Clinical trial results:
Semaglutide cardiovascular outcomes trial in patients with type 2 diabetes (SOUL)

Summary

EudraCT number	2018-003141-42
Trial protocol	DK NL GB SK DE BE AT ES CZ FR HR IT RO
Global end of trial date	23 August 2024

Results information

Result version number	v1 (current)
This version publication date	09 September 2025
First version publication date	09 September 2025

Trial information

Trial identification

Sponsor protocol code	EX9924-4473

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03914326
WHO universal trial number (UTN)	U1111-1218-5368

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	19 September 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 August 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that oral semaglutide lowers the risk of major adverse cardiovascular events (MACE) compared to placebo, both added to standard of care in patients with type 2 diabetes (T2D) and at high risk of cardiovascular (CV) events.

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki (Oct 2013) and ICH Good Clinical Practice, including archiving of essential documents (May 1996) and EN ISO 14155 Part 1 and 2 and FDA 21 CFR 312.120.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 June 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 413
Country: Number of subjects enrolled	Austria: 111
Country: Number of subjects enrolled	Belgium: 110
Country: Number of subjects enrolled	Brazil: 283
Country: Number of subjects enrolled	Canada: 314
Country: Number of subjects enrolled	China: 60
Country: Number of subjects enrolled	Colombia: 111
Country: Number of subjects enrolled	Czechia: 181
Country: Number of subjects enrolled	Germany: 313
Country: Number of subjects enrolled	Denmark: 110
Country: Number of subjects enrolled	Spain: 205
Country: Number of subjects enrolled	France: 90
Country: Number of subjects enrolled	United Kingdom: 375
Country: Number of subjects enrolled	Hong Kong: 80
Country: Number of subjects enrolled	Croatia: 191
Country: Number of subjects enrolled	India: 788
Country: Number of subjects enrolled	Israel: 189
Country: Number of subjects enrolled	Italy: 199
Country: Number of subjects enrolled	Japan: 408

Country: Number of subjects enrolled	Korea, Republic of: 148
Country: Number of subjects enrolled	Mexico: 417
Country: Number of subjects enrolled	Malaysia: 206
Country: Number of subjects enrolled	Netherlands: 171
Country: Number of subjects enrolled	Romania: 200
Country: Number of subjects enrolled	Russian Federation: 535
Country: Number of subjects enrolled	Serbia: 314
Country: Number of subjects enrolled	Slovakia: 317
Country: Number of subjects enrolled	Thailand: 205
Country: Number of subjects enrolled	Türkiye: 314
Country: Number of subjects enrolled	Taiwan: 80
Country: Number of subjects enrolled	Ukraine: 329
Country: Number of subjects enrolled	United States: 1598
Country: Number of subjects enrolled	South Africa: 285
Worldwide total number of subjects	9650
EEA total number of subjects	2198

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)	4034
From 65 to 84 years	5581
85 years and over	35

Subject disposition

Recruitment

Recruitment details:

The trial was conducted at 446 sites in 34 countries.

Pre-assignment

Screening details:

A total of 9,651 subjects were enrolled/randomized (1:1) to treatment with oral semaglutide (4,825 subjects) or placebo (4,826 subjects). One subject was randomised twice in the trial. Thus, the FAS comprised 9,650 subjects (4,825 subjects in the oral semaglutide group and 4,825 subjects in the placebo group).

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	Investigator, Subject, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Oral Semaglutide

Arm description:

Subjects were to receive once daily semaglutide tablets with a dose escalation every 4 weeks in doses 3 mg (week 0 to week 4), 7 mg (week 4 to week 8) until maintenance dose of 14 mg was reached and maintained till the end of treatment visit (up to week 260).

Arm type	Experimental
Investigational medicinal product name	Semaglutide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Semaglutide was administered orally once daily.

Arm title	Placebo

Arm description:

Subjects were to receive once daily placebo matching oral semaglutide until end of the treatment visit (up to week 260).

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Semaglutide matched placebo was administered orally once daily.

Number of subjects in period 1	Oral Semaglutide	Placebo
Started	4825	4825
Full analysis set	4825	4825
Exposed	4814	4816
Completed	4755	4740
Not completed	70	85
Consent withdrawn by subject	27	34
Lost to follow-up	43	51

Baseline characteristics

Reporting groups	
Reporting group title	Oral Semaglutide
Reporting group description:	
Subjects were to receive once daily semaglutide tablets with a dose escalation every 4 weeks in doses 3 mg (week 0 to week 4), 7 mg (week 4 to week 8) until maintenance dose of 14 mg was reached and maintained till the end of treatment visit (up to week 260).	
Reporting group title	Placebo
Reporting group description:	
Subjects were to receive once daily placebo matching oral semaglutide until end of the treatment visit (up to week 260).	

Reporting group values	Oral Semaglutide	Placebo	Total
Number of subjects	4825	4825	9650
Age Categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2058	1976	4034
From 65-84 years	2750	2831	5581
85 years and over	17	18	35
Age Continuous			
Units: years			
arithmetic mean	66.1	66.1	
standard deviation	± 7.6	± 7.5	-
Gender Categorical			
Units: Subjects			
Female	1376	1414	2790
Male	3449	3411	6860

End points

End points reporting groups

Reporting group title	Oral Semaglutide

Reporting group description:

Subjects were to receive once daily semaglutide tablets with a dose escalation every 4 weeks in doses 3 mg (week 0 to week 4), 7 mg (week 4 to week 8) until maintenance dose of 14 mg was reached and maintained till the end of treatment visit (up to week 260).

Reporting group title	Placebo

Reporting group description:

Subjects were to receive once daily placebo matching oral semaglutide until end of the treatment visit (up to week 260).

Primary: Number of subjects from randomization to first occurrence of a major adverse cardiovascular event (MACE), a composite endpoint consisting of: cardiovascular (CV) death/non-fatal myocardial infarction/non-fatal stroke

End point title	Number of subjects from randomization to first occurrence of a major adverse cardiovascular event (MACE), a composite endpoint consisting of: cardiovascular (CV) death/non-fatal myocardial infarction/non-fatal stroke

End point description:

Number of subjects with first occurrence of EAC (event adjudication committee) confirmed major adverse cardiovascular event (MACE), a composite end-point. i.e., from time of randomization to first occurrence of cardiovascular (CV) death, non-fatal myocardial infarction and non-fatal stroke combined data during in-trial period were reported. In-trial observation period was defined as the period from date of randomization to the first of (both inclusive): date of follow-up visit, date when subject withdrew consent, date of last contact with subject (for subject lost to follow-up), and date of death. FAS included all unique randomized subject who were grouped according to the treatment assigned at randomization.

End point type	Primary

End point timeframe:

From randomisation (week 0) up to week 265

End point values	Oral Semaglutide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4825	4825		
Units: Subjects	579	668		

Statistical analyses

Statistical analysis title	Oral Semaglutide versus Placebo

Statistical analysis description:

Time from randomisation to first EAC-confirmed MACE was analysed using a Cox proportional hazards model with treatment as categorical fixed factor.

Comparison groups	Oral Semaglutide v Placebo

Number of subjects included in analysis	9650
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0028
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	0.96

Secondary: Number of subjects from randomization to first occurrence of CV death;renal death;onset of persistent≥50% reduction in eGFR(CKD-EPI);onset of persistent eGFR(CKD-EPI)<15 mL/min/1.73m^2;initiation of chronic renal replacement therapy

End point title	Number of subjects from randomization to first occurrence of CV death;renal death;onset of persistent≥50% reduction in eGFR(CKD-EPI);onset of persistent eGFR(CKD-EPI)<15 mL/min/1.73m^2;initiation of chronic renal replacement therapy

End point description:

Number of subjects with first occurrence of a composite endpoint. i.e., from time of randomization to first occurrence of CV death, renal death, onset of persistent greater than or equal to (≥) 50% reduction in estimated glomerular filtration rate (eGFR) (chronic kidney disease epidemiology collaboration CKD-EPI), onset of persistent eGFR (CKD-EPI) less than (<)15 milliliters per minute per 1.73 square meters (mL/min/1.73 m^2), initiation of chronic renal replacement therapy (dialysis or kidney transplantation) combined data during in-trial period were reported. In-trial observation period was defined as the period from date of randomization to the first of (both inclusive): date of follow-up visit, date when subject withdrew consent, date of last contact with subject (for subject lost to follow-up), and date of death. FAS included all unique randomized subject who were grouped according to the treatment assigned at randomization.

End point type	Secondary

End point timeframe:

From randomisation (week 0) up to week 265

End point values	Oral Semaglutide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4825	4825		
Units: Subjects	403	435		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects from randomization to time of occurrence of CV

death

End point title	Number of subjects from randomization to time of occurrence of CV death

End point description:

Number of subjects from time of randomization to time to occurrence of EAC confirmed CV death during in-trial period were reported. In-trial observation period was defined as the period from date of randomization to the first of (both inclusive): date of follow-up visit, date when subject withdrew consent, date of last contact with subject (for subject lost to follow-up), and date of death. FAS included all unique randomized subject who were grouped according to the treatment assigned at randomization.

End point type	Secondary

End point timeframe:

From randomisation (week 0) up to week 265

End point values	Oral Semaglutide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4825	4825		
Units: Subjects	301	320		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects from randomization to first occurrence of major adverse limb events (MALE), a composite endpoint consisting of: acute limb ischemia hospitalisation/chronic limb ischemia hospitalisation

End point title	Number of subjects from randomization to first occurrence of major adverse limb events (MALE), a composite endpoint consisting of: acute limb ischemia hospitalisation/chronic limb ischemia hospitalisation

End point description:

Number of subjects from randomization to first occurrence of EAC confirmed major adverse limb events (MALE), a composite endpoint consisting of: acute limb ischemia hospitalisation/chronic limb ischemia hospitalisation combined data during in-trial period were reported. In-trial observation period was defined as the period from date of randomization to the first of (both inclusive): date of follow-up visit, date when subject withdrew consent, date of last contact with subject (for subject lost to follow-up), and date of death. FAS included all unique randomized subject who were grouped according to the treatment assigned at randomization.

End point type	Secondary

End point timeframe:

From randomisation (week 0) up to week 265

End point values	Oral Semaglutide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4825	4825		
Units: Subjects	71	99		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Week 0 up to Week 265

Adverse event reporting additional description:

The safety evaluation data as reported by the investigator was based on the FAS using the in-trial observation period which is defined as the period from date of randomization to the first of (both inclusive):date of follow-up visit,date when subject withdrew consent,date of last contact with subject, and date of death.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22

Reporting groups

Reporting group title	Placebo

Reporting group description:

Subjects were to receive once daily placebo matching oral semaglutide until end of the treatment visit (up to week 260).

Reporting group title	Oral Semaglutide

Reporting group description:

Subjects were to receive once daily semaglutide tablets with a dose escalation every 4 weeks in doses 3 mg (week 0 to week 4), 7 mg (week 4 to week 8) until maintenance dose of 14 mg was reached and maintained till the end of treatment visit (up to week 260).

Serious adverse events	Placebo	Oral Semaglutide	
Total subjects affected by serious adverse events			
subjects affected / exposed	2427 / 4825 (50.30%)	2312 / 4825 (47.92%)	
number of deaths (all causes)	579	526	
number of deaths resulting from adverse events	20	24	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute myeloid leukaemia			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma pancreas			

subjects affected / exposed	2 / 4825 (0.04%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 2	
Adenocarcinoma			
subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Adenocarcinoma gastric			
subjects affected / exposed	4 / 4825 (0.08%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma metastatic			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	11 / 4825 (0.23%)	13 / 4825 (0.27%)	
occurrences causally related to treatment / all	0 / 11	1 / 13	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenoid cystic carcinoma of salivary gland			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal neoplasm			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiosarcoma			

subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anogenital warts			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Apocrine breast carcinoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	9 / 4825 (0.19%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	0 / 9	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer recurrent			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign biliary neoplasm			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign lung neoplasm			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign ovarian tumour			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign pancreatic neoplasm			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign renal neoplasm			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct adenocarcinoma			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder papilloma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	9 / 4825 (0.19%)	12 / 4825 (0.25%)	
occurrences causally related to treatment / all	1 / 9	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 2	
Bladder transitional cell carcinoma recurrent			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Breast cancer in situ			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer recurrent			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage I			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage III			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial carcinoma			

subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Breast cancer			
subjects affected / exposed	3 / 4825 (0.06%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cancer pain			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac valve fibroelastoma			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix cancer metastatic			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cervix carcinoma			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	5 / 4825 (0.10%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	1 / 5	1 / 7	
deaths causally related to treatment / all	0 / 3	1 / 3	
Cholesteatoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia			

subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear cell renal cell carcinoma			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	9 / 4825 (0.19%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	1 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Colon cancer metastatic			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Colon cancer recurrent			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer stage IV			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Colorectal adenocarcinoma			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colorectal adenoma			

subjects affected / exposed	3 / 4825 (0.06%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 3	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma			
subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
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 III			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	1 / 2	
deaths causally related to treatment / all	0 / 1	1 / 2	
Endometrial adenocarcinoma			
subjects affected / exposed	5 / 4825 (0.10%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential thrombocythaemia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Follicular lymphoma stage IV			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder cancer metastatic			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Gastric neoplasm			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	1 / 2	0 / 4	
deaths causally related to treatment / all	1 / 1	0 / 1	
Gastric adenoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal lymphoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal tract adenoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glottis carcinoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma of liver			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HER2 positive breast cancer			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic adenoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Hepatic cancer metastatic			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic cancer stage IV			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic neoplasm			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary cancer			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	12 / 4825 (0.25%)	13 / 4825 (0.27%)	
occurrences causally related to treatment / all	2 / 12	1 / 14	
deaths causally related to treatment / all	2 / 8	0 / 8	
Hodgkin's disease nodular sclerosis stage III			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hormone receptor positive breast cancer			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal adenocarcinoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive lobular breast carcinoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive papillary breast carcinoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			

subjects affected / exposed	5 / 4825 (0.10%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive breast carcinoma			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Kaposi's sarcoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal squamous cell carcinoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine benign neoplasm			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (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	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leiomyoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip and/or oral cavity cancer			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			

subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liposarcoma			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung adenocarcinoma stage I			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	7 / 4825 (0.15%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 2	0 / 2	
Lung adenocarcinoma recurrent			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma stage IV			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Lung cancer metastatic			
subjects affected / exposed	3 / 4825 (0.06%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 3	
Lung neoplasm			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung neoplasm malignant			

subjects affected / exposed	6 / 4825 (0.12%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 6	1 / 6	
deaths causally related to treatment / all	0 / 3	1 / 3	
Lung squamous cell carcinoma metastatic			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Lung squamous cell carcinoma stage III			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung squamous cell carcinoma stage IV			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant melanoma			
subjects affected / exposed	4 / 4825 (0.08%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	1 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma in situ			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma stage I			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma stage II			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mantle cell lymphoma			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medullary thyroid cancer			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma benign			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic neoplasm			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to abdominal wall			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone			

subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone marrow			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to liver			
subjects affected / exposed	9 / 4825 (0.19%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 9	0 / 0	
deaths causally related to treatment / all	0 / 6	0 / 0	
Metastases to lung			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to lymph nodes			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
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 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to pleura			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic bronchial carcinoma			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic carcinoma of the bladder			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Metastatic gastric cancer			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 2	
Metastatic malignant melanoma			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Metastatic squamous cell carcinoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic renal cell carcinoma			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myelodysplastic syndrome			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Myelofibrosis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Myeloproliferative neoplasm			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngeal cancer metastatic			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Neoplasm malignant			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neoplasm prostate			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodular melanoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma metastatic			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma of the skin			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine tumour			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer metastatic			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophageal carcinoma			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal adenocarcinoma			
subjects affected / exposed	4 / 4825 (0.08%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal cancer metastatic			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer stage IV			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal squamous cell carcinoma			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer metastatic			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ovarian cancer stage IV			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ovarian germ cell teratoma benign			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian neoplasm			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma metastatic			

subjects affected / exposed	2 / 4825 (0.04%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	1 / 2	0 / 6	
deaths causally related to treatment / all	1 / 2	0 / 6	
Pancreatic carcinoma stage IV			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	1 / 2	0 / 0	
Pancreatic neuroendocrine tumour			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic neuroendocrine tumour metastatic			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Papillary cystadenoma lymphomatosum			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	1 / 4825 (0.02%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	4 / 4825 (0.08%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 4	3 / 6	
deaths causally related to treatment / all	0 / 1	2 / 3	
Parathyroid tumour benign			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasmacytoma			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	3 / 4825 (0.06%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Plasma cell myeloma recurrent			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasmablastic lymphoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural mesothelioma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Primary myelofibrosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer metastatic			
subjects affected / exposed	7 / 4825 (0.15%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Prostate cancer stage I			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage II			

subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage III			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage IV			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic adenoma			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	23 / 4825 (0.48%)	40 / 4825 (0.83%)	
occurrences causally related to treatment / all	1 / 23	2 / 40	
deaths causally related to treatment / all	0 / 1	0 / 1	
Rectal adenocarcinoma			
subjects affected / exposed	5 / 4825 (0.10%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Rectal cancer			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Rectal cancer stage II			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid cancer			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid cancer stage IV			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	0 / 4825 (0.00%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer metastatic			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal cancer stage I			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	2 / 4825 (0.04%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal oncocytoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland adenoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland cancer			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Small cell lung cancer			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Small cell lung cancer metastatic			
subjects affected / exposed	3 / 4825 (0.06%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 3	
Small intestine adenocarcinoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestine carcinoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	4 / 4825 (0.08%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 1	
Squamous cell carcinoma of skin			

subjects affected / exposed	6 / 4825 (0.12%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the cervix			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Spinal meningioma benign			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer metastatic			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer metastatic			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thymic carcinoma			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue carcinoma stage I			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 the renal pelvis and ureter			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	4 / 4825 (0.08%)	12 / 4825 (0.25%)	
occurrences causally related to treatment / all	0 / 4	1 / 12	
deaths causally related to treatment / all	0 / 0	0 / 1	
Transitional cell carcinoma metastatic			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Tumour of ampulla of Vater			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyosarcoma			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Waldenstrom's macroglobulinaemia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm ruptured			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic aneurysm			
subjects affected / exposed	4 / 4825 (0.08%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic arteriosclerosis			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic dissection			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic occlusion			

subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic thrombosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial rupture			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial stenosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial thrombosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	12 / 4825 (0.25%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	1 / 12	1 / 9	
deaths causally related to treatment / all	1 / 5	1 / 4	
Brachiocephalic arteriosclerosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Deep vein thrombosis			
subjects affected / exposed	11 / 4825 (0.23%)	12 / 4825 (0.25%)	
occurrences causally related to treatment / all	1 / 11	1 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic vascular disorder			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic macroangiopathy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry gangrene			
subjects affected / exposed	6 / 4825 (0.12%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Embolism arterial			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	3 / 4825 (0.06%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery dissection			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery aneurysm			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haematoma			
subjects affected / exposed	4 / 4825 (0.08%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	20 / 4825 (0.41%)	13 / 4825 (0.27%)	
occurrences causally related to treatment / all	1 / 22	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 2	
Hypertensive crisis			
subjects affected / exposed	6 / 4825 (0.12%)	12 / 4825 (0.25%)	
occurrences causally related to treatment / all	0 / 6	1 / 13	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypertensive emergency			
subjects affected / exposed	6 / 4825 (0.12%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive end-organ damage			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive urgency			
subjects affected / exposed	5 / 4825 (0.10%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 5	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	9 / 4825 (0.19%)	27 / 4825 (0.56%)	
occurrences causally related to treatment / all	0 / 9	1 / 27	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hypovolaemic shock			
subjects affected / exposed	4 / 4825 (0.08%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Iliac artery stenosis			
subjects affected / exposed	4 / 4825 (0.08%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent claudication			
subjects affected / exposed	4 / 4825 (0.08%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	1 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic limb pain			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leriche syndrome			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoedema			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant hypertension			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	6 / 4825 (0.12%)	10 / 4825 (0.21%)	
occurrences causally related to treatment / all	2 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penetrating aortic ulcer			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	64 / 4825 (1.33%)	60 / 4825 (1.24%)	
occurrences causally related to treatment / all	1 / 75	3 / 72	
deaths causally related to treatment / all	0 / 3	0 / 2	
Peripheral artery aneurysm			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	11 / 4825 (0.23%)	15 / 4825 (0.31%)	
occurrences causally related to treatment / all	0 / 12	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			

subjects affected / exposed	11 / 4825 (0.23%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	0 / 13	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral circulatory failure			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peripheral ischaemia			
subjects affected / exposed	17 / 4825 (0.35%)	21 / 4825 (0.44%)	
occurrences causally related to treatment / all	0 / 21	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral venous disease			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	8 / 4825 (0.17%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scalp haematoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			

subjects affected / exposed	3 / 4825 (0.06%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 3	
Shock haemorrhagic			
subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Subclavian artery occlusion			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian artery stenosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superficial vein thrombosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subgaleal haematoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Thrombosis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicophlebitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			

subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular occlusion			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stenosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vena cava thrombosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular calcification			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Aortic valve replacement			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula operation			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac resynchronisation therapy			

subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ablation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker insertion			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	2 / 4825 (0.04%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central venous catheter removal			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniotomy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystoprostatectomy			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dialysis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Finger amputation			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric bypass			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemodialysis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip arthroplasty			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable defibrillator replacement			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee arthroplasty			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal polypectomy			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leg amputation			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic surgery			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve repair			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve replacement			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurosurgery			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroidectomy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polypectomy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal transplant			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Revascularisation procedure			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleeve gastrectomy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fusion surgery			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylectomy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transcatheter aortic valve implantation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral prostatectomy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethrotomy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasodilation procedure			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			

Accidental death			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Asthenia			
subjects affected / exposed	10 / 4825 (0.21%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	0 / 10	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 2	
Cardiac death			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chest discomfort			
subjects affected / exposed	3 / 4825 (0.06%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	21 / 4825 (0.44%)	20 / 4825 (0.41%)	
occurrences causally related to treatment / all	1 / 21	2 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chills			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	52 / 4825 (1.08%)	43 / 4825 (0.89%)	
occurrences causally related to treatment / all	1 / 52	0 / 43	
deaths causally related to treatment / all	1 / 52	0 / 43	
Fatigue			

subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Generalised oedema			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing			
subjects affected / exposed	2 / 4825 (0.04%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Implant site dehiscence			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated hernia			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device pain			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 inflammation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site joint pain			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	11 / 4825 (0.23%)	14 / 4825 (0.29%)	
occurrences causally related to treatment / all	0 / 11	0 / 14	
deaths causally related to treatment / all	0 / 9	0 / 13	
Non-cardiac chest pain			
subjects affected / exposed	24 / 4825 (0.50%)	39 / 4825 (0.81%)	
occurrences causally related to treatment / all	3 / 25	1 / 43	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	3 / 4825 (0.06%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pacemaker syndrome			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic mass			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Polyp			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 stenosis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prosthetic cardiac valve regurgitation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	6 / 4825 (0.12%)	15 / 4825 (0.31%)	
occurrences causally related to treatment / all	0 / 6	2 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			

subjects affected / exposed	1 / 4825 (0.02%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sudden death			
subjects affected / exposed	19 / 4825 (0.39%)	17 / 4825 (0.35%)	
occurrences causally related to treatment / all	1 / 19	2 / 17	
deaths causally related to treatment / all	1 / 19	2 / 17	
Sudden cardiac death			
subjects affected / exposed	10 / 4825 (0.21%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	1 / 10	1 / 9	
deaths causally related to treatment / all	1 / 10	1 / 9	
Ulcer			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	1 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	9 / 4825 (0.19%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	1 / 9	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	0 / 4825 (0.00%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Allergy to arthropod sting			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Drug hypersensitivity			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food allergy			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Loss of personal independence in daily activities			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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			

Benign prostatic hyperplasia			
subjects affected / exposed	16 / 4825 (0.33%)	13 / 4825 (0.27%)	
occurrences causally related to treatment / all	1 / 16	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast mass			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus prostatic			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia with cellular atypia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erectile dysfunction			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermenstrual bleeding			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile vascular disorder			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peyronie's disease			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	3 / 4825 (0.06%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterovaginal prolapse			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	18 / 4825 (0.37%)	13 / 4825 (0.27%)	
occurrences causally related to treatment / all	0 / 19	0 / 17	
deaths causally related to treatment / all	0 / 6	0 / 4	
Acute respiratory distress syndrome			
subjects affected / exposed	5 / 4825 (0.10%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 5	1 / 3	
deaths causally related to treatment / all	0 / 4	1 / 2	
Acute respiratory failure			
subjects affected / exposed	50 / 4825 (1.04%)	33 / 4825 (0.68%)	
occurrences causally related to treatment / all	0 / 61	0 / 43	
deaths causally related to treatment / all	0 / 13	0 / 9	
Asphyxia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Asthma			
subjects affected / exposed	1 / 4825 (0.02%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 1	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis chronic			

subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	24 / 4825 (0.50%)	19 / 4825 (0.39%)	
occurrences causally related to treatment / all	0 / 25	0 / 25	
deaths causally related to treatment / all	0 / 5	0 / 3	
Chronic respiratory failure			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cough			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	24 / 4825 (0.50%)	19 / 4825 (0.39%)	
occurrences causally related to treatment / all	1 / 26	1 / 19	
deaths causally related to treatment / all	0 / 4	0 / 1	
Dyspnoea exertional			
subjects affected / exposed	6 / 4825 (0.12%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 6	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eosinophilic pneumonia			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	6 / 4825 (0.12%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	1 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	3 / 4825 (0.06%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemothorax			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiccups			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypoxia			
subjects affected / exposed	5 / 4825 (0.10%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Interstitial lung disease			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal oedema			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung consolidation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infiltration			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung opacity			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal polyps			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive airways disorder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive sleep apnoea syndrome			
subjects affected / exposed	3 / 4825 (0.06%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthopnoea			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal haemorrhage			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pickwickian syndrome			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural thickening			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	15 / 4825 (0.31%)	16 / 4825 (0.33%)	
occurrences causally related to treatment / all	2 / 16	0 / 18	
deaths causally related to treatment / all	0 / 2	0 / 4	
Pneumonitis			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Pneumothorax			
subjects affected / exposed	3 / 4825 (0.06%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	2 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis aspiration			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary embolism			

subjects affected / exposed	19 / 4825 (0.39%)	17 / 4825 (0.35%)	
occurrences causally related to treatment / all	1 / 20	1 / 17	
deaths causally related to treatment / all	0 / 6	0 / 6	
Pulmonary fibrosis			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary haemorrhage			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary hypertension			
subjects affected / exposed	5 / 4825 (0.10%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pulmonary mass			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	18 / 4825 (0.37%)	10 / 4825 (0.21%)	
occurrences causally related to treatment / all	0 / 20	0 / 10	
deaths causally related to treatment / all	0 / 2	0 / 0	
Respiratory acidosis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory depression			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory failure			
subjects affected / exposed	27 / 4825 (0.56%)	24 / 4825 (0.50%)	
occurrences causally related to treatment / all	0 / 28	1 / 24	
deaths causally related to treatment / all	0 / 9	0 / 12	
Sleep apnoea syndrome			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic haemorrhage			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord cyst			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord leukoplakia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord polyp			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol use disorder			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			

subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 3	
Confusional state			
subjects affected / exposed	7 / 4825 (0.15%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	1 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	4 / 4825 (0.08%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Delirium			
subjects affected / exposed	7 / 4825 (0.15%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Delusion			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delusional disorder, unspecified type			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised anxiety disorder			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination, visual			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insomnia			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	1 / 4825 (0.02%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mania			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
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	1 / 4825 (0.02%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	0 / 1	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic attack			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic disorder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tobacco abuse			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	4 / 4825 (0.08%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device power source issue			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lead dislodgement			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prosthetic cardiac valve malfunction			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stent malfunction			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis in device			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute cholecystitis necrotic			
subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatic failure			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Alcoholic liver disease			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune hepatitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	6 / 4825 (0.12%)	8 / 4825 (0.17%)	
occurrences causally related to treatment / all	1 / 6	4 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary obstruction			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac cirrhosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	9 / 4825 (0.19%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	3 / 9	4 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cholecystitis chronic			
subjects affected / exposed	6 / 4825 (0.12%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	4 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	19 / 4825 (0.39%)	31 / 4825 (0.64%)	
occurrences causally related to treatment / all	7 / 19	10 / 36	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cholestasis			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cholangitis acute			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis chronic			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	12 / 4825 (0.25%)	17 / 4825 (0.35%)	
occurrences causally related to treatment / all	5 / 12	6 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	30 / 4825 (0.62%)	29 / 4825 (0.60%)	
occurrences causally related to treatment / all	10 / 30	12 / 29	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder rupture			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder oedema			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	6 / 4825 (0.12%)	8 / 4825 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 2	
Hepatic failure			

subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hepatic function abnormal			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatic infarction			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic lesion			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatomegaly			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatorenal syndrome			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocholecystis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (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	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic hepatitis			

subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Jaundice cholestatic			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	1 / 2	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-alcoholic fatty liver			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Porcelain gallbladder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Angiocardiogram			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Anticoagulation drug level above therapeutic				
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Blood potassium increased				
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Blood creatinine increased				
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Blood glucose abnormal				
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Blood glucose fluctuation				
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)		
occurrences causally related to treatment / all	0 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Blood glucose increased				
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
Blood pressure increased				
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Blood urine present				

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood sodium decreased			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheterisation cardiac			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram ST segment depression			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exercise electrocardiogram abnormal			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oxygen saturation decreased			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic specific antigen increased			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Red blood cell sedimentation rate increased			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			

Accident at home			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic leak			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal bite			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	11 / 4825 (0.23%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	1 / 11	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic restenosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula occlusion			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula thrombosis			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod bite			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder injury			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain contusion			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns third degree			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Buttock injury			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbon monoxide poisoning			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery restenosis			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract operation complication			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cement embolism			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
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	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Comminuted fracture			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	5 / 4825 (0.10%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	4 / 4825 (0.08%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Corneal abrasion			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery restenosis			
subjects affected / exposed	11 / 4825 (0.23%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	1 / 13	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary bypass stenosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary vascular graft occlusion			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary vascular graft stenosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.12%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 1	
Craniofacial fracture			
subjects affected / exposed	1 / 4825 (0.02%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Cystitis radiation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decompression sickness			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eschar			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extra-axial haemorrhage			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid injury			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	44 / 4825 (0.91%)	25 / 4825 (0.52%)	
occurrences causally related to treatment / all	0 / 50	0 / 26	
deaths causally related to treatment / all	0 / 4	0 / 1	
Extraskeletal ossification			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	23 / 4825 (0.48%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	0 / 23	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 0	
Femoral neck fracture			
subjects affected / exposed	16 / 4825 (0.33%)	10 / 4825 (0.21%)	
occurrences causally related to treatment / all	1 / 16	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flail chest			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fractured sacrum			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis radiation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal stoma necrosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gun shot wound			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	6 / 4825 (0.12%)	14 / 4825 (0.29%)	
occurrences causally related to treatment / all	0 / 6	1 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			

subjects affected / exposed	14 / 4825 (0.29%)	10 / 4825 (0.21%)	
occurrences causally related to treatment / all	0 / 15	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	16 / 4825 (0.33%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	2 / 16	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Immunisation reaction			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intentional overdose			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	3 / 4825 (0.06%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw fracture			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			

subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb crushing injury			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	6 / 4825 (0.12%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	
Limb traumatic amputation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	4 / 4825 (0.08%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	4 / 4825 (0.08%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			

subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
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	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Muscle injury			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle rupture			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal injury			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	3 / 4825 (0.06%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			

subjects affected / exposed	4 / 4825 (0.08%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 4	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery restenosis			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve injury			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprocedural myocardial infarction			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprosthetic fracture			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax traumatic			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Poisoning			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Post procedural stroke			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Post-traumatic neck syndrome			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural myocardial infarction			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematuria			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 4825 (0.00%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural hypotension			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural inflammation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative delirium			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural shock			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Postoperative thoracic procedure complication			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative thrombosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound complication			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural dizziness			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural intestinal perforation			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural nausea			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative ileus			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural vomiting			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary contusion			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation pneumonitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	7 / 4825 (0.15%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal injury			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			

subjects affected / exposed	14 / 4825 (0.29%)	12 / 4825 (0.25%)	
occurrences causally related to treatment / all	2 / 14	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	10 / 4825 (0.21%)	12 / 4825 (0.25%)	
occurrences causally related to treatment / all	0 / 10	1 / 12	
deaths causally related to treatment / all	0 / 4	0 / 2	
Scapula fracture			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shoulder fracture			
subjects affected / exposed	5 / 4825 (0.10%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shunt stenosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skeletal injury			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin abrasion			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			
subjects affected / exposed	2 / 4825 (0.04%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fracture			

subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fractured base			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Snake bite			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Spinal cord injury cervical			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic rupture			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal fracture			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial rupture			

subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	5 / 4825 (0.10%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Subdural haematoma			
subjects affected / exposed	9 / 4825 (0.19%)	12 / 4825 (0.25%)	
occurrences causally related to treatment / all	0 / 9	0 / 14	
deaths causally related to treatment / all	0 / 3	0 / 1	
Thermal burn			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Third degree chemical burn of skin			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	3 / 4825 (0.06%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon injury			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	4 / 4825 (0.08%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			

subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	5 / 4825 (0.10%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic liver injury			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transfusion-related acute lung injury			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic arthritis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic arthrosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic fracture			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemorrhage			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haemorrhage			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ulna fracture			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	1 / 4825 (0.02%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stricture postoperative			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention postoperative			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular access malfunction			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular bypass dysfunction			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft occlusion			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft restenosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft stenosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haemorrhage			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound complication			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	4 / 4825 (0.08%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound evisceration			

subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	4 / 4825 (0.08%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound necrosis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchogenic cyst			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal dystrophy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Developmental hip dysplasia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial bridging			

subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	22 / 4825 (0.46%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	0 / 24	0 / 11	
deaths causally related to treatment / all	0 / 5	0 / 1	
Acute left ventricular failure			
subjects affected / exposed	12 / 4825 (0.25%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	3 / 14	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute myocardial infarction			
subjects affected / exposed	229 / 4825 (4.75%)	175 / 4825 (3.63%)	
occurrences causally related to treatment / all	13 / 251	16 / 196	
deaths causally related to treatment / all	1 / 31	4 / 31	
Angina pectoris			
subjects affected / exposed	103 / 4825 (2.13%)	83 / 4825 (1.72%)	
occurrences causally related to treatment / all	6 / 111	2 / 96	
deaths causally related to treatment / all	0 / 2	0 / 0	
Angina unstable			
subjects affected / exposed	104 / 4825 (2.16%)	80 / 4825 (1.66%)	
occurrences causally related to treatment / all	7 / 117	1 / 97	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anginal equivalent			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			

subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease mixed			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	22 / 4825 (0.46%)	24 / 4825 (0.50%)	
occurrences causally related to treatment / all	1 / 22	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arrhythmia			
subjects affected / exposed	7 / 4825 (0.15%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 6	
Arteriosclerosis coronary artery			
subjects affected / exposed	12 / 4825 (0.25%)	17 / 4825 (0.35%)	
occurrences causally related to treatment / all	0 / 12	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
Atrial tachycardia			
subjects affected / exposed	1 / 4825 (0.02%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial enlargement			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			

subjects affected / exposed	95 / 4825 (1.97%)	99 / 4825 (2.05%)	
occurrences causally related to treatment / all	4 / 111	3 / 106	
deaths causally related to treatment / all	0 / 2	0 / 1	
Atrial flutter			
subjects affected / exposed	11 / 4825 (0.23%)	12 / 4825 (0.25%)	
occurrences causally related to treatment / all	0 / 13	3 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial thrombosis			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
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	10 / 4825 (0.21%)	13 / 4825 (0.27%)	
occurrences causally related to treatment / all	1 / 10	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atrioventricular block first degree			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	6 / 4825 (0.12%)	12 / 4825 (0.25%)	
occurrences causally related to treatment / all	0 / 6	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bifascicular block			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			

subjects affected / exposed	9 / 4825 (0.19%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block right			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block left			
subjects affected / exposed	5 / 4825 (0.10%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiac ventricular thrombosis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	14 / 4825 (0.29%)	20 / 4825 (0.41%)	
occurrences causally related to treatment / all	0 / 14	2 / 22	
deaths causally related to treatment / all	0 / 12	0 / 19	
Cardiac amyloidosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	31 / 4825 (0.64%)	36 / 4825 (0.75%)	
occurrences causally related to treatment / all	1 / 33	2 / 36	
deaths causally related to treatment / all	1 / 29	1 / 30	
Cardiac asthma			

subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac discomfort			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac failure			
subjects affected / exposed	116 / 4825 (2.40%)	107 / 4825 (2.22%)	
occurrences causally related to treatment / all	0 / 157	2 / 141	
deaths causally related to treatment / all	0 / 23	0 / 24	
Cardiac failure acute			
subjects affected / exposed	43 / 4825 (0.89%)	33 / 4825 (0.68%)	
occurrences causally related to treatment / all	2 / 51	1 / 42	
deaths causally related to treatment / all	0 / 5	0 / 4	
Cardiac failure chronic			
subjects affected / exposed	33 / 4825 (0.68%)	33 / 4825 (0.68%)	
occurrences causally related to treatment / all	5 / 38	0 / 36	
deaths causally related to treatment / all	2 / 5	0 / 10	
Cardiac failure congestive			
subjects affected / exposed	58 / 4825 (1.20%)	67 / 4825 (1.39%)	
occurrences causally related to treatment / all	6 / 65	6 / 78	
deaths causally related to treatment / all	1 / 9	1 / 9	
Cardiac flutter			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic shock			

subjects affected / exposed	17 / 4825 (0.35%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	1 / 17	0 / 9	
deaths causally related to treatment / all	1 / 13	0 / 5	
Cardiomyopathy			
subjects affected / exposed	4 / 4825 (0.08%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 2	
Cardiorenal syndrome			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiovascular disorder			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular insufficiency			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Cardiomegaly			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic coronary syndrome			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic left ventricular failure			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conduction disorder			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	108 / 4825 (2.24%)	102 / 4825 (2.11%)	
occurrences causally related to treatment / all	5 / 117	4 / 105	
deaths causally related to treatment / all	0 / 5	0 / 8	
Coronary artery insufficiency			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	11 / 4825 (0.23%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 13	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coronary artery perforation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	47 / 4825 (0.97%)	43 / 4825 (0.89%)	
occurrences causally related to treatment / all	0 / 50	0 / 44	
deaths causally related to treatment / all	0 / 0	0 / 0	
Defect conduction intraventricular			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dressler's syndrome			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dilated cardiomyopathy			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Diastolic dysfunction			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrasystoles			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart failure with midrange ejection fraction			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart failure with preserved ejection fraction			
subjects affected / exposed	4 / 4825 (0.08%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 4	1 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Heart failure with reduced ejection fraction			
subjects affected / exposed	7 / 4825 (0.15%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	1 / 7	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 0	
Heart valve incompetence			

subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart valve stenosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive heart disease			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	7 / 4825 (0.15%)	8 / 4825 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 3	0 / 0	
Left ventricular failure			
subjects affected / exposed	6 / 4825 (0.12%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	1 / 6	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Left ventricular dysfunction			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	2 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve disease			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	5 / 4825 (0.10%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve stenosis			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial fibrosis			
subjects affected / exposed	3 / 4825 (0.06%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 2	
Myocardial infarction			
subjects affected / exposed	47 / 4825 (0.97%)	40 / 4825 (0.83%)	
occurrences causally related to treatment / all	3 / 48	3 / 40	
deaths causally related to treatment / all	2 / 23	1 / 16	
Myocardial ischaemia			
subjects affected / exposed	46 / 4825 (0.95%)	25 / 4825 (0.52%)	
occurrences causally related to treatment / all	3 / 52	1 / 26	
deaths causally related to treatment / all	1 / 8	0 / 4	
Myocardial rupture			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myopericarditis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal arrhythmia			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	5 / 4825 (0.10%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			

subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	5 / 4825 (0.10%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Prinzmetal angina			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulseless electrical activity			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Right ventricular failure			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinoatrial block			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	8 / 4825 (0.17%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	1 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	5 / 4825 (0.10%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular bradycardia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	4 / 4825 (0.08%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 4	1 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	1 / 4825 (0.02%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 1	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trifascicular block			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			

subjects affected / exposed	2 / 4825 (0.04%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	1 / 3	
Ventricular extrasystoles			
subjects affected / exposed	5 / 4825 (0.10%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 5	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular septal defect acquired			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	20 / 4825 (0.41%)	13 / 4825 (0.27%)	
occurrences causally related to treatment / all	3 / 21	0 / 16	
deaths causally related to treatment / all	1 / 2	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	9 / 4825 (0.19%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 9	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Altered state of consciousness			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			

subjects affected / exposed	3 / 4825 (0.06%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bell's palsy			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia infarction			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia stroke			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basilar artery aneurysm			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Basilar artery occlusion			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	0 / 4825 (0.00%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 4	
Brain oedema			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Brain stem haemorrhage			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Brain stem infarction			
subjects affected / exposed	6 / 4825 (0.12%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	1 / 6	1 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Brain stem stroke			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brainstem compression			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Carotid artery disease			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	7 / 4825 (0.15%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	19 / 4825 (0.39%)	31 / 4825 (0.64%)	
occurrences causally related to treatment / all	0 / 19	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	3 / 4825 (0.06%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			

subjects affected / exposed	30 / 4825 (0.62%)	27 / 4825 (0.56%)	
occurrences causally related to treatment / all	2 / 31	3 / 28	
deaths causally related to treatment / all	0 / 4	0 / 5	
Central nervous system lesion			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar atrophy			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar ischaemia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar stroke			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebellar syndrome			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral amyloid angiopathy			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral arteriosclerosis			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cerebral artery embolism			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery occlusion			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery stenosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral atrophy			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	8 / 4825 (0.17%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Cerebral ischaemia			
subjects affected / exposed	5 / 4825 (0.10%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebral small vessel ischaemic disease			

subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	38 / 4825 (0.79%)	30 / 4825 (0.62%)	
occurrences causally related to treatment / all	2 / 40	2 / 30	
deaths causally related to treatment / all	0 / 8	2 / 10	
Cerebrovascular disorder			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicobrachial syndrome			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral microhaemorrhage			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	4 / 4825 (0.08%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coma			

subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Cytotoxic lesions of corpus callosum			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	8 / 4825 (0.17%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 9	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia Alzheimer's type			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Demyelinating polyneuropathy			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressed level of consciousness			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic hyperosmolar coma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathy			
subjects affected / exposed	3 / 4825 (0.06%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 3	2 / 7	
deaths causally related to treatment / all	0 / 0	1 / 1	
Diabetic hyperglycaemic coma			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Disturbance in attention			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	6 / 4825 (0.12%)	14 / 4825 (0.29%)	
occurrences causally related to treatment / all	1 / 7	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic cerebellar infarction			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic cerebral infarction			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	6 / 4825 (0.12%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalomalacia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			

subjects affected / exposed	8 / 4825 (0.17%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Epilepsy			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial nerve disorder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paresis			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	6 / 4825 (0.12%)	10 / 4825 (0.21%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 3	0 / 6	
Haemorrhagic cerebral infarction			

subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Headache			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiataxia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemihyperaesthesia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.02%)	0 / 4825 (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	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiplegia			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			

subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hydrocephalus			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersomnia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive encephalopathy			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypnic headache			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic coma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic seizure			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic unconsciousness			

subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	2 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
IIIrd nerve paralysis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
IVth nerve disorder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intercostal neuralgia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial haematoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cerebral infarction			

subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraventricular haemorrhage			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic neuropathy			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	59 / 4825 (1.22%)	65 / 4825 (1.35%)	
occurrences causally related to treatment / all	2 / 67	2 / 72	
deaths causally related to treatment / all	0 / 7	0 / 13	
Lacunar infarction			
subjects affected / exposed	7 / 4825 (0.15%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	1 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar stroke			
subjects affected / exposed	4 / 4825 (0.08%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	3 / 4825 (0.06%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			

subjects affected / exposed	10 / 4825 (0.21%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 2	
Migraine			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mixed dementia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Motor neurone disease			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Middle cerebral artery stroke			
subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myasthenia gravis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	4 / 4825 (0.08%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myoclonus			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Narcolepsy			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurological decompensation			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Occipital neuralgia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic neuritis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			

subjects affected / exposed	4 / 4825 (0.08%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraparesis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parietal lobe stroke			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease			
subjects affected / exposed	4 / 4825 (0.08%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Partial seizures			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral sensorimotor neuropathy			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve lesion			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			

subjects affected / exposed	4 / 4825 (0.08%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychogenic seizure			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radial nerve palsy			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Restless legs syndrome			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sacral radiculopathy			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	8 / 4825 (0.17%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	1 / 9	0 / 10	
deaths causally related to treatment / all	0 / 1	0 / 1	
Senile dementia			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 2	
Sensory disturbance			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	4 / 4825 (0.08%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Speech disorder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal claudication			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitic myelopathy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinocerebellar disorder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	7 / 4825 (0.15%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 2	
Syncope			
subjects affected / exposed	35 / 4825 (0.73%)	37 / 4825 (0.77%)	
occurrences causally related to treatment / all	1 / 36	4 / 42	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamic infarction			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamic stroke			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tension headache			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic cerebral infarction			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Toxic encephalopathy			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Thrombotic stroke			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient aphasia			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	43 / 4825 (0.89%)	42 / 4825 (0.87%)	
occurrences causally related to treatment / all	2 / 48	4 / 51	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigeminal neuralgia			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumefactive multiple sclerosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unresponsive to stimuli			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uraemic encephalopathy			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIth nerve paralysis			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIth nerve paresis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.04%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vascular encephalopathy			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery occlusion			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar stroke			
subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord paresis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia folate deficiency			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia macrocytic			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	44 / 4825 (0.91%)	33 / 4825 (0.68%)	
occurrences causally related to treatment / all	2 / 48	1 / 39	
deaths causally related to treatment / all	0 / 3	0 / 1	
Autoimmune haemolytic anaemia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood disorder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Blood loss anaemia			
subjects affected / exposed	5 / 4825 (0.10%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	0 / 5	1 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated intravascular coagulation			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Febrile neutropenia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	14 / 4825 (0.29%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	1 / 14	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	0 / 4825 (0.00%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Leukopenia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenitis			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy mediastinal			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelosuppression			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nephrogenic anaemia			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic anaemia			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normocytic anaemia			

subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Splenic artery perforation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	3 / 4825 (0.06%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Acute vestibular syndrome			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness neurosensory			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis of external ear canal			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Middle ear inflammation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otolithiasis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanic membrane perforation			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	9 / 4825 (0.19%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	1 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	4 / 4825 (0.08%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	1 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Blepharospasm			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	49 / 4825 (1.02%)	39 / 4825 (0.81%)	
occurrences causally related to treatment / all	1 / 59	0 / 46	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract diabetic			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Choroidal neovascularisation			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystoid macular oedema			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic eye disease			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	15 / 4825 (0.31%)	29 / 4825 (0.60%)	
occurrences causally related to treatment / all	8 / 16	15 / 32	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinal oedema			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiretinal membrane			
subjects affected / exposed	5 / 4825 (0.10%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	2 / 5	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	4 / 4825 (0.08%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iridocyclitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iritis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lens disorder			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular hole			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular oedema			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meibomian gland dysfunction			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neovascular age-related macular degeneration			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular myasthenia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open angle glaucoma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic atrophy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posterior capsule opacification			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	2 / 4825 (0.04%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein occlusion			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein thrombosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy proliferative			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tolosa-Hunt syndrome			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tractional retinal detachment			

subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uveitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual acuity reduced			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	9 / 4825 (0.19%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	2 / 10	3 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			

subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	6 / 4825 (0.12%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	1 / 7	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	4 / 4825 (0.08%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	0 / 4	3 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute abdomen			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic pancreatitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fissure			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal incontinence			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendiceal mucocoele			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	4 / 4825 (0.08%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Barrett's oesophagus			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	3 / 4825 (0.06%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 3	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastrointestinal bleeding			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	3 / 4825 (0.06%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 3	2 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colitis ulcerative			
subjects affected / exposed	1 / 4825 (0.02%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	2 / 4825 (0.04%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	1 / 2	1 / 5	
deaths causally related to treatment / all	0 / 0	1 / 4	
Constipation			

subjects affected / exposed	7 / 4825 (0.15%)	8 / 4825 (0.17%)	
occurrences causally related to treatment / all	1 / 7	4 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gastroparesis			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	10 / 4825 (0.21%)	12 / 4825 (0.25%)	
occurrences causally related to treatment / all	2 / 10	2 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dieulafoy's vascular malformation			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diverticulum			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer perforation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	4 / 4825 (0.08%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	1 / 5	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	4 / 4825 (0.08%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical fistula			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			

subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive oesophagitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecaloma			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	1 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Frequent bowel movements			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric polyps			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	9 / 4825 (0.19%)	17 / 4825 (0.35%)	
occurrences causally related to treatment / all	0 / 9	1 / 18	
deaths causally related to treatment / all	0 / 2	0 / 2	
Gastrointestinal inflammation			

subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal ischaemia			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	5 / 4825 (0.10%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 5	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer perforation			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	16 / 4825 (0.33%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	2 / 16	3 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	2 / 4825 (0.04%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	1 / 2	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorder			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal ulcer haemorrhage			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal polyp haemorrhage			

subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal necrosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal wall thickening			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 4825 (0.06%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	2 / 3	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	1 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	1 / 4825 (0.02%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hernial eventration			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 4825 (0.02%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 1	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	15 / 4825 (0.31%)	28 / 4825 (0.58%)	
occurrences causally related to treatment / all	0 / 16	0 / 29	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal angina			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	1 / 4825 (0.02%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Intestinal obstruction			

subjects affected / exposed	5 / 4825 (0.10%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 6	1 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intestinal perforation			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal haematoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal haemorrhage			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Large intestinal stenosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal ulcer			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal ulcer haemorrhage			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	10 / 4825 (0.21%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 12	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukoplakia oral			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant ascites			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mechanical ileus			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	4 / 4825 (0.08%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery thrombosis			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mesenteric vein thrombosis			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	3 / 4825 (0.06%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	1 / 3	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	5 / 4825 (0.10%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	1 / 5	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedematous pancreatitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer haemorrhage			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophagitis			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis ulcerative			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic cyst			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	2 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	14 / 4825 (0.29%)	16 / 4825 (0.33%)	
occurrences causally related to treatment / all	9 / 18	12 / 16	
deaths causally related to treatment / all	0 / 0	0 / 2	
Pancreatitis chronic			
subjects affected / exposed	5 / 4825 (0.10%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	3 / 6	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer haemorrhage			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneocutaneous fistula			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumoperitoneum			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	5 / 4825 (0.10%)	8 / 4825 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rectal perforation			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haematoma			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	6 / 4825 (0.12%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	1 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spigelian hernia			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal perforation			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated umbilical hernia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swollen tongue			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue oedema			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	7 / 4825 (0.15%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	5 / 4825 (0.10%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 5	1 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Varices oesophageal			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 5	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	7 / 4825 (0.15%)	13 / 4825 (0.27%)	
occurrences causally related to treatment / all	2 / 7	7 / 16	
deaths causally related to treatment / all	0 / 0	0 / 2	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blister			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cutaneous vasculitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	5 / 4825 (0.10%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	2 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			

subjects affected / exposed	23 / 4825 (0.48%)	20 / 4825 (0.41%)	
occurrences causally related to treatment / all	0 / 25	1 / 24	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dermatitis bullous			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic wound			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema multiforme			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperhidrosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkeratosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic skin ulcer			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melanocytic hyperplasia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrobiosis lipoidica diabeticorum			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pemphigoid			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin necrosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	17 / 4825 (0.35%)	12 / 4825 (0.25%)	
occurrences causally related to treatment / all	0 / 20	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 0	
Subcutaneous emphysema			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	151 / 4825 (3.13%)	123 / 4825 (2.55%)	
occurrences causally related to treatment / all	14 / 177	17 / 145	
deaths causally related to treatment / all	1 / 24	2 / 10	
Anuria			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atonic urinary bladder			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Azotaemia			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder diverticulum			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder metaplasia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck obstruction			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder ulcer			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder obstruction			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urethral			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	44 / 4825 (0.91%)	31 / 4825 (0.64%)	
occurrences causally related to treatment / all	1 / 46	1 / 31	
deaths causally related to treatment / all	0 / 5	0 / 1	
Cystitis haemorrhagic			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis noninfective			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic nephropathy			

subjects affected / exposed	3 / 4825 (0.06%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dysuria			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	21 / 4825 (0.44%)	14 / 4825 (0.29%)	
occurrences causally related to treatment / all	0 / 21	0 / 17	
deaths causally related to treatment / all	0 / 3	0 / 2	
Glomerulosclerosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis membranous			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	8 / 4825 (0.17%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	7 / 4825 (0.15%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive nephropathy			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney congestion			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephritis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	13 / 4825 (0.27%)	20 / 4825 (0.41%)	
occurrences causally related to treatment / all	0 / 14	2 / 21	
deaths causally related to treatment / all	0 / 0	1 / 1	
Nephropathy toxic			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurogenic bladder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvi-ureteric obstruction			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pollakiuria			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
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 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proteinuria			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stenosis			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal atrophy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			

subjects affected / exposed	9 / 4825 (0.19%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 10	1 / 10	
deaths causally related to treatment / all	0 / 3	0 / 4	
Renal impairment			
subjects affected / exposed	7 / 4825 (0.15%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	0 / 7	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal infarct			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal mass			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stag horn calculus			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric obstruction			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	9 / 4825 (0.19%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 10	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral haemorrhage			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral meatus stenosis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	4 / 4825 (0.08%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder haemorrhage			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder polyp			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			

subjects affected / exposed	9 / 4825 (0.19%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	2 / 11	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cushing's syndrome			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia of malignancy			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hyperparathyroidism primary			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidic goitre			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	7 / 4825 (0.15%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	2 / 4825 (0.04%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis reactive			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arthrofibrosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back disorder			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	13 / 4825 (0.27%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	0 / 13	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bursitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest wall mass			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chondrocalcinosis			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondropathy			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment syndrome			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			

subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dactylitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dupuytren's contracture			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facet joint syndrome			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fistula			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			

subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma muscle			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc displacement			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	7 / 4825 (0.15%)	18 / 4825 (0.37%)	
occurrences causally related to treatment / all	0 / 7	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint range of motion decreased			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint swelling			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb deformity			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	14 / 4825 (0.29%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 14	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medial tibial stress syndrome			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mobility decreased			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	2 / 4825 (0.04%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	5 / 4825 (0.10%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	4 / 4825 (0.08%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myositis			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic arthropathy			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	3 / 4825 (0.06%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	58 / 4825 (1.20%)	39 / 4825 (0.81%)	
occurrences causally related to treatment / all	0 / 66	0 / 41	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	4 / 4825 (0.08%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	6 / 4825 (0.12%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 6	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periostitis			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyositis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudarthrosis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (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 / 4825 (0.04%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	9 / 4825 (0.19%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff tear arthropathy			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scoliosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal ligament ossification			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue disorder			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue swelling			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal disorder			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal instability			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondyloarthropathy			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	5 / 4825 (0.10%)	8 / 4825 (0.17%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	6 / 4825 (0.12%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon disorder			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis stenosans			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigger finger			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral lateral recess stenosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral osteophyte			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			

subjects affected / exposed	5 / 4825 (0.10%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Abscess of external ear			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Alpha haemolytic streptococcal infection			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Antibiotic associated colitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	3 / 4825 (0.06%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	0 / 3	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			

subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	2 / 4825 (0.04%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspergilloma			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	3 / 4825 (0.06%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Bacteraemia			
subjects affected / exposed	4 / 4825 (0.08%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 5	2 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	
Bacterial infection			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 2	0 / 0	
Bacterial prostatitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			

subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bacteriuria			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biloma infected			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blister infected			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast abscess			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone abscess			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone tuberculosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain abscess			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Breast cellulitis			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bronchitis			
subjects affected / exposed	10 / 4825 (0.21%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 10	1 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis infective			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	141 / 4825 (2.92%)	121 / 4825 (2.51%)	
occurrences causally related to treatment / all	0 / 143	0 / 122	
deaths causally related to treatment / all	0 / 26	0 / 19	
COVID-19 pneumonia			
subjects affected / exposed	182 / 4825 (3.77%)	138 / 4825 (2.86%)	
occurrences causally related to treatment / all	1 / 186	0 / 141	
deaths causally related to treatment / all	0 / 57	0 / 33	
Campylobacter colitis			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	62 / 4825 (1.28%)	29 / 4825 (0.60%)	
occurrences causally related to treatment / all	3 / 71	0 / 32	
deaths causally related to treatment / all	0 / 1	0 / 0	
Catheter site infection			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis streptococcal			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic hepatitis C			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			

subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridial infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridial sepsis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon gangrene			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic abscess			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivitis			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Creutzfeldt-Jakob disease			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	6 / 4825 (0.12%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 6	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis bacterial			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis escherichia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis klebsiella			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus viraemia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	6 / 4825 (0.12%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	1 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Device related infection			

subjects affected / exposed	5 / 4825 (0.10%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	1 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related sepsis			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetic foot infection			
subjects affected / exposed	8 / 4825 (0.17%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	3 / 11	1 / 8	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetic gangrene			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	6 / 4825 (0.12%)	13 / 4825 (0.27%)	
occurrences causally related to treatment / all	0 / 7	1 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis intestinal perforated			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Douglas' abscess			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysentery			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear infection			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Endocarditis			
subjects affected / exposed	0 / 4825 (0.00%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endophthalmitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter bacteraemia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal infection			

subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal sepsis			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Epiglottitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis bacterial			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Epididymitis			
subjects affected / exposed	2 / 4825 (0.04%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottic abscess			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epstein-Barr virus infection			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	5 / 4825 (0.10%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia infection			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	6 / 4825 (0.12%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 6	1 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Escherichia urinary tract infection			
subjects affected / exposed	7 / 4825 (0.15%)	8 / 4825 (0.17%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Erysipelas			
subjects affected / exposed	8 / 4825 (0.17%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	
Extradural abscess			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder abscess			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Focal peritonitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder empyema			
subjects affected / exposed	1 / 4825 (0.02%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 1	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric infection			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gas gangrene			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	22 / 4825 (0.46%)	15 / 4825 (0.31%)	
occurrences causally related to treatment / all	1 / 24	0 / 17	
deaths causally related to treatment / all	0 / 2	0 / 1	
Gastritis bacterial			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	16 / 4825 (0.33%)	20 / 4825 (0.41%)	
occurrences causally related to treatment / all	6 / 17	2 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis clostridial			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis salmonella			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital infection fungal			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin abscess			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter gastritis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis A			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis E			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes sepsis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes simplex			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.04%)	4 / 4825 (0.08%)		
occurrences causally related to treatment / all	0 / 2	0 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
Infected seroma				
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Infected skin ulcer				
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)		
occurrences causally related to treatment / all	0 / 2	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Infection				
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)		
occurrences causally related to treatment / all	0 / 0	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
Infectious pleural effusion				
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Infective exacerbation of bronchiectasis				
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Infective exacerbation of chronic obstructive airways disease				
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Infective spondylitis				
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Influenza				

subjects affected / exposed	7 / 4825 (0.15%)	10 / 4825 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intervertebral discitis			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella urinary tract infection			
subjects affected / exposed	4 / 4825 (0.08%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint abscess			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella bacteraemia			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Localised infection			
subjects affected / exposed	5 / 4825 (0.10%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	5 / 4825 (0.10%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection bacterial			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphangitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastoiditis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			

subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis bacterial			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis leptospiral			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metapneumovirus infection			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metapneumovirus pneumonia			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Morganella infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycobacterium chelonae infection			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycoplasma infection			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nail infection			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising fasciitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal candidiasis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	22 / 4825 (0.46%)	12 / 4825 (0.25%)	
occurrences causally related to treatment / all	0 / 26	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 0	
Orchitis			
subjects affected / exposed	4 / 4825 (0.08%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis bacterial			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis chronic			

subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis externa			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media acute			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis acute			
subjects affected / exposed	4 / 4825 (0.08%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic abscess			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae virus infection			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paracancerous pneumonia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Paronychia			
subjects affected / exposed	1 / 4825 (0.02%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotid abscess			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic abscess			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perihepatic abscess			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	7 / 4825 (0.15%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peritonsillar abscess			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pertussis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pilonidal disease			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasmodium falciparum infection			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	6 / 4825 (0.12%)	8 / 4825 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pneumonia			
subjects affected / exposed	129 / 4825 (2.67%)	129 / 4825 (2.67%)	
occurrences causally related to treatment / all	1 / 148	3 / 146	
deaths causally related to treatment / all	0 / 30	0 / 19	
Pneumonia acinetobacter			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia aspiration			
subjects affected / exposed	15 / 4825 (0.31%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	0 / 15	0 / 11	
deaths causally related to treatment / all	0 / 6	0 / 3	
Pneumonia bacterial			
subjects affected / exposed	12 / 4825 (0.25%)	19 / 4825 (0.39%)	
occurrences causally related to treatment / all	0 / 13	1 / 23	
deaths causally related to treatment / all	0 / 2	0 / 2	
Pneumonia chlamydial			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia fungal			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia influenzal			

subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia klebsiella			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia legionella			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pseudomonal			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
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	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural cellulitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural pneumonia			

subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative abscess			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	7 / 4825 (0.15%)	8 / 4825 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic abscess			
subjects affected / exposed	4 / 4825 (0.08%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prosthetic valve endocarditis			

subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary tuberculosis			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonal bacteraemia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonal sepsis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonas infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pyoderma			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis chronic			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyonephrosis			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Purulent discharge			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	10 / 4825 (0.21%)	7 / 4825 (0.15%)	
occurrences causally related to treatment / all	0 / 13	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	6 / 4825 (0.12%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 6	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyomyositis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal abscess			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
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 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	5 / 4825 (0.10%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salpingitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinovirus infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SARS-CoV-2 sepsis			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Sialoadenitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal cellulitis			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrub typhus			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	43 / 4825 (0.89%)	50 / 4825 (1.04%)	
occurrences causally related to treatment / all	0 / 46	2 / 57	
deaths causally related to treatment / all	0 / 11	0 / 20	
Septic arthritis streptococcal			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	32 / 4825 (0.66%)	22 / 4825 (0.46%)	
occurrences causally related to treatment / all	0 / 32	1 / 22	
deaths causally related to treatment / all	0 / 18	0 / 16	
Serratia infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	2 / 4825 (0.04%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin bacterial infection			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	3 / 4825 (0.06%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue infection			

subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Splenic abscess			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal bacteraemia			
subjects affected / exposed	2 / 4825 (0.04%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal infection			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Streptococcal urinary tract infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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	4 / 4825 (0.08%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	3 / 4825 (0.06%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Superinfection bacterial			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suspected COVID-19			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Superinfection			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheitis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	3 / 4825 (0.06%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Trichomoniasis			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	4 / 4825 (0.08%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection pseudomonal			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	62 / 4825 (1.28%)	63 / 4825 (1.31%)	
occurrences causally related to treatment / all	2 / 70	3 / 69	
deaths causally related to treatment / all	0 / 1	0 / 1	
Urinary tract infection bacterial			
subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
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 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	23 / 4825 (0.48%)	17 / 4825 (0.35%)	
occurrences causally related to treatment / all	0 / 25	0 / 18	
deaths causally related to treatment / all	0 / 3	0 / 2	
Vascular device infection			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft infection			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular neuronitis			
subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral sepsis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval abscess			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound cellulitis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			

subjects affected / exposed	5 / 4825 (0.10%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection bacterial			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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			
Acetonaemia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acidosis			
subjects affected / exposed	0 / 4825 (0.00%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acidosis hyperchloraemic			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (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 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic ketoacidosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Decreased appetite			
subjects affected / exposed	2 / 4825 (0.04%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 2	2 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Dehydration			
subjects affected / exposed	13 / 4825 (0.27%)	17 / 4825 (0.35%)	
occurrences causally related to treatment / all	0 / 13	5 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	16 / 4825 (0.33%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 18	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	10 / 4825 (0.21%)	10 / 4825 (0.21%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetic ketoacidosis			
subjects affected / exposed	13 / 4825 (0.27%)	8 / 4825 (0.17%)	
occurrences causally related to treatment / all	0 / 13	1 / 8	
deaths causally related to treatment / all	0 / 3	1 / 2	
Diabetic metabolic decompensation			
subjects affected / exposed	5 / 4825 (0.10%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Electrolyte imbalance			
subjects affected / exposed	4 / 4825 (0.08%)	4 / 4825 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 0	
Euglycaemic diabetic ketoacidosis			

subjects affected / exposed	3 / 4825 (0.06%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glucose tolerance impaired			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	2 / 4825 (0.04%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperinsulinaemic hypoglycaemia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	41 / 4825 (0.85%)	38 / 4825 (0.79%)	
occurrences causally related to treatment / all	2 / 49	2 / 45	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic crisis			
subjects affected / exposed	2 / 4825 (0.04%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	5 / 4825 (0.10%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hyperkalaemia			

subjects affected / exposed	32 / 4825 (0.66%)	11 / 4825 (0.23%)	
occurrences causally related to treatment / all	2 / 37	0 / 12	
deaths causally related to treatment / all	0 / 3	0 / 1	
Hyperlipasaemia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypernatraemia			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypomagnesaemia			
subjects affected / exposed	5 / 4825 (0.10%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	12 / 4825 (0.25%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 12	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypoosmolar state			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophagia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertriglyceridaemia			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia			

subjects affected / exposed	8 / 4825 (0.17%)	10 / 4825 (0.21%)	
occurrences causally related to treatment / all	0 / 12	1 / 15	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hypoalbuminaemia			
subjects affected / exposed	1 / 4825 (0.02%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	44 / 4825 (0.91%)	37 / 4825 (0.77%)	
occurrences causally related to treatment / all	17 / 51	11 / 45	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hyponatraemia			
subjects affected / exposed	12 / 4825 (0.25%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	4 / 4825 (0.08%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 4	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketoacidosis			
subjects affected / exposed	0 / 4825 (0.00%)	3 / 4825 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lactic acidosis			
subjects affected / exposed	3 / 4825 (0.06%)	6 / 4825 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Magnesium metabolism disorder			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			

subjects affected / exposed	1 / 4825 (0.02%)	2 / 4825 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metabolic disorder			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	11 / 4825 (0.23%)	9 / 4825 (0.19%)	
occurrences causally related to treatment / all	0 / 11	0 / 9	
deaths causally related to treatment / all	0 / 2	0 / 2	
Obesity			
subjects affected / exposed	1 / 4825 (0.02%)	0 / 4825 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudohyponatraemia			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Starvation ketoacidosis			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	3 / 4825 (0.06%)	5 / 4825 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitamin B12 deficiency			
subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitamin D deficiency			

subjects affected / exposed	0 / 4825 (0.00%)	1 / 4825 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	Oral Semaglutide	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1599 / 4825 (33.14%)	1761 / 4825 (36.50%)	
Eye disorders			
Diabetic retinopathy			
subjects affected / exposed	932 / 4825 (19.32%)	943 / 4825 (19.54%)	
occurrences (all)	1116	1122	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	62 / 4825 (1.28%)	344 / 4825 (7.13%)	
occurrences (all)	66	442	
Infections and infestations			
COVID-19			
subjects affected / exposed	777 / 4825 (16.10%)	756 / 4825 (15.67%)	
occurrences (all)	836	838	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 December 2020	Protocol Amendment 2.0: The exclusion and discontinuation criteria were amended to allow for simultaneous participation in COVID-19 trials. In addition, the AE collection was expanded to include the reporting of non-serious COVID-19 events

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported