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	• Correction of full data set The update corresponding to the time frame in the study.

Trial information

Trial identification

Sponsor protocol code	EX9536-4388

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

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

End points

End points reporting groups

Reporting group title	Semaglutide

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

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

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

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

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

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

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 compete the trial and did not withraw 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

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

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 evalulated 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

Dictionary used

Dictionary name	MedDRA
Dictionary version	26

Reporting groups

Reporting group title	Semaglutide

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

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	
Hypertransaminasaemia			

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	
VIth 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	
Epiploic 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