8803 (0.03%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	1 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer recurrent		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Bladder papilloma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	10 / 8803 (0.11%)	17 / 8801 (0.19%)
occurrences causally related to treatment / all	0 / 10	2 / 18
deaths causally related to treatment / all	0 / 0	0 / 2
Bowen's disease		
subjects affected / exposed	6 / 8803 (0.07%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 17	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer		
subjects affected / exposed	2 / 8803 (0.02%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer metastatic		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer recurrent		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer stage II		

subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer stage IV		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial carcinoma		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Carcinoid tumour		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carcinoid tumour pulmonary		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2
Cervix carcinoma stage II		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Choroid melanoma		

subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		
subjects affected / exposed	6 / 8803 (0.07%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 6	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia stage 1		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	9 / 8803 (0.10%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Colon cancer stage III		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal adenocarcinoma		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal adenoma		
subjects affected / exposed	11 / 8803 (0.12%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	1 / 12	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer metastatic		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colon cancer metastatic			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diffuse large B-cell lymphoma			
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diffuse large B-cell lymphoma stage I			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma stage III			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Endometrial adenocarcinoma			
subjects affected / exposed	2 / 8803 (0.02%)	6 / 8801 (0.07%)	
occurrences causally related to treatment / all	0 / 2	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer			
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential thrombocythaemia			

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epithelioid mesothelioma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Extranodal marginal zone B-cell lymphoma (MALT type)		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid seborrhoeic keratosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fibroadenoma of breast		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Follicular lymphoma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Follicular thyroid cancer		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer stage I		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder adenocarcinoma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder cancer		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal adenocarcinoma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal tumour		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal tract adenoma		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal cancer metastatic		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Glioblastoma		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Haemangioma		

subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemangioma of bone		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Head and neck cancer metastatic		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1
Hormone receptor positive breast cancer		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular carcinoma		
subjects affected / exposed	9 / 8803 (0.10%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 6	0 / 3
Hodgkin's disease		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hormone receptor positive HER2 negative breast cancer		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypopharyngeal cancer		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal adenocarcinoma		

subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal proliferative breast lesion		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive papillary breast carcinoma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive lobular breast carcinoma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	8 / 8803 (0.09%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	2 / 8	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Keratoacanthoma		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large cell lung cancer metastatic		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Large intestine benign neoplasm		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		

subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal squamous cell carcinoma		
subjects affected / exposed	4 / 8803 (0.05%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lentigo maligna		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lip and/or oral cavity cancer		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lipoma		
subjects affected / exposed	1 / 8803 (0.01%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Liposarcoma recurrent		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	10 / 8803 (0.11%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	0 / 10	1 / 8
deaths causally related to treatment / all	0 / 2	1 / 1
Lung adenocarcinoma recurrent		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma stage I		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma stage III		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic		
subjects affected / exposed	2 / 8803 (0.02%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 3
Lung carcinoma cell type unspecified stage II		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage IV		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Lung neoplasm		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm malignant		
subjects affected / exposed	5 / 8803 (0.06%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 2
Lung squamous cell carcinoma metastatic		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Lymphoma		

subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant melanoma		
subjects affected / exposed	10 / 8803 (0.11%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma in situ		
subjects affected / exposed	5 / 8803 (0.06%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of ampulla of Vater		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of renal pelvis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of unknown primary site		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant neoplasm of uterine adnexa		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mantle cell lymphoma stage III		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medullary thyroid cancer		

subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Melanoma recurrent		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma benign		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to peritoneum		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesothelioma		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to bone		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 4	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0
Metastases to central nervous system		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 1	1 / 2
Metastases to liver		

subjects affected / exposed	4 / 8803 (0.05%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	2 / 4	1 / 2
deaths causally related to treatment / all	2 / 2	0 / 0
Metastases to lung		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Metastases to spine		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic gastric cancer		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic malignant melanoma		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1
Metastatic neoplasm		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Metastatic salivary gland cancer		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic uterine cancer		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to soft tissue		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasopharyngeal cancer		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelofibrosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelodysplastic syndrome		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Neoplasm malignant		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm prostate		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine breast tumour		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Neuroendocrine carcinoma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma metastatic		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Neuroendocrine carcinoma of prostate		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma of the skin		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Neuroendocrine tumour of the lung		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine tumour of the lung metastatic		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Non-small cell lung cancer		
subjects affected / exposed	4 / 8803 (0.05%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Non-small cell lung cancer stage IV		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	4 / 8803 (0.05%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2
Oesophageal adenocarcinoma		

recurrent			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal adenocarcinoma stage IV			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	3 / 8803 (0.03%)	3 / 8801 (0.03%)	
occurrences causally related to treatment / all	1 / 3	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophageal squamous cell carcinoma			
subjects affected / exposed	1 / 8803 (0.01%)	4 / 8801 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral papilloma			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal cancer			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal squamous cell carcinoma			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoma			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Ovarian adenoma			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian epithelial cancer			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian granulosa cell tumour			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic neuroendocrine tumour			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary cystadenoma lymphomatosum			
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary renal cell carcinoma			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	4 / 8803 (0.05%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma			

subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Pancreatic carcinoma metastatic		
subjects affected / exposed	3 / 8803 (0.03%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	2 / 3	2 / 5
deaths causally related to treatment / all	2 / 2	2 / 5
Pancreatic neoplasm		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid tumour benign		
subjects affected / exposed	3 / 8803 (0.03%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	1 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Penile squamous cell carcinoma		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Philadelphia positive chronic myeloid leukaemia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Phyllodes tumour		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	5 / 8803 (0.06%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Plasmacytoma		

subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Polycythaemia vera		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	5 / 8803 (0.06%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	0 / 5	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer		
subjects affected / exposed	60 / 8803 (0.68%)	54 / 8801 (0.61%)
occurrences causally related to treatment / all	0 / 60	1 / 54
deaths causally related to treatment / all	0 / 1	0 / 0
Prostate cancer stage I		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage II		
subjects affected / exposed	1 / 8803 (0.01%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage III		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Primary myelofibrosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer recurrent		

subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage IV		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		
subjects affected / exposed	4 / 8803 (0.05%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectosigmoid cancer		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	4 / 8803 (0.05%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer metastatic		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal neoplasm		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma		
subjects affected / exposed	4 / 8803 (0.05%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer metastatic		
subjects affected / exposed	4 / 8803 (0.05%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 4	0 / 0
Salivary gland cancer		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland cancer stage IV		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seminoma		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sebaceous carcinoma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinonasal papilloma		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin squamous cell carcinoma recurrent		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	6 / 8803 (0.07%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	1 / 6	0 / 3
deaths causally related to treatment / all	1 / 4	0 / 1
Small cell lung cancer metastatic		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 2
Small intestine carcinoma metastatic		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Soft tissue sarcoma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer recurrent		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord neoplasm		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamoproliferative lesion		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		
subjects affected / exposed	5 / 8803 (0.06%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of head and neck		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		
subjects affected / exposed	5 / 8803 (0.06%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 4
Squamous cell carcinoma of skin		
subjects affected / exposed	11 / 8803 (0.12%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	0 / 13	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Squamous cell carcinoma of the tongue		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
T-cell lymphoma		

subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Testicular cancer metastatic		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid adenoma		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma recurrent		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell cancer of renal pelvis and ureter metastatic		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Transitional cell cancer of the renal pelvis and ureter		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell cancer of the renal pelvis and ureter localised		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma		

subjects affected / exposed	10 / 8803 (0.11%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	1 / 10	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Transitional cell carcinoma metastatic		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Tracheal cancer		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine leiomyoma		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Waldenstrom's macroglobulinaemia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acrochordon		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal squamous cell carcinoma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of prostate		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone cancer metastatic		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Carcinoid tumour of the gastrointestinal tract		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of thymus		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer stage II		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Conjunctival neoplasm		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye haemangioma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive breast carcinoma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage III		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant pleural effusion		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal cancer metastatic		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Oesophageal carcinoma recurrent		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Oncologic complication		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural mesothelioma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Papillary serous endometrial carcinoma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestine neuroendocrine tumour		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Seborrhoeic keratosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tumour haemorrhage		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spindle cell sarcoma			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superficial spreading melanoma stage I			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid neoplasm			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ureteric cancer			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm ruptured			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm thrombosis			

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic aneurysm		
subjects affected / exposed	18 / 8803 (0.20%)	17 / 8801 (0.19%)
occurrences causally related to treatment / all	0 / 18	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 1
Aortic aneurysm rupture		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Aortic arteriosclerosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic dissection		
subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 1
Aortic occlusion		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic stenosis		
subjects affected / exposed	6 / 8803 (0.07%)	19 / 8801 (0.22%)
occurrences causally related to treatment / all	0 / 6	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 1
Aorto-atrial fistula		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial disorder		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Arteriovenous fistula		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Behcet's syndrome		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bleeding varicose vein		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure fluctuation		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	3 / 8803 (0.03%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Deep vein thrombosis		
subjects affected / exposed	13 / 8803 (0.15%)	13 / 8801 (0.15%)
occurrences causally related to treatment / all	0 / 14	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 0
Dry gangrene		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism arterial		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery aneurysm		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery embolism		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Giant cell arteritis		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		

subjects affected / exposed	27 / 8803 (0.31%)	24 / 8801 (0.27%)
occurrences causally related to treatment / all	0 / 30	1 / 24
deaths causally related to treatment / all	0 / 1	0 / 0
Hypertensive crisis		
subjects affected / exposed	4 / 8803 (0.05%)	13 / 8801 (0.15%)
occurrences causally related to treatment / all	0 / 5	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive urgency		
subjects affected / exposed	5 / 8803 (0.06%)	13 / 8801 (0.15%)
occurrences causally related to treatment / all	1 / 5	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Hypotension		
subjects affected / exposed	23 / 8803 (0.26%)	25 / 8801 (0.28%)
occurrences causally related to treatment / all	2 / 24	1 / 30
deaths causally related to treatment / all	0 / 1	0 / 1
Iliac artery disease		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery occlusion		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery stenosis		

subjects affected / exposed	2 / 8803 (0.02%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	6 / 8803 (0.07%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Inferior vena cava stenosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leriche syndrome		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Macroangiopathy		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	15 / 8803 (0.17%)	10 / 8801 (0.11%)
occurrences causally related to treatment / all	1 / 15	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Penetrating aortic ulcer		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		

subjects affected / exposed	4 / 8803 (0.05%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	37 / 8803 (0.42%)	45 / 8801 (0.51%)
occurrences causally related to treatment / all	1 / 41	0 / 58
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	9 / 8803 (0.10%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 10	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	6 / 8803 (0.07%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	8 / 8803 (0.09%)	10 / 8801 (0.11%)
occurrences causally related to treatment / all	0 / 8	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	4 / 8803 (0.05%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral venous disease		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		

subjects affected / exposed	4 / 8803 (0.05%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Popliteal artery entrapment syndrome		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		
subjects affected / exposed	7 / 8803 (0.08%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	1 / 7	0 / 2
deaths causally related to treatment / all	1 / 3	0 / 2
Shock haemorrhagic		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Subclavian artery occlusion		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery stenosis		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian vein thrombosis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Superficial vein thrombosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Takayasu's arteritis		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose vein		
subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose ulceration		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Venous thrombosis limb		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular stenosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular occlusion		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial occlusive disease		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Granulomatosis with polyangiitis		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential hypertension			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Internal haemorrhage			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphatic fistula			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Angioplasty			
subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial stent insertion			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial septal defect repair			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract operation			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary angioplasty			

subjects affected / exposed	48 / 8803 (0.55%)	64 / 8801 (0.73%)
occurrences causally related to treatment / all	0 / 51	0 / 68
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary arterial stent insertion		
subjects affected / exposed	245 / 8803 (2.78%)	279 / 8801 (3.17%)
occurrences causally related to treatment / all	3 / 270	3 / 343
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery bypass		
subjects affected / exposed	69 / 8803 (0.78%)	79 / 8801 (0.90%)
occurrences causally related to treatment / all	0 / 69	1 / 79
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary revascularisation		
subjects affected / exposed	23 / 8803 (0.26%)	37 / 8801 (0.42%)
occurrences causally related to treatment / all	0 / 27	0 / 38
deaths causally related to treatment / all	0 / 0	0 / 0
Hospitalisation		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Implantable defibrillator insertion		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-cerebral aneurysm operation		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Knee arthroplasty		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liposuction		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Percutaneous coronary intervention		
subjects affected / exposed	70 / 8803 (0.80%)	114 / 8801 (1.30%)
occurrences causally related to treatment / all	2 / 81	5 / 124
deaths causally related to treatment / all	0 / 0	0 / 1
Sequestrectomy		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sleeve gastrectomy		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stent placement		
subjects affected / exposed	10 / 8803 (0.11%)	12 / 8801 (0.14%)
occurrences causally related to treatment / all	0 / 10	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Transurethral prostatectomy		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast reconstruction		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac pacemaker replacement		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hip arthroplasty		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Accidental death			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asthenia			
subjects affected / exposed	10 / 8803 (0.11%)	5 / 8801 (0.06%)	
occurrences causally related to treatment / all	2 / 11	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Catheter site haemorrhage			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	44 / 8803 (0.50%)	47 / 8801 (0.53%)	
occurrences causally related to treatment / all	3 / 45	3 / 48	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	4 / 8803 (0.05%)	7 / 8801 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			

subjects affected / exposed	55 / 8803 (0.62%)	57 / 8801 (0.65%)
occurrences causally related to treatment / all	4 / 55	1 / 57
deaths causally related to treatment / all	4 / 55	1 / 57
Device related thrombosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Discomfort		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug intolerance		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocution		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Fat necrosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Feeling cold		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fatigue		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gait disturbance		

subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
General physical health deterioration		
subjects affected / exposed	4 / 8803 (0.05%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Generalised oedema		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Granuloma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hanging		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hernia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperthermia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypothermia		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Impaired healing		

subjects affected / exposed	6 / 8803 (0.07%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated hernia		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Injection site haematoma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza like illness		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site ulcer		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple organ dysfunction syndrome		
subjects affected / exposed	3 / 8803 (0.03%)	10 / 8801 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 10
deaths causally related to treatment / all	0 / 3	0 / 10
Non-cardiac chest pain		
subjects affected / exposed	88 / 8803 (1.00%)	103 / 8801 (1.17%)
occurrences causally related to treatment / all	2 / 96	7 / 112
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema		

subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	1 / 8803 (0.01%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pain		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral swelling		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyp		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural failure		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prosthetic cardiac valve stenosis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pyrexia		
subjects affected / exposed	5 / 8803 (0.06%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 6	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Sensation of foreign body		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stent-graft endoleak		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden cardiac death		
subjects affected / exposed	8 / 8803 (0.09%)	12 / 8801 (0.14%)
occurrences causally related to treatment / all	0 / 8	0 / 12
deaths causally related to treatment / all	0 / 8	0 / 12
Sudden death		
subjects affected / exposed	5 / 8803 (0.06%)	16 / 8801 (0.18%)
occurrences causally related to treatment / all	0 / 5	1 / 16
deaths causally related to treatment / all	0 / 5	1 / 16
Systemic inflammatory response syndrome		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tissue infiltration		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Treatment noncompliance		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ulcer haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular device occlusion		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	22 / 8803 (0.25%)	21 / 8801 (0.24%)	
occurrences causally related to treatment / all	0 / 22	1 / 25	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	2 / 8803 (0.02%)	8 / 8801 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exercise tolerance decreased			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised oedema			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Allergy to arthropod sting			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyloidosis			

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Anaphylactic reaction		
subjects affected / exposed	2 / 8803 (0.02%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Anaphylactic shock		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Contrast media allergy		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug hypersensitivity		
subjects affected / exposed	4 / 8803 (0.05%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Food allergy		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Heart transplant rejection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypersensitivity		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney transplant rejection		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Secondary immunodeficiency			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anti-neutrophil cytoplasmic antibody positive vasculitis			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adnexa uteri cyst			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	34 / 8803 (0.39%)	21 / 8801 (0.24%)	
occurrences causally related to treatment / all	0 / 35	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast fibrosis			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast oedema			

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical polyp		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystocele		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysmenorrhoea		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymal disorder		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial hyperplasia		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Erectile dysfunction		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Female genital tract fistula		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gynaecomastia		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heavy menstrual bleeding		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrometra		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cyst		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cyst ruptured		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic organ prolapse		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postmenopausal haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic obstruction		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatitis		

subjects affected / exposed	4 / 8803 (0.05%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatomegaly		
subjects affected / exposed	5 / 8803 (0.06%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectocele		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal cyst		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spermatic cord disorder		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterovaginal prolapse		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine prolapse		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine polyp		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix disorder		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal pain			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	28 / 8803 (0.32%)	46 / 8801 (0.52%)	
occurrences causally related to treatment / all	0 / 30	1 / 51	
deaths causally related to treatment / all	0 / 8	0 / 15	
Acute respiratory distress syndrome			
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Acute pulmonary oedema			
subjects affected / exposed	5 / 8803 (0.06%)	7 / 8801 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asthma			
subjects affected / exposed	5 / 8803 (0.06%)	13 / 8801 (0.15%)	
occurrences causally related to treatment / all	0 / 7	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			

subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	32 / 8803 (0.36%)	50 / 8801 (0.57%)
occurrences causally related to treatment / all	0 / 43	1 / 63
deaths causally related to treatment / all	0 / 4	0 / 3
Cough		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Dysphonia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		
subjects affected / exposed	19 / 8803 (0.22%)	35 / 8801 (0.40%)
occurrences causally related to treatment / all	1 / 20	0 / 36
deaths causally related to treatment / all	0 / 2	0 / 0
Dyspnoea at rest		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea exertional		
subjects affected / exposed	1 / 8803 (0.01%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0
Emphysema		
subjects affected / exposed	2 / 8803 (0.02%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Epiglottic cyst		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	9 / 8803 (0.10%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Haemothorax		
subjects affected / exposed	3 / 8803 (0.03%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Hydrothorax		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercapnia		

subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypersensitivity pneumonitis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	3 / 8803 (0.03%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Idiopathic interstitial pneumonia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic pulmonary fibrosis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Immune-mediated lung disease		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Lung consolidation		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum deviation		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasopharyngeal polyp		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive airways disorder		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive sleep apnoea syndrome		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Organising pneumonia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Painful respiration		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumomediastinum		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	12 / 8803 (0.14%)	16 / 8801 (0.18%)
occurrences causally related to treatment / all	0 / 13	1 / 16
deaths causally related to treatment / all	0 / 1	0 / 2
Pleurisy		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonitis		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonitis aspiration		
subjects affected / exposed	3 / 8803 (0.03%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Pneumothorax		
subjects affected / exposed	6 / 8803 (0.07%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax spontaneous		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	38 / 8803 (0.43%)	43 / 8801 (0.49%)
occurrences causally related to treatment / all	4 / 39	2 / 44
deaths causally related to treatment / all	0 / 8	2 / 8
Pulmonary fibrosis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Pulmonary haematoma		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary infarction		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mass		
subjects affected / exposed	4 / 8803 (0.05%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary microemboli		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	8 / 8803 (0.09%)	12 / 8801 (0.14%)
occurrences causally related to treatment / all	0 / 8	0 / 12
deaths causally related to treatment / all	0 / 2	0 / 2
Pulmonary hypertension		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory arrest		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Respiratory disorder		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory distress		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory failure		
subjects affected / exposed	10 / 8803 (0.11%)	16 / 8801 (0.18%)
occurrences causally related to treatment / all	0 / 10	1 / 16
deaths causally related to treatment / all	0 / 6	0 / 9
Sleep apnoea syndrome		
subjects affected / exposed	1 / 8803 (0.01%)	10 / 8801 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Snoring		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stridor		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic sclerosis pulmonary		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheal compression		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheal stenosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheomalacia		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord thickening			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic respiratory failure			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngospasm			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary granuloma			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			

subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Alcohol use disorder		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety		
subjects affected / exposed	6 / 8803 (0.07%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety disorder		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar disorder		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Confusional state		
subjects affected / exposed	4 / 8803 (0.05%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Completed suicide		
subjects affected / exposed	5 / 8803 (0.06%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 5	0 / 2
Conversion disorder		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depression suicidal		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	13 / 8803 (0.15%)	10 / 8801 (0.11%)
occurrences causally related to treatment / all	0 / 14	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Dissociative amnesia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dissociative identity disorder		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug abuse		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal somatic symptom disorder		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		
subjects affected / exposed	2 / 8803 (0.02%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Mania		

subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mental disorder		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes		
subjects affected / exposed	4 / 8803 (0.05%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2
Mixed anxiety and depressive disorder		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Panic attack		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Persistent depressive disorder		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psychotic disorder		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Schizophrenia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sleep disorder		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Substance-induced psychotic disorder		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Suicidal ideation		
subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Suicide attempt		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Alcohol abuse		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Bipolar I disorder		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Catatonia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination, visual		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neurosis		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paranoia			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Personality change			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Withdrawal catatonia			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device breakage			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	3 / 8803 (0.03%)	7 / 8801 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			

subjects affected / exposed	2 / 8803 (0.02%)	4 / 8801 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lead dislodgement			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prosthetic cardiac valve malfunction			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Alcoholic liver disease			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	16 / 8803 (0.18%)	10 / 8801 (0.11%)	
occurrences causally related to treatment / all	7 / 16	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Biliary colic			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary obstruction			
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis obstructive			

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis migration		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	44 / 8803 (0.50%)	31 / 8801 (0.35%)
occurrences causally related to treatment / all	17 / 46	12 / 33
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis chronic		
subjects affected / exposed	10 / 8803 (0.11%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	3 / 10	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	27 / 8803 (0.31%)	30 / 8801 (0.34%)
occurrences causally related to treatment / all	13 / 27	17 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis		
subjects affected / exposed	13 / 8803 (0.15%)	15 / 8801 (0.17%)
occurrences causally related to treatment / all	3 / 13	6 / 15
deaths causally related to treatment / all	0 / 0	0 / 1
Cholangitis acute		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Cholangitis		
subjects affected / exposed	6 / 8803 (0.07%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	1 / 6	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Drug-induced liver injury		

subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	2 / 3	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder rupture		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder polyp		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder cholesterolosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder disorder		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder necrosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic failure		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Hepatic cirrhosis		
subjects affected / exposed	1 / 8803 (0.01%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic fibrosis		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic steatosis		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis acute		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis alcoholic		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatorenal syndrome		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic function abnormal		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1
Hyperbilirubinaemia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperplastic cholecystopathy		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertransaminaemia		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic hepatitis			
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Liver disorder			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Non-alcoholic steatohepatitis			
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal hypertensive biliopathy			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portosplenomesenteric venous thrombosis			

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post cholecystectomy syndrome			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sphincter of Oddi dysfunction			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suspected drug-induced liver injury			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cryptogenic cirrhosis			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 8803 (0.02%)	4 / 8801 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Amylase increased			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level above therapeutic			
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			

subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Blood alkaline phosphatase increased		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood bilirubin increased		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Blood calcitonin increased		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	1 / 2	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Blood creatinine increased		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood osmolarity decreased		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium decreased		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium increased		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure increased		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood urine present		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Body temperature decreased		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Body temperature increased		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
C-reactive protein increased		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac stress test abnormal		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Catheterisation cardiac		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coagulation time shortened		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Culture positive		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction decreased		
subjects affected / exposed	4 / 8803 (0.05%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram ST segment abnormal		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exercise electrocardiogram abnormal		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
False positive investigation result		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibrin D dimer increased		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric pH decreased		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gamma-glutamyltransferase increased		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glycosylated haemoglobin increased		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate irregular			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme abnormal			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipase increased			
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Occult blood positive			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic enzymes increased			

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
SARS-CoV-2 test positive		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Transaminases increased		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Troponin increased		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Troponin abnormal		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urine analysis abnormal		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Weight decreased		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Weight increased		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anti-thyroid antibody positive		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Body mass index increased			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial necrosis marker increased			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Accident at home			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Accident at work			
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Accidental overdose			
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			

subjects affected / exposed	3 / 8803 (0.03%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 3	1 / 4
deaths causally related to treatment / all	0 / 2	1 / 1
Anaemia postoperative		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anastomotic ulcer haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ankle fracture		
subjects affected / exposed	5 / 8803 (0.06%)	12 / 8801 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Anterior cord syndrome		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic pseudoaneurysm		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial injury		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial restenosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Back injury		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain contusion		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Burns second degree		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac procedure complication		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cartilage injury		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chest injury		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical vertebral fracture		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle fracture		
subjects affected / exposed	0 / 8803 (0.00%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		

subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	4 / 8803 (0.05%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery reocclusion		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery restenosis		
subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary bypass stenosis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary vascular graft occlusion		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary vascular graft stenosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis radiation		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		

subjects affected / exposed	6 / 8803 (0.07%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 1
Crush injury		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Deep vein thrombosis postoperative		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural haematoma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eye injury		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Face injury		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	2 / 8803 (0.02%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	51 / 8803 (0.58%)	35 / 8801 (0.40%)
occurrences causally related to treatment / all	1 / 55	0 / 39
deaths causally related to treatment / all	0 / 1	0 / 0
Extraskeletal ossification		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	11 / 8803 (0.12%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Femur fracture		
subjects affected / exposed	13 / 8803 (0.15%)	11 / 8801 (0.12%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	5 / 8803 (0.06%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body in gastrointestinal tract		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body in respiratory tract		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal organ contusion		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal procedural complication			
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stoma complication			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroparesis postoperative			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	8 / 8803 (0.09%)	10 / 8801 (0.11%)	
occurrences causally related to treatment / all	0 / 8	1 / 10	
deaths causally related to treatment / all	0 / 1	1 / 1	
Heat exhaustion			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heat illness			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			

subjects affected / exposed	11 / 8803 (0.12%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 11	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	7 / 8803 (0.08%)	11 / 8801 (0.12%)
occurrences causally related to treatment / all	0 / 8	1 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Immunisation reaction		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated incisional hernia		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site haemorrhage		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	6 / 8803 (0.07%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia, obstructive		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intentional overdose		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Injury		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw fracture		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	7 / 8803 (0.08%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		
subjects affected / exposed	6 / 8803 (0.07%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament rupture		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Limb crushing injury		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	5 / 8803 (0.06%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Limb traumatic amputation		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lisfranc fracture		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament sprain		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	3 / 8803 (0.03%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbosacral plexus injury		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Maisonneuve fracture		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		
subjects affected / exposed	8 / 8803 (0.09%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes postoperative		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle rupture		

subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle strain		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple injuries		
subjects affected / exposed	2 / 8803 (0.02%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 2
Nerve injury		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Open globe injury		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Overdose		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		
subjects affected / exposed	3 / 8803 (0.03%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	8 / 8803 (0.09%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	1 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial reocclusion		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery restenosis		
subjects affected / exposed	2 / 8803 (0.02%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Periprosthetic fracture		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax traumatic		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Poisoning		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Post procedural fever		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural complication		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematuria		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	1 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		

subjects affected / exposed	12 / 8803 (0.14%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural inflammation		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural myocardial infarction		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural pulmonary embolism		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural stroke		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postpericardiotomy syndrome		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic pain		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative ileus		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative renal failure		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative respiratory distress		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative thrombosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural haemorrhage		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pneumothorax		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary contusion		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	4 / 8803 (0.05%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	15 / 8803 (0.17%)	21 / 8801 (0.24%)
occurrences causally related to treatment / all	0 / 16	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	11 / 8803 (0.12%)	17 / 8801 (0.19%)
occurrences causally related to treatment / all	0 / 11	0 / 17
deaths causally related to treatment / all	0 / 5	0 / 6
Scapula fracture		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatic nerve injury		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Seroma		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fracture		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shoulder fracture		

subjects affected / exposed	4 / 8803 (0.05%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Skin laceration		
subjects affected / exposed	10 / 8803 (0.11%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 10	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fractured base		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue injury		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		
subjects affected / exposed	8 / 8803 (0.09%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury cervical		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sternal fracture		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stoma obstruction		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stoma site haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stomal hernia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	16 / 8803 (0.18%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 16	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Subdural haemorrhage		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	5 / 8803 (0.06%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial rupture		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon injury		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	5 / 8803 (0.06%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	2 / 8803 (0.02%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	1 / 8803 (0.01%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic arthrosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haematoma		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemothorax		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic heart injury		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haematoma		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic pancreatitis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic arthritis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ulnar nerve injury		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna fracture		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	1 / 8803 (0.01%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention postoperative		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular access site pseudoaneurysm		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular procedure complication		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular injury		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Vascular graft thrombosis		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft stenosis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft restenosis		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft occlusion		
subjects affected / exposed	7 / 8803 (0.08%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Wound		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound necrosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wrist fracture		
subjects affected / exposed	3 / 8803 (0.03%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Wound dehiscence		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anastomotic ulcer		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Animal bite		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bone contusion		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatobiliary procedural complication		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural fistula		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural complication			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Reactive gastropathy			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal haematoma			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stoma complication			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access site haematoma			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bicuspid aortic valve			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CADASIL			

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Corneal dystrophy		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Factor II mutation		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal arteriovenous malformation		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocele		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertrophic cardiomyopathy		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Odontogenic cyst		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Patent ductus arteriosus		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Type IIa hyperlipidaemia		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular septal defect			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gilbert's syndrome			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitello-intestinal duct remnant			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	22 / 8803 (0.25%)	18 / 8801 (0.20%)	
occurrences causally related to treatment / all	0 / 23	0 / 18	
deaths causally related to treatment / all	0 / 2	0 / 2	
Acute myocardial infarction			
subjects affected / exposed	209 / 8803 (2.37%)	293 / 8801 (3.33%)	
occurrences causally related to treatment / all	6 / 220	9 / 324	
deaths causally related to treatment / all	0 / 20	0 / 22	
Acute left ventricular failure			
subjects affected / exposed	6 / 8803 (0.07%)	7 / 8801 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 1	
Angina pectoris			
subjects affected / exposed	116 / 8803 (1.32%)	150 / 8801 (1.70%)	
occurrences causally related to treatment / all	2 / 126	3 / 176	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			

subjects affected / exposed	182 / 8803 (2.07%)	209 / 8801 (2.37%)
occurrences causally related to treatment / all	5 / 205	7 / 242
deaths causally related to treatment / all	0 / 0	0 / 0
Anginal equivalent		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve incompetence		
subjects affected / exposed	3 / 8803 (0.03%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve stenosis		
subjects affected / exposed	7 / 8803 (0.08%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia		
subjects affected / exposed	7 / 8803 (0.08%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 2
Arrhythmia supraventricular		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmic storm		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	7 / 8803 (0.08%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1
Atrial tachycardia		

subjects affected / exposed	2 / 8803 (0.02%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		
subjects affected / exposed	127 / 8803 (1.44%)	152 / 8801 (1.73%)
occurrences causally related to treatment / all	7 / 139	4 / 181
deaths causally related to treatment / all	0 / 3	0 / 3
Atrial flutter		
subjects affected / exposed	23 / 8803 (0.26%)	22 / 8801 (0.25%)
occurrences causally related to treatment / all	0 / 24	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial thrombosis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	7 / 8803 (0.08%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block first degree		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	4 / 8803 (0.05%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 4	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	4 / 8803 (0.05%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		

subjects affected / exposed	9 / 8803 (0.10%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	0 / 9	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Bundle branch block left		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block right		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac disorder		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac aneurysm		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	26 / 8803 (0.30%)	33 / 8801 (0.37%)
occurrences causally related to treatment / all	3 / 26	0 / 33
deaths causally related to treatment / all	2 / 18	0 / 26
Cardiac failure		
subjects affected / exposed	88 / 8803 (1.00%)	113 / 8801 (1.28%)
occurrences causally related to treatment / all	4 / 114	1 / 127
deaths causally related to treatment / all	0 / 15	0 / 17
Cardiopulmonary failure		
subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 2
Cardiac failure chronic		

subjects affected / exposed	23 / 8803 (0.26%)	28 / 8801 (0.32%)
occurrences causally related to treatment / all	0 / 24	1 / 29
deaths causally related to treatment / all	0 / 2	0 / 3
Cardiac failure congestive		
subjects affected / exposed	31 / 8803 (0.35%)	36 / 8801 (0.41%)
occurrences causally related to treatment / all	2 / 37	2 / 51
deaths causally related to treatment / all	0 / 4	0 / 4
Cardiac perforation		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiac perfusion defect		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac tamponade		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac valve disease		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac ventricular thrombosis		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	11 / 8803 (0.12%)	11 / 8801 (0.12%)
occurrences causally related to treatment / all	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 11	0 / 8
Cardiogenic shock		

subjects affected / exposed	6 / 8803 (0.07%)	10 / 8801 (0.11%)
occurrences causally related to treatment / all	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 5	0 / 6
Cardiomyopathy		
subjects affected / exposed	0 / 8803 (0.00%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 3
Cardiac failure acute		
subjects affected / exposed	32 / 8803 (0.36%)	44 / 8801 (0.50%)
occurrences causally related to treatment / all	2 / 46	0 / 50
deaths causally related to treatment / all	0 / 2	0 / 6
Chronic coronary syndrome		
subjects affected / exposed	3 / 8803 (0.03%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	79 / 8803 (0.90%)	106 / 8801 (1.20%)
occurrences causally related to treatment / all	2 / 80	1 / 113
deaths causally related to treatment / all	0 / 2	0 / 3
Cor pulmonale		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery dissection		
subjects affected / exposed	1 / 8803 (0.01%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery occlusion		
subjects affected / exposed	11 / 8803 (0.12%)	12 / 8801 (0.14%)
occurrences causally related to treatment / all	2 / 11	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		

subjects affected / exposed	44 / 8803 (0.50%)	53 / 8801 (0.60%)
occurrences causally related to treatment / all	2 / 49	1 / 58
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery thrombosis		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Coronary ostial stenosis		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery insufficiency		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diastolic dysfunction		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dilated cardiomyopathy		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive heart disease		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Intracardiac thrombus		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		

subjects affected / exposed	9 / 8803 (0.10%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 4	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	1 / 8803 (0.01%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 2
Left ventricular failure		
subjects affected / exposed	4 / 8803 (0.05%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 4	2 / 6
deaths causally related to treatment / all	0 / 1	1 / 2
Mitral valve stenosis		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		
subjects affected / exposed	1 / 8803 (0.01%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Microvascular coronary artery disease		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial fibrosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Myocardial infarction		
subjects affected / exposed	35 / 8803 (0.40%)	31 / 8801 (0.35%)
occurrences causally related to treatment / all	0 / 36	1 / 32
deaths causally related to treatment / all	0 / 15	1 / 11
Myocardial injury		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial ischaemia		
subjects affected / exposed	21 / 8803 (0.24%)	31 / 8801 (0.35%)
occurrences causally related to treatment / all	0 / 21	0 / 31
deaths causally related to treatment / all	0 / 4	0 / 5
Myocarditis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myopericarditis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	3 / 8803 (0.03%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		
subjects affected / exposed	5 / 8803 (0.06%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	3 / 8803 (0.03%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 3	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Prinzmetal angina		

subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Right ventricular failure		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sinoatrial block		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	3 / 8803 (0.03%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		
subjects affected / exposed	7 / 8803 (0.08%)	15 / 8801 (0.17%)
occurrences causally related to treatment / all	0 / 7	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Silent myocardial infarction		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stress cardiomyopathy		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular extrasystoles		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		

subjects affected / exposed	18 / 8803 (0.20%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	2 / 19	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Tachyarrhythmia		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	4 / 8803 (0.05%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid valve incompetence		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular arrhythmia		
subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 2
Ventricular tachyarrhythmia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Ventricular tachycardia		
subjects affected / exposed	36 / 8803 (0.41%)	38 / 8801 (0.43%)
occurrences causally related to treatment / all	0 / 36	1 / 49
deaths causally related to treatment / all	0 / 0	0 / 3
Ventricular fibrillation		
subjects affected / exposed	7 / 8803 (0.08%)	11 / 8801 (0.12%)
occurrences causally related to treatment / all	1 / 7	1 / 12
deaths causally related to treatment / all	0 / 1	0 / 2
Ventricular extrasystoles		

subjects affected / exposed	12 / 8803 (0.14%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	1 / 12	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve disease mixed		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bifascicular block		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiomegaly		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiorenal syndrome		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Chordae tendinae rupture		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic mitral regurgitation		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulseless electrical activity		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Sinus arrest		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia induced cardiomyopathy			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular dysfunction			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Nervous system disorders			
Amnesia			
subjects affected / exposed	1 / 8803 (0.01%)	5 / 8801 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aphasia			
subjects affected / exposed	3 / 8803 (0.03%)	3 / 8801 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia stroke			
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basilar artery aneurysm			

subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Basilar artery occlusion		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bell's palsy		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain injury		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Brain oedema		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Brain stem infarction		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid arterial embolus		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid arteriosclerosis		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carpal tunnel syndrome		

subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid sinus syndrome		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery thrombosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery stenosis		
subjects affected / exposed	22 / 8803 (0.25%)	24 / 8801 (0.27%)
occurrences causally related to treatment / all	0 / 23	1 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery occlusion		
subjects affected / exposed	1 / 8803 (0.01%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery disease		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery aneurysm		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral small vessel ischaemic disease		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral infarction		

subjects affected / exposed	17 / 8803 (0.19%)	23 / 8801 (0.26%)
occurrences causally related to treatment / all	1 / 18	1 / 25
deaths causally related to treatment / all	1 / 2	0 / 2
Cerebral haemorrhage		
subjects affected / exposed	7 / 8803 (0.08%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 4	0 / 5
Cerebral haematoma		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral circulatory failure		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery embolism		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar stroke		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar ischaemia		
subjects affected / exposed	0 / 8803 (0.00%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar infarction		
subjects affected / exposed	3 / 8803 (0.03%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Cerebellar haemorrhage		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Central pain syndrome		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Central nervous system vasculitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Central nervous system inflammation		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ischaemia		
subjects affected / exposed	8 / 8803 (0.09%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Cerebrovascular accident		
subjects affected / exposed	35 / 8803 (0.40%)	48 / 8801 (0.55%)
occurrences causally related to treatment / all	1 / 36	3 / 50
deaths causally related to treatment / all	0 / 8	1 / 12
Cervicobrachial syndrome		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical radiculopathy		
subjects affected / exposed	2 / 8803 (0.02%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical cord compression		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular insufficiency		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cerebrovascular disorder		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Conus medullaris syndrome		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coordination abnormal		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Corticobasal degeneration		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cranial nerve disorder		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia with Lewy bodies		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Demyelinating polyneuropathy		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diplegia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	10 / 8803 (0.11%)	14 / 8801 (0.16%)
occurrences causally related to treatment / all	2 / 10	3 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness postural		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dural arteriovenous fistula		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic cerebral infarction		
subjects affected / exposed	3 / 8803 (0.03%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic stroke		
subjects affected / exposed	6 / 8803 (0.07%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalitis autoimmune		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0
Encephalopathy		
subjects affected / exposed	3 / 8803 (0.03%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	4 / 8803 (0.05%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Facial nerve disorder		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paralysis		

subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paresis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Frontotemporal dementia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Haemorrhagic stroke		
subjects affected / exposed	7 / 8803 (0.08%)	12 / 8801 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 5
Haemorrhagic transformation stroke		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Headache		

subjects affected / exposed	7 / 8803 (0.08%)	11 / 8801 (0.12%)
occurrences causally related to treatment / all	1 / 8	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Hemianopia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparaesthesia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	4 / 8803 (0.05%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiplegia		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	1 / 1
Hemiplegic migraine		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Hydrocephalus		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		

subjects affected / exposed	3 / 8803 (0.03%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive encephalopathy		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokinesia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
IIIrd nerve paresis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2
Intercostal neuralgia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intensive care unit acquired weakness		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial haematoma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Intracranial aneurysm		

subjects affected / exposed	1 / 8803 (0.01%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 1	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial hypotension		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial mass		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	79 / 8803 (0.90%)	80 / 8801 (0.91%)
occurrences causally related to treatment / all	3 / 87	3 / 84
deaths causally related to treatment / all	1 / 9	1 / 8
Ischaemic cerebral infarction		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intraventricular haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar infarction		
subjects affected / exposed	6 / 8803 (0.07%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar stroke		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		

subjects affected / exposed	5 / 8803 (0.06%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	5 / 8803 (0.06%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbosacral radiculopathy		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Memory impairment		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningoradiculitis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	5 / 8803 (0.06%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Migraine		
subjects affected / exposed	6 / 8803 (0.07%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	1 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine with aura		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myasthenia gravis		

subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple sclerosis		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myelomalacia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve compression		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuritis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgic amyotrophy		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Occipital neuralgia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Paraparesis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinsonian rest tremor		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinsonism		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Partial seizures		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral nerve lesion		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post stroke seizure		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic headache		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post stroke epilepsy		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	14 / 8803 (0.16%)	15 / 8801 (0.17%)
occurrences causally related to treatment / all	0 / 14	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Primary progressive multiple sclerosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudostroke		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudoradicular syndrome		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculopathy		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Relapsing-remitting multiple sclerosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Reversible cerebral vasoconstriction syndrome		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ruptured cerebral aneurysm		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Sciatica		
subjects affected / exposed	7 / 8803 (0.08%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		
subjects affected / exposed	14 / 8803 (0.16%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	1 / 14	2 / 6
deaths causally related to treatment / all	0 / 3	0 / 0
Seizure like phenomena		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sensory disturbance		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sensory loss		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Speech disorder		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal claudication		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord infarction		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal epidural haematoma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Status epilepticus		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	6 / 8803 (0.07%)	12 / 8801 (0.14%)
occurrences causally related to treatment / all	2 / 6	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 4
Status migrainosus		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	65 / 8803 (0.74%)	55 / 8801 (0.62%)
occurrences causally related to treatment / all	11 / 71	3 / 63
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombotic stroke		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Tension headache		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thalamic infarction		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thalamus haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombotic cerebral infarction		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Transient aphasia		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient global amnesia		
subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		
subjects affected / exposed	39 / 8803 (0.44%)	59 / 8801 (0.67%)
occurrences causally related to treatment / all	0 / 42	0 / 63
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Trigeminal neuralgia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Typical aura without headache		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular dementia		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vagus nerve paralysis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular encephalopathy		

subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertigo CNS origin		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar stroke		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency		
subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar artery dissection		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery stenosis		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute disseminated encephalomyelitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Alcohol induced persisting dementia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Altered state of consciousness		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic inflammatory demyelinating polyradiculoneuropathy		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Focal dyscognitive seizures		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hashimoto's encephalopathy		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial pressure increased		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Monoparesis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Motor neurone disease		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Moyamoya disease		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple sclerosis relapse		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normal pressure hydrocephalus		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Optic neuritis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic tremor		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy alcoholic		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral paralysis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peroneal nerve palsy		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord compression		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitic myelopathy		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamic stroke			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vlith nerve paralysis			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord paralysis			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Abdominal lymphadenopathy			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agranulocytosis			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	36 / 8803 (0.41%)	30 / 8801 (0.34%)	
occurrences causally related to treatment / all	1 / 40	0 / 38	
deaths causally related to treatment / all	0 / 2	0 / 0	
Antiphospholipid syndrome			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			

subjects affected / exposed	10 / 8803 (0.11%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Coagulopathy		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Febrile neutropenia		
subjects affected / exposed	4 / 8803 (0.05%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemolysis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochromic anaemia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	8 / 8803 (0.09%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	1 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		
subjects affected / exposed	3 / 8803 (0.03%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Leukopenia		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		

subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy mediastinal		
subjects affected / exposed	3 / 8803 (0.03%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoid tissue hyperplasia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Methaemoglobinaemia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenia		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normochromic normocytic anaemia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normocytic anaemia		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancytopenia		

subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polycythaemia		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic infarction		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombocytopenia		
subjects affected / exposed	6 / 8803 (0.07%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	2 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombocytosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia of chronic disease		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Normochromic anaemia		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniere's disease			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	3 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	3 / 8803 (0.03%)	7 / 8801 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	18 / 8803 (0.20%)	7 / 8801 (0.08%)	
occurrences causally related to treatment / all	0 / 18	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute vestibular syndrome			

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular ataxia			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness transient			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	12 / 8803 (0.14%)	18 / 8801 (0.20%)	
occurrences causally related to treatment / all	0 / 14	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal degeneration			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal erosion			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryostenosis acquired			

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocrine ophthalmopathy		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epiretinal membrane		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular degeneration		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Macular hole		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular rupture		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Maculopathy		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Macular oedema		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neovascular age-related macular degeneration		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ocular hypertension		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Optic ischaemic neuropathy		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vascular occlusion		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery embolism		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery occlusion		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery thrombosis		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal detachment		
subjects affected / exposed	5 / 8803 (0.06%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	1 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal tear		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vein occlusion		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhegmatogenous retinal detachment		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retinopathy hypertensive		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vitreous haemorrhage		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vitreous detachment		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vitreoretinal traction syndrome		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Visual impairment		
subjects affected / exposed	1 / 8803 (0.01%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Amaurosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract cortical		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Conjunctival haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatochalasis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid ptosis		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lenticular opacities		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myopia			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual field defect			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	5 / 8803 (0.06%)	6 / 8801 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	9 / 8803 (0.10%)	18 / 8801 (0.20%)	
occurrences causally related to treatment / all	2 / 10	5 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal adhesions			
subjects affected / exposed	7 / 8803 (0.08%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	2 / 8	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	2 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal symptom			

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal strangulated hernia		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	11 / 8803 (0.12%)	12 / 8801 (0.14%)
occurrences causally related to treatment / all	2 / 12	4 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain lower		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Acute abdomen		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	1 / 8803 (0.01%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 1	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Anal polyp		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal prolapse		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anorectal varices haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendix disorder		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's oesophagus		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breath odour		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic gastritis		
subjects affected / exposed	4 / 8803 (0.05%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	14 / 8803 (0.16%)	10 / 8801 (0.11%)
occurrences causally related to treatment / all	4 / 15	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		

subjects affected / exposed	9 / 8803 (0.10%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	3 / 9	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Colitis ulcerative		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon dysplasia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	8 / 8803 (0.09%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	3 / 8	2 / 6
deaths causally related to treatment / all	1 / 1	0 / 1
Crohn's disease		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dental alveolar anomaly		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea haemorrhagic		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dieulafoy's vascular malformation		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	23 / 8803 (0.26%)	16 / 8801 (0.18%)
occurrences causally related to treatment / all	13 / 23	4 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	2 / 8803 (0.02%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 2	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Diverticulum intestinal		
subjects affected / exposed	7 / 8803 (0.08%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	1 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	2 / 8803 (0.02%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	4 / 8803 (0.05%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer perforation		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	1 / 1
Duodenitis		
subjects affected / exposed	4 / 8803 (0.05%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	3 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		

subjects affected / exposed	5 / 8803 (0.06%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	4 / 5	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	5 / 8803 (0.06%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	3 / 8803 (0.03%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	1 / 3	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Epiplonic appendagitis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enlarged uvula		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterovesical fistula		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive duodenitis		

subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Eructation		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Faeces discoloured		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral hernia		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Flatulence		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Functional gastrointestinal disorder		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric perforation		

subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Gastric polyps		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	5 / 8803 (0.06%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer perforation		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastric volvulus		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	14 / 8803 (0.16%)	13 / 8801 (0.15%)
occurrences causally related to treatment / all	5 / 14	2 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal ulcer		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	3 / 8803 (0.03%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	1 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal disorder		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	22 / 8803 (0.25%)	15 / 8801 (0.17%)
occurrences causally related to treatment / all	1 / 22	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 2
Gastrointestinal inflammation		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal oedema		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal polyp		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal vascular malformation haemorrhagic		

subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal wall thickening		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	12 / 8803 (0.14%)	13 / 8801 (0.15%)
occurrences causally related to treatment / all	5 / 13	5 / 13
deaths causally related to treatment / all	0 / 0	0 / 1
Haematemesis		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Haematochezia		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	4 / 8803 (0.05%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 4	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		

subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus paralytic		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Impaired gastric emptying		
subjects affected / exposed	4 / 8803 (0.05%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated inguinal hernia		
subjects affected / exposed	4 / 8803 (0.05%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated umbilical hernia		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	39 / 8803 (0.44%)	24 / 8801 (0.27%)
occurrences causally related to treatment / all	1 / 41	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haematoma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal polyp		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		

subjects affected / exposed	11 / 8803 (0.12%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	2 / 11	2 / 10
deaths causally related to treatment / all	0 / 2	0 / 0
Intestinal ischaemia		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Intestinal haematoma		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Irritable bowel syndrome		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal haemorrhage		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal obstruction		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Large intestine polyp		
subjects affected / exposed	11 / 8803 (0.12%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	0 / 11	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Leukoplakia oral		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	3 / 8803 (0.03%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Malabsorption		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mechanical ileus		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-Weiss syndrome		
subjects affected / exposed	6 / 8803 (0.07%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	2 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery embolism		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric vein thrombosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Narcotic bowel syndrome		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	12 / 8803 (0.14%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	9 / 12	3 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema mouth		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive pancreatitis		
subjects affected / exposed	4 / 8803 (0.05%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	1 / 4	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Oesophageal disorder		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal polyp		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal stenosis		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		

subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	3 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis ulcerative		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oedematous pancreatitis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic cyst		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	5 / 8803 (0.06%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	3 / 5	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	9 / 8803 (0.10%)	14 / 8801 (0.16%)
occurrences causally related to treatment / all	4 / 12	5 / 15
deaths causally related to treatment / all	2 / 2	0 / 0
Peptic ulcer		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngo-oesophageal diverticulum		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Portal hypertensive gastropathy		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	3 / 8803 (0.03%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal prolapse		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Reflux gastritis		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haematoma		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal obstruction		

subjects affected / exposed	10 / 8803 (0.11%)	10 / 8801 (0.11%)
occurrences causally related to treatment / all	1 / 10	2 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Strangulated umbilical hernia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subileus		
subjects affected / exposed	0 / 8803 (0.00%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Terminal ileitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toothache		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia		
subjects affected / exposed	9 / 8803 (0.10%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	1 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	12 / 8803 (0.14%)	14 / 8801 (0.16%)
occurrences causally related to treatment / all	0 / 13	1 / 14
deaths causally related to treatment / all	0 / 0	0 / 2
Varices oesophageal		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Volvulus		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vomiting		
subjects affected / exposed	18 / 8803 (0.20%)	12 / 8801 (0.14%)
occurrences causally related to treatment / all	12 / 18	3 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal hernia obstructive		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acquired oesophageal web		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diaphragmatic hernia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal ulcer haemorrhage		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Erosive oesophagitis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal pseudo-obstruction		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Intra-abdominal haemorrhage		

subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal ulcer			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis relapsing			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal spasm			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic floor dysfunction			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctitis			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative gastritis			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			

subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blister			
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dermatitis			
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis contact			
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ecchymosis			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema nummular			

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Excessive skin		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperhidrosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Purpura fulminans		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Purpura		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin oedema		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin ulcer		
subjects affected / exposed	3 / 8803 (0.03%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Stasis dermatitis		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lichenoid keratosis			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pemphigoid			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic lupus erythematosus rash			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	79 / 8803 (0.90%)	105 / 8801 (1.19%)	
occurrences causally related to treatment / all	12 / 87	6 / 116	
deaths causally related to treatment / all	0 / 5	0 / 6	
Anticoagulant-related nephropathy			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder stenosis			

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus bladder		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urethral		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		
subjects affected / exposed	7 / 8803 (0.08%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	1 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		
subjects affected / exposed	7 / 8803 (0.08%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	1 / 7	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Dysuria		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Focal segmental glomerulosclerosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		

subjects affected / exposed	16 / 8803 (0.18%)	11 / 8801 (0.12%)
occurrences causally related to treatment / all	1 / 17	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	6 / 8803 (0.07%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 6	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Incontinence		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney fibrosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower urinary tract symptoms		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Microalbuminuria		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Micturition urgency		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	25 / 8803 (0.28%)	24 / 8801 (0.27%)
occurrences causally related to treatment / all	3 / 27	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrosclerosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oliguria		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvi-ureteric obstruction		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyuria		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prerenal failure		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Proteinuria		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal mass		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	0 / 8803 (0.00%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	5 / 8803 (0.06%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cortical necrosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 4	1 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Renal impairment		
subjects affected / exposed	3 / 8803 (0.03%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Renal infarct		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular dysfunction		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal vein thrombosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular necrosis		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress urinary incontinence		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcapsular renal haematoma		
subjects affected / exposed	3 / 8803 (0.03%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract obstruction		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric stenosis		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		
subjects affected / exposed	20 / 8803 (0.23%)	10 / 8801 (0.11%)
occurrences causally related to treatment / all	2 / 21	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral meatus stenosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral obstruction		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stenosis		
subjects affected / exposed	4 / 8803 (0.05%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urge incontinence		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary incontinence		
subjects affected / exposed	0 / 8803 (0.00%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention		
subjects affected / exposed	11 / 8803 (0.12%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 11	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Urate nephropathy		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lupus nephritis			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal haematoma			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal pseudoaneurysm			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder haemorrhage			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal mass			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune thyroiditis			
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cushing's syndrome			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			

subjects affected / exposed	7 / 8803 (0.08%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Graves' disease		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperparathyroidism		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperparathyroidism primary		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperaldosteronism		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperthyroidism		
subjects affected / exposed	4 / 8803 (0.05%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoparathyroidism secondary		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypothyroidism		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic goitre		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroiditis			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroiditis acute			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	7 / 8803 (0.08%)	10 / 8801 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	19 / 8803 (0.22%)	11 / 8801 (0.12%)	
occurrences causally related to treatment / all	1 / 19	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthrofibrosis			

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Back disorder		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Back pain		
subjects affected / exposed	14 / 8803 (0.16%)	26 / 8801 (0.30%)
occurrences causally related to treatment / all	0 / 14	1 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Bone deformity		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone fistula		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical spinal stenosis		
subjects affected / exposed	5 / 8803 (0.06%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Compartment syndrome		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		

subjects affected / exposed	0 / 8803 (0.00%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Diastasis recti abdominis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture		
subjects affected / exposed	3 / 8803 (0.03%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Flank pain		
subjects affected / exposed	3 / 8803 (0.03%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibromyalgia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemarthrosis		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Greater trochanteric pain syndrome		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Groin pain		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc disorder		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	16 / 8803 (0.18%)	15 / 8801 (0.17%)
occurrences causally related to treatment / all	0 / 17	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc displacement		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Joint ankylosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint range of motion decreased		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint instability		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint effusion		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Limb discomfort		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	19 / 8803 (0.22%)	15 / 8801 (0.17%)
occurrences causally related to treatment / all	0 / 20	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscopathy		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle haemorrhage		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle necrosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle spasms		

subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		
subjects affected / exposed	1 / 8803 (0.01%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	13 / 8803 (0.15%)	13 / 8801 (0.15%)
occurrences causally related to treatment / all	0 / 14	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		
subjects affected / exposed	4 / 8803 (0.05%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia intercostal		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myopathy		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neck deformity		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neck pain		

subjects affected / exposed	1 / 8803 (0.01%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporosis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	84 / 8803 (0.95%)	79 / 8801 (0.90%)
occurrences causally related to treatment / all	0 / 93	0 / 86
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondrosis		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		
subjects affected / exposed	2 / 8803 (0.02%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporotic fracture		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	5 / 8803 (0.06%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pathological fracture		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		
subjects affected / exposed	2 / 8803 (0.02%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	13 / 8803 (0.15%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 15	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Sacroiliitis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scoliosis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sacral pain		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		

subjects affected / exposed	5 / 8803 (0.06%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal stenosis		
subjects affected / exposed	7 / 8803 (0.08%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal synovial cyst		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	5 / 8803 (0.06%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial cyst		
subjects affected / exposed	4 / 8803 (0.05%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Synovitis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic lupus erythematosus		

subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon disorder		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendonitis		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tenosynovitis stenosans		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tenosynovitis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Undifferentiated spondyloarthritis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral osteophyte		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral foraminal stenosis		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse idiopathic skeletal hyperostosis		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facet joint syndrome			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal retrolisthesis			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abscess limb			
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acinetobacter bacteraemia			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alpha haemolytic streptococcal infection			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	5 / 8803 (0.06%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendiceal abscess			

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	6 / 8803 (0.07%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Appendicitis		
subjects affected / exposed	18 / 8803 (0.20%)	16 / 8801 (0.18%)
occurrences causally related to treatment / all	1 / 18	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		
subjects affected / exposed	1 / 8803 (0.01%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis infective		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial sepsis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atypical pneumonia		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Bacteraemia		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial colitis		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiolitis		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	9 / 8803 (0.10%)	15 / 8801 (0.17%)
occurrences causally related to treatment / all	0 / 9	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis viral		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Burn infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis mycoplasmal		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
COVID-19		
subjects affected / exposed	124 / 8803 (1.41%)	137 / 8801 (1.56%)
occurrences causally related to treatment / all	0 / 126	0 / 137
deaths causally related to treatment / all	0 / 18	0 / 31
COVID-19 pneumonia		
subjects affected / exposed	119 / 8803 (1.35%)	148 / 8801 (1.68%)
occurrences causally related to treatment / all	1 / 119	0 / 148
deaths causally related to treatment / all	0 / 27	0 / 35
Campylobacter gastroenteritis		

subjects affected / exposed	3 / 8803 (0.03%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carbuncle		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	29 / 8803 (0.33%)	41 / 8801 (0.47%)
occurrences causally related to treatment / all	1 / 31	0 / 43
deaths causally related to treatment / all	1 / 1	0 / 0
Cellulitis staphylococcal		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest wall abscess		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicitis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis infective		
subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	1 / 4	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis infective		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Chronic sinusitis		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridial sepsis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	4 / 8803 (0.05%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic abscess		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Complicated appendicitis		
subjects affected / exposed	0 / 8803 (0.00%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Conjunctivitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronavirus infection		
subjects affected / exposed	2 / 8803 (0.02%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		

subjects affected / exposed	5 / 8803 (0.06%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis bacterial		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		
subjects affected / exposed	3 / 8803 (0.03%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue haemorrhagic fever		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related bacteraemia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		
subjects affected / exposed	3 / 8803 (0.03%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		

subjects affected / exposed	14 / 8803 (0.16%)	23 / 8801 (0.26%)
occurrences causally related to treatment / all	1 / 17	4 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal perforated		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	4 / 8803 (0.05%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Endocarditis bacterial		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Endophthalmitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterobacter sepsis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal bacteraemia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis viral		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	10 / 8803 (0.11%)	13 / 8801 (0.15%)
occurrences causally related to treatment / all	0 / 11	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia pyelonephritis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Focal peritonitis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		

subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Gastroenteritis		
subjects affected / exposed	15 / 8803 (0.17%)	11 / 8801 (0.12%)
occurrences causally related to treatment / all	4 / 16	4 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis rotavirus		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis salmonella		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal bacterial overgrowth		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal viral infection		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Graft infection		

subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Giardiasis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma infection		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
H1N1 influenza		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter gastritis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter infection		
subjects affected / exposed	3 / 8803 (0.03%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes ophthalmic		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	2 / 8803 (0.02%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site infection		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious pleural effusion		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected bite		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected cyst		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected lymphocele		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Injection site cellulitis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		

subjects affected / exposed	9 / 8803 (0.10%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	3 / 8803 (0.03%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal gangrene		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Joint abscess		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella urinary tract infection		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella bacteraemia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine infection		
subjects affected / exposed	4 / 8803 (0.05%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngitis		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leptospirosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	3 / 8803 (0.03%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	5 / 8803 (0.06%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Lymphangitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lyme disease		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mastitis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis bacterial		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Meningitis tuberculous		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Mesenteric abscess		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metapneumovirus infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metapneumovirus pneumonia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mycetoma mycotic		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenic sepsis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nosocomial infection		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal candidiasis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmic herpes zoster		
subjects affected / exposed	3 / 8803 (0.03%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	4 / 8803 (0.05%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis chronic		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media chronic		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis externa candida		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paronychia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parotitis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perianal streptococcal infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perineal abscess		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal abscess		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	3 / 8803 (0.03%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	1 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 2
Peritonitis bacterial		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillar abscess		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	89 / 8803 (1.01%)	132 / 8801 (1.50%)
occurrences causally related to treatment / all	0 / 102	2 / 146
deaths causally related to treatment / all	0 / 9	1 / 11
Pneumonia bacterial		
subjects affected / exposed	5 / 8803 (0.06%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumonia chlamydial		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia klebsiella		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia legionella		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia necrotising		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pseudomonal		

subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia streptococcal		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumonia viral		
subjects affected / exposed	2 / 8803 (0.02%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonia aspiration		
subjects affected / exposed	4 / 8803 (0.05%)	9 / 8801 (0.10%)
occurrences causally related to treatment / all	1 / 4	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 3
Post procedural cellulitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural sepsis		
subjects affected / exposed	1 / 8803 (0.01%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	2 / 8803 (0.02%)	6 / 8801 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Post-acute COVID-19 syndrome		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		

subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	8 / 8803 (0.09%)	8 / 8801 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic abscess		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prosthetic valve endocarditis		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Pseudomembranous colitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudoaneurysm infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonal bacteraemia		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate infection		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary sepsis		

subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	11 / 8803 (0.12%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	1 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	4 / 8803 (0.05%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal abscess		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		
subjects affected / exposed	1 / 8803 (0.01%)	5 / 8801 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Respiratory tract infection viral		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
SARS-CoV-2 sepsis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Rhinovirus infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salmonella sepsis		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salmonellosis		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal abscess		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal cellulitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal infection		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	36 / 8803 (0.41%)	35 / 8801 (0.40%)
occurrences causally related to treatment / all	0 / 36	1 / 35
deaths causally related to treatment / all	0 / 6	0 / 10
Septic shock		
subjects affected / exposed	11 / 8803 (0.12%)	15 / 8801 (0.17%)
occurrences causally related to treatment / all	1 / 12	0 / 15
deaths causally related to treatment / all	0 / 5	0 / 8
Serratia bacteraemia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinusitis		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord abscess		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		
subjects affected / exposed	3 / 8803 (0.03%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Streptococcal sepsis		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal bacteraemia		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subperiosteal abscess		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis bacterial		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth abscess		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection pseudomonal		

subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract candidiasis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	32 / 8803 (0.36%)	43 / 8801 (0.49%)
occurrences causally related to treatment / all	1 / 40	0 / 46
deaths causally related to treatment / all	0 / 1	0 / 1
Urinary tract infection bacterial		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection enterococcal		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	14 / 8803 (0.16%)	14 / 8801 (0.16%)
occurrences causally related to treatment / all	0 / 15	0 / 15
deaths causally related to treatment / all	0 / 1	0 / 0
Vascular device infection		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Vascular graft infection		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vestibular neuronitis		

subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Viral upper respiratory tract infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral diarrhoea		
subjects affected / exposed	1 / 8803 (0.01%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection pseudomonas		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection staphylococcal		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Wound sepsis		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal abscess		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal sepsis		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Wound infection		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection bacterial		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial pyelonephritis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cellulitis orbital		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Central nervous system infection		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Clostridium difficile infection		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer helicobacter		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes simplex meningitis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis bacterial		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infective spondylitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella sepsis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal abscess		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Norovirus infection		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Onychomycosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmic herpes simplex		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising fasciitis		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal abscess		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia staphylococcal		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraspinal abscess		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parotid abscess		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia influenzal		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic encephalopathy			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stoma site infection			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdiaphragmatic abscess			
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	19 / 8803 (0.22%)	14 / 8801 (0.16%)	
occurrences causally related to treatment / all	3 / 21	3 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketosis		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Failure to thrive		
subjects affected / exposed	0 / 8803 (0.00%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Food intolerance		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	1 / 8803 (0.01%)	3 / 8801 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		

subjects affected / exposed	3 / 8803 (0.03%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Hypervolaemia		
subjects affected / exposed	1 / 8803 (0.01%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	3 / 8803 (0.03%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	2 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	19 / 8803 (0.22%)	18 / 8801 (0.20%)
occurrences causally related to treatment / all	2 / 25	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	5 / 8803 (0.06%)	7 / 8801 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	2 / 8803 (0.02%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochloraemia		

subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic acidosis		
subjects affected / exposed	2 / 8803 (0.02%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Malnutrition		
subjects affected / exposed	2 / 8803 (0.02%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metabolic acidosis		
subjects affected / exposed	1 / 8803 (0.01%)	2 / 8801 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Obesity		
subjects affected / exposed	0 / 8803 (0.00%)	4 / 8801 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Type 1 diabetes mellitus		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tumour lysis syndrome		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	3 / 8803 (0.03%)	15 / 8801 (0.17%)
occurrences causally related to treatment / all	0 / 3	2 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Vitamin D deficiency		

subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acidosis hyperchloraemic		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adult failure to thrive		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoalbuminaemia		
subjects affected / exposed	0 / 8803 (0.00%)	1 / 8801 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hypernatraemia		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vitamin B12 deficiency		
subjects affected / exposed	1 / 8803 (0.01%)	0 / 8801 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Semaglutide	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3944 / 8803 (44.80%)	2440 / 8801 (27.72%)	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	715 / 8803 (8.12%)	231 / 8801 (2.62%)	
occurrences (all)	855	256	
Vomiting			
subjects affected / exposed	576 / 8803 (6.54%)	87 / 8801 (0.99%)	
occurrences (all)	752	106	
Dyspepsia			
subjects affected / exposed	468 / 8803 (5.32%)	94 / 8801 (1.07%)	
occurrences (all)	629	102	
Nausea			
subjects affected / exposed	1592 / 8803 (18.08%)	337 / 8801 (3.83%)	
occurrences (all)	2260	414	
Diarrhoea			
subjects affected / exposed	933 / 8803 (10.60%)	353 / 8801 (4.01%)	
occurrences (all)	1417	429	
Infections and infestations			
COVID-19			
subjects affected / exposed	1787 / 8803 (20.30%)	1785 / 8801 (20.28%)	
occurrences (all)	1933	1935	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	585 / 8803 (6.65%)	112 / 8801 (1.27%)	
occurrences (all)	655	123	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 January 2021	The protocol was amended to include: 1) wash-out period and consequently follow-up period and period for contraception use after treatment discontinuation, updated to 5 weeks. 2) WRSSM deleted from supportive secondary endpoints and included in exploratory endpoints. 3) Text revised to simplify the requirements for the naming of the specific process document. 4) Text included for collection of COVID-19 concomitant medication.
09 February 2022	The protocol was amended to include: 1) Inclusion of HF composite endpoint in the testing hierarchy. 2) Co-participation in COVID-19 trials was not allowed in Algeria and Germany due to local requirements

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/32916609>

<http://www.ncbi.nlm.nih.gov/pubmed/36502289>