



## Clinical trial results:

**LEADER® liraglutide effect and action in diabetes: Evaluation of cardiovascular outcome results - A long-term, multi-centre, international, randomised double-blind, placebo-controlled trial to determine liraglutide effects on cardiovascular events.**

### Summary

EudraCT number	2009-012201-19
Trial protocol	FR IE SE DE NL FI AT GB CZ BE DK PL GR ES IT
Global end of trial date	17 December 2015

### Results information

Result version number	v1 (current)
This version publication date	01 January 2017
First version publication date	01 January 2017

### Trial information

#### Trial identification

Sponsor protocol code	EX2211-3748
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01179048
WHO universal trial number (UTN)	U1111-1113-7090

Notes:

### Sponsors

Sponsor organisation name	Novo Nordisk A/S
Sponsor organisation address	Novo Allé, Bagsvaerd, Denmark, 2880
Public contact	Global Clinical Registry (GCR, 1452), Novo Nordisk A/S, clinicaltrials@novonordisk.com
Scientific contact	Global Clinical Registry (GCR, 1452), 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	29 August 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 December 2015
Global end of trial reached?	Yes
Global end of trial date	17 December 2015
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To assess the effect of treatment with liraglutide compared to placebo for at least 3.5 year and up to 5 years on the incidence of cardiovascular events, as defined by the primary and secondary endpoints in adults with type 2 diabetes that are at high risk for cardiovascular events.

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki and ICH Good Clinical Practice.

Background therapy:

At the discretion of the investigator, subjects were provided standard of care therapy, with the option of adding glucose-lowering or cardiovascular medication to achieve prespecified guideline targets for glycaemic control, blood pressure and lipids.

Evidence for comparator:

Not applicable

Actual start date of recruitment	31 August 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 222
Country: Number of subjects enrolled	Austria: 119
Country: Number of subjects enrolled	Belgium: 77
Country: Number of subjects enrolled	Brazil: 939
Country: Number of subjects enrolled	Canada: 333
Country: Number of subjects enrolled	China: 92
Country: Number of subjects enrolled	Czech Republic: 55
Country: Number of subjects enrolled	Denmark: 167
Country: Number of subjects enrolled	Finland: 132
Country: Number of subjects enrolled	France: 61
Country: Number of subjects enrolled	Germany: 448
Country: Number of subjects enrolled	Greece: 86
Country: Number of subjects enrolled	India: 401
Country: Number of subjects enrolled	Ireland: 40
Country: Number of subjects enrolled	Israel: 122
Country: Number of subjects enrolled	Italy: 203
Country: Number of subjects enrolled	Korea, Republic of: 103

Country: Number of subjects enrolled	Mexico: 243
Country: Number of subjects enrolled	Netherlands: 153
Country: Number of subjects enrolled	Norway: 88
Country: Number of subjects enrolled	Poland: 388
Country: Number of subjects enrolled	Romania: 252
Country: Number of subjects enrolled	Russian Federation: 335
Country: Number of subjects enrolled	Serbia: 100
Country: Number of subjects enrolled	South Africa: 395
Country: Number of subjects enrolled	Spain: 205
Country: Number of subjects enrolled	Sweden: 146
Country: Number of subjects enrolled	Taiwan: 115
Country: Number of subjects enrolled	Turkey: 322
Country: Number of subjects enrolled	United Arab Emirates: 31
Country: Number of subjects enrolled	United Kingdom: 453
Country: Number of subjects enrolled	United States: 2514
Worldwide total number of subjects	9340
EEA total number of subjects	3073

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)	5011
From 65 to 84 years	4287
85 years and over	42

## Subject disposition

### Recruitment

#### Recruitment details:

410 sites in 32 countries across the 4 regions recruited subjects. Number of sites that recruited subjects is given in parenthesis. Europe (143), North America (135) (US, Canada) , Asia (33) (China, Taiwan, Korea, India) and Rest of the world (99) (Brazil, Mexico, Australia, South Africa, Turkey, Russian Federation, United Arab Emirates).

### Pre-assignment

#### Screening details:

Of the 12076 subjects screened, 2002 were screening failures and 456 withdrew before run-in. Of the 9618 subjects who entered the run-in phase, 106 subjects were run-in failures and 172 subjects withdrew prior to randomisation. All subjects received placebo during the run-in period and were instructed how to administer the trial product.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Liraglutide

#### Arm description:

Subjects received liraglutide once daily by subcutaneous injection in the abdomen, thigh or upper arm, at any time of the day and irrespective of meals for a treatment period of 42 to 60 months. It was recommended to keep the time of injection consistent from day to day. Liraglutide was initiated at a dose of 0.6 mg and up-titrated to 1.2 mg after 1 week and to 1.8 mg after one additional week upto 42-60 months.

Arm type	Experimental
Investigational medicinal product name	Victoza®
Investigational medicinal product code	
Other name	Liraglutide
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

#### Dosage and administration details:

Liraglutide was available at a concentration of 6.0 mg/mL and supplied in a 3 mL disposable peninjector. Liraglutide was administered once daily by subcutaneous injection in the abdomen, thigh or upper arm. Injection could be done at any time of the day and irrespective of meals, but it was recommended to keep the time of injection consistent from day to day. Subjects were started on 0.6 mg of liraglutide. Dose escalation of liraglutide, proceeded to 1.2 mg after one week followed by dose escalation to 1.8 mg after one additional week.

<b>Arm title</b>	Placebo
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#### Arm description:

Subjects received placebo (matched to liraglutide) daily by subcutaneous injection in the abdomen, thigh or upper arm, at any time of the day and irrespective of meals for a treatment period of 42 to 60 months. It was recommended to keep the time of injection consistent from day to day. Placebo was initiated at a dose of 0.6 mg and up-titrated to 1.2 mg after 1 week and to 1.8 mg after one additional week upto 42-60 months.

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

Dosage and administration details:

Placebo was available at a concentration of 6.0 mg/mL and supplied in a 3 mL disposable peninjector. Placebo was administered once daily by subcutaneous injection in the abdomen, thigh or upper arm. Injection could be done at any time of the day and irrespective of meals, but it was recommended to keep the time of injection consistent from day to day. Subjects were started on 0.6 mg of placebo. Dose escalation of placebo, proceeded to 1.2 mg after one week followed by dose escalation to 1.8 mg after one additional week.

<b>Number of subjects in period 1</b>	Liraglutide	Placebo
Started	4668	4672
Completed	4529	4513
Not completed	139	159
Alive	127	142
Withdrawn - does not allow contact	4	8
Lost to follow-up	8	9

## Baseline characteristics

### Reporting groups

Reporting group title	Liraglutide
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Reporting group description:

Subjects received liraglutide once daily by subcutaneous injection in the abdomen, thigh or upper arm, at any time of the day and irrespective of meals for a treatment period of 42 to 60 months. It was recommended to keep the time of injection consistent from day to day. Liraglutide was initiated at a dose of 0.6 mg and up-titrated to 1.2 mg after 1 week and to 1.8 mg after one additional week upto 42-60 months.

Reporting group title	Placebo
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Reporting group description:

Subjects received placebo (matched to liraglutide) daily by subcutaneous injection in the abdomen, thigh or upper arm, at any time of the day and irrespective of meals for a treatment period of 42 to 60 months. It was recommended to keep the time of injection consistent from day to day. Placebo was initiated at a dose of 0.6 mg and up-titrated to 1.2 mg after 1 week and to 1.8 mg after one additional week upto 42-60 months.

Reporting group values	Liraglutide	Placebo	Total
Number of subjects	4668	4672	9340
Age Categorical Units: Subjects			
18-64 years	2512	2499	5011
From 65-84 years	2139	2148	4287
85 years and over	17	25	42
Age Continuous Units: years			
arithmetic mean	64.2	64.4	
standard deviation	± 7.2	± 7.2	-
Gender Categorical Units: Subjects			
Female	1657	1680	3337
Male	3011	2992	6003

## End points

### End points reporting groups

Reporting group title	Liraglutide
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Reporting group description:

Subjects received liraglutide once daily by subcutaneous injection in the abdomen, thigh or upper arm, at any time of the day and irrespective of meals for a treatment period of 42 to 60 months. It was recommended to keep the time of injection consistent from day to day. Liraglutide was initiated at a dose of 0.6 mg and up-titrated to 1.2 mg after 1 week and to 1.8 mg after one additional week upto 42-60 months.

Reporting group title	Placebo
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Reporting group description:

Subjects received placebo (matched to liraglutide) daily by subcutaneous injection in the abdomen, thigh or upper arm, at any time of the day and irrespective of meals for a treatment period of 42 to 60 months. It was recommended to keep the time of injection consistent from day to day. Placebo was initiated at a dose of 0.6 mg and up-titrated to 1.2 mg after 1 week and to 1.8 mg after one additional week upto 42-60 months.

### Primary: Time from randomisation to first occurrence of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke (a composite cardiovascular outcome).

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

Subjects experiencing a first event of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke (a composite cardiovascular outcome) from randomisation up to last follow-up. Analysis population: full analysis set included all randomised subjects.

End point type	Primary
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End point timeframe:

from randomisation (visit 3; month 0) to last contact (visit 16; up to month 60+30 days)

End point values	Liraglutide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4668	4672		
Units: percentage of subjects				
number (not applicable)	13	14.9		

### Statistical analyses

Statistical analysis title	Non-inferiority test
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Statistical analysis description:

The cox regression analysis estimated the hazard ratio (HR) (liraglutide/placebo) and the 2-sided 95% confidence interval (CI) including treatment group as factor. Non-inferiority of liraglutide versus placebo was considered confirmed, if the upper limit of the two-sided 95% CI for the HR was below 1.3 or if the p-value for the one-sided test of H0 (null hypothesis) : HR  $\geq$  1.3 against Ha (alternative hypothesis): HR < 1.3 was less than 2.5% (or equivalent to 5% in two-sided test).

Comparison groups	Liraglutide v Placebo
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Number of subjects included in analysis	9340
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.001 <sup>[1]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.868
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.778
upper limit	0.968

Notes:

[1] - p-value is reported for one-sided ( $\alpha$ -level 0.025) test for non-inferiority (hazard ratio  $\geq 1.3$ ).

<b>Statistical analysis title</b>	Superiority test
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Statistical analysis description:

If non-inferiority was established for the primary outcome, a test for superiority was performed.

Superiority of liraglutide versus placebo was considered confirmed, if the upper limit of the two-sided 95% CI for the hazard ratio was below 1.0 or equivalent if the p-value for the one-sided test of H0 (null hypothesis): HR  $\geq 1.0$  against Ha (alternative hypothesis): HR  $< 1.0$  was less than 2.5% (or equivalent to 5% in two-sided test).

Comparison groups	Liraglutide v Placebo
Number of subjects included in analysis	9340
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005 <sup>[2]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.868
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.778
upper limit	0.968

Notes:

[2] - p-value is reported for one-sided ( $\alpha$ -level 0.025) test for superiority (hazard ratio  $\geq 1.0$ ).



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse events from randomisation (visit 3; month 0) and until follow up (visit 16; month 60+30 days of post-treatment follow-up).

Adverse event reporting additional description:

Safety was assessed using the full analysis set which included all randomised subjects. Serious adverse events were systematically collected. Non-serious adverse events included both systematically collected as well as non-systematically collected adverse events.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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### Reporting groups

Reporting group title	Liraglutide
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Reporting group description:

Subjects received liraglutide once daily by subcutaneous injection in the abdomen, thigh or upper arm, at any time of the day and irrespective of meals, for a treatment period of 42 to 60 months. It was recommended to keep the time of injection consistent from day to day. Liraglutide was initiated at a dose of 0.6 mg and up-titrated to 1.2 mg after 1 week and to 1.8 mg after one additional week upto 42-60 months.

Reporting group title	Placebo
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Reporting group description:

Subjects received placebo (matched to liraglutide) daily by subcutaneous injection in the abdomen, thigh or upper arm, at any time of the day and irrespective of meals, for a treatment period of 42 to 60 months. It was recommended to keep the time of injection consistent from day to day. Placebo was initiated at a dose of 0.6 mg and up-titrated to 1.2 mg after 1 week and to 1.8 mg after one additional week upto 42-60 months.

Serious adverse events	Liraglutide	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	2320 / 4668 (49.70%)	2354 / 4672 (50.39%)	
number of deaths (all causes)	382	447	
number of deaths resulting from adverse events	382	447	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	2 / 2	

Adenocarcinoma gastric			
subjects affected / exposed	3 / 4668 (0.06%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	3 / 3	3 / 3	
deaths causally related to treatment / all	1 / 1	1 / 1	
Adenocarcinoma of colon			
subjects affected / exposed	14 / 4668 (0.30%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	15 / 15	11 / 11	
deaths causally related to treatment / all	2 / 2	1 / 1	
Adenocarcinoma of the cervix			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	4 / 4668 (0.09%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	4 / 4	1 / 1	
deaths causally related to treatment / all	3 / 3	1 / 1	
Adrenal adenoma			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal neoplasm			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal squamous cell carcinoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiomyolipoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell lymphoma			

subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell unclassifiable lymphoma low grade			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	14 / 4668 (0.30%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	17 / 17	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basosquamous carcinoma			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign anorectal neoplasm			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign breast neoplasm			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of bladder			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of prostate			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of thyroid gland			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign ovarian tumour			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign soft tissue neoplasm			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary adenoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	3 / 4668 (0.06%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	3 / 3	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer recurrent			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer stage 0, with cancer in situ			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer stage III			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			

subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
Bladder squamous cell carcinoma stage unspecified			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	4 / 4668 (0.09%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	4 / 4	5 / 5	
deaths causally related to treatment / all	1 / 1	0 / 0	
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma stage III			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blepharal papilloma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone neoplasm			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	6 / 4668 (0.13%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	6 / 6	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer female			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer in situ			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Bronchial carcinoma			
subjects affected / exposed	3 / 4668 (0.06%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	3 / 3	2 / 2	
deaths causally related to treatment / all	2 / 2	2 / 2	
Carcinoid tumour of the small bowel			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid tumour pulmonary			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central nervous system lymphoma			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Cerebellar tumour			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cerebral haemangioma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	5 / 4668 (0.11%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	5 / 5	3 / 3	
deaths causally related to treatment / all	4 / 4	1 / 1	
Cholesteatoma			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholesterol granuloma			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrosarcoma metastatic			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Chondrosarcoma recurrent			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (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 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia stage 1			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myelomonocytic leukaemia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Clear cell renal cell carcinoma			
subjects affected / exposed	6 / 4668 (0.13%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	6 / 6	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	13 / 4668 (0.28%)	16 / 4672 (0.34%)	
occurrences causally related to treatment / all	14 / 14	18 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	3 / 4668 (0.06%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	3 / 3	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer metastatic			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	2 / 2	0 / 0	
Colon cancer stage 0			



subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenocarcinoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extranodal marginal zone B-cell lymphoma (MALT type)			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Follicle centre lymphoma, follicular grade I, II, III stage I			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Follicle centre lymphoma, follicular grade I, II, III stage IV			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder adenocarcinoma			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Gastric cancer stage III			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Gastrointestinal tract adenoma			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Giant cell tumour of tendon sheath			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	2 / 2	1 / 1	
Glioblastoma multiforme			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Glomus tumour			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma of bone			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma of spleen			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hairy cell leukaemia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	3 / 3	1 / 1	
Hepatic cancer metastatic			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	5 / 4668 (0.11%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	5 / 5	4 / 4	
deaths causally related to treatment / all	2 / 2	1 / 1	
Hypopharyngeal cancer			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Intraductal proliferative breast lesion			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive breast carcinoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	11 / 4668 (0.24%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	11 / 11	9 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive lobular breast carcinoma			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratoacanthoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large cell lung cancer			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large granular lymphocytosis			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine benign neoplasm			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer stage I			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal squamous cell carcinoma			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Lip squamous cell carcinoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liposarcoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liposarcoma metastatic			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	6 / 4668 (0.13%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	6 / 6	3 / 3	
deaths causally related to treatment / all	2 / 2	0 / 0	
Lung adenocarcinoma metastatic			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	1 / 1	3 / 3	
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Lung cancer metastatic			
subjects affected / exposed	3 / 4668 (0.06%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	3 / 3	2 / 2	
deaths causally related to treatment / all	3 / 3	2 / 2	
Lung carcinoma cell type unspecified stage III			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Lung neoplasm			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	2 / 4668 (0.04%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	2 / 2	10 / 10	
deaths causally related to treatment / all	2 / 2	5 / 5	
Lung squamous cell carcinoma stage III			

subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Lung squamous cell carcinoma stage IV			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Malignant glioma			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	8 / 4668 (0.17%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	8 / 8	6 / 6	
deaths causally related to treatment / all	1 / 1	0 / 0	
Malignant melanoma in situ			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of pleura			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medullary thyroid cancer			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melanocytic naevus			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			

subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma benign			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma malignant			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Metastases to central nervous system			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	2 / 2	0 / 0	
Metastases to liver			
subjects affected / exposed	5 / 4668 (0.11%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	6 / 6	4 / 4	
deaths causally related to treatment / all	3 / 3	2 / 2	
Metastases to lung			
subjects affected / exposed	3 / 4668 (0.06%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	3 / 3	2 / 2	
deaths causally related to treatment / all	1 / 1	1 / 1	
Metastases to lymph nodes			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to peritoneum			



subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	1 / 1	1 / 1	
Metastases to spine			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Metastatic bronchial carcinoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic malignant melanoma			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	1 / 1	0 / 0	
Metastatic neoplasm			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	2 / 2	0 / 0	
Metastatic renal cell carcinoma			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	2 / 2	
Mucinous breast carcinoma			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			

subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Myxofibrosarcoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm of appendix			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm skin			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Neuroendocrine carcinoma of the skin			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Non-Hodgkin's lymphoma			
subjects affected / exposed	3 / 4668 (0.06%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	3 / 3	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Non-Hodgkin's lymphoma recurrent			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma stage III			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	4 / 4668 (0.09%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	4 / 4	2 / 2	
deaths causally related to treatment / all	2 / 2	2 / 2	
Non-small cell lung cancer metastatic			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	1 / 1	1 / 1	
Non-small cell lung cancer stage I			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal adenocarcinoma			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	2 / 2	0 / 0	
Oesophageal adenocarcinoma metastatic			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Oesophageal cancer metastatic			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Oesophageal squamous cell carcinoma			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal squamous cell carcinoma stage IV			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Oropharyngeal cancer stage IV			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Ovarian adenoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer metastatic			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Ovarian epithelial cancer			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Ovarian epithelial cancer metastatic			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	4 / 4668 (0.09%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	4 / 4	7 / 7	
deaths causally related to treatment / all	4 / 4	6 / 6	
Pancreatic carcinoma metastatic			

subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	2 / 2	2 / 2	
Pancreatic carcinoma stage IV			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pancreatic neoplasm			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Papillary cystadenoma lymphomatosum			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary serous endometrial carcinoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	4 / 4668 (0.09%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	5 / 5	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid tumour benign			
subjects affected / exposed	3 / 4668 (0.06%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	3 / 3	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic neoplasm			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phyllodes tumour			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pituitary tumour benign			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	3 / 4668 (0.06%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	3 / 3	5 / 5	
deaths causally related to treatment / all	2 / 2	2 / 2	
Plasmacytoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural mesothelioma			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	24 / 4668 (0.51%)	39 / 4672 (0.83%)	
occurrences causally related to treatment / all	24 / 24	39 / 39	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer metastatic			
subjects affected / exposed	2 / 4668 (0.04%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	2 / 2	4 / 4	
deaths causally related to treatment / all	1 / 1	1 / 1	
Prostate cancer recurrent			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage II			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma			
subjects affected / exposed	6 / 4668 (0.13%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	6 / 6	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenoma			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			
subjects affected / exposed	4 / 4668 (0.09%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	4 / 4	3 / 3	
deaths causally related to treatment / all	1 / 1	1 / 1	
Rectal cancer metastatic			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	1 / 1	1 / 1	
Rectal cancer stage II			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer metastatic			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer recurrent			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	2 / 4668 (0.04%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma stage II			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal neoplasm			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland neoplasm			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seborrhoeic keratosis			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin cancer			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Small cell lung cancer metastatic			



subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	2 / 2	1 / 1	
Small intestine carcinoma			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Small intestine carcinoma metastatic			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	4 / 4668 (0.09%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	4 / 4	2 / 2	
deaths causally related to treatment / all	1 / 1	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 4668 (0.02%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	1 / 1	5 / 5	
deaths causally related to treatment / all	1 / 1	3 / 3	
Squamous cell carcinoma of skin			
subjects affected / exposed	7 / 4668 (0.15%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	8 / 8	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the cervix			
subjects affected / exposed	4 / 4668 (0.09%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	5 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the tongue			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the vulva			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid adenoma			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid neoplasm			
subjects affected / exposed	4 / 4668 (0.09%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	4 / 4	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	8 / 4668 (0.17%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	8 / 8	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma metastatic			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Urinary tract neoplasm			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyosarcoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord neoplasm			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval neoplasm			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	1 / 4668 (0.02%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	1 / 1	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Air embolism			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	8 / 4668 (0.17%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	8 / 8	5 / 5	
deaths causally related to treatment / all	1 / 1	0 / 0	
Aortic aneurysm rupture			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic arteriosclerosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Aortic occlusion			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Aortic stenosis			
subjects affected / exposed	11 / 4668 (0.24%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	11 / 11	7 / 7	
deaths causally related to treatment / all	1 / 1	0 / 0	
Arteriosclerosis			
subjects affected / exposed	3 / 4668 (0.06%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	3 / 3	5 / 5	
deaths causally related to treatment / all	0 / 0	1 / 1	
Blood pressure fluctuation			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure inadequately controlled			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			

subjects affected / exposed	4 / 4668 (0.09%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	5 / 5	6 / 6	
deaths causally related to treatment / all	2 / 2	1 / 1	
Deep vein thrombosis			
subjects affected / exposed	20 / 4668 (0.43%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	23 / 23	11 / 11	
deaths causally related to treatment / all	1 / 1	1 / 1	
Diabetic vascular disorder			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry gangrene			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	4 / 4668 (0.09%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	4 / 4	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery occlusion			
subjects affected / exposed	6 / 4668 (0.13%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	7 / 7	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Granulomatosis with polyangiitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			

subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Hypertension			
subjects affected / exposed	32 / 4668 (0.69%)	25 / 4672 (0.54%)	
occurrences causally related to treatment / all	36 / 36	27 / 27	
deaths causally related to treatment / all	2 / 2	2 / 2	
Hypertensive crisis			
subjects affected / exposed	14 / 4668 (0.30%)	12 / 4672 (0.26%)	
occurrences causally related to treatment / all	18 / 18	13 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	18 / 4668 (0.39%)	16 / 4672 (0.34%)	
occurrences causally related to treatment / all	18 / 18	17 / 17	
deaths causally related to treatment / all	1 / 1	1 / 1	
Hypovolaemic shock			
subjects affected / exposed	2 / 4668 (0.04%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	2 / 2	1 / 1	
Iliac artery occlusion			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent claudication			
subjects affected / exposed	5 / 4668 (0.11%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	7 / 7	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Internal haemorrhage			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Labile hypertension			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leriche syndrome			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphocele			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoedema			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant hypertension			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microangiopathy			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrosis ischaemic			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurogenic shock			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Orthostatic hypotension			
subjects affected / exposed	10 / 4668 (0.21%)	8 / 4672 (0.17%)	
occurrences causally related to treatment / all	10 / 10	8 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penetrating atherosclerotic ulcer			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	24 / 4668 (0.51%)	34 / 4672 (0.73%)	
occurrences causally related to treatment / all	27 / 27	38 / 38	
deaths causally related to treatment / all	0 / 0	2 / 2	
Peripheral artery aneurysm			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	8 / 4668 (0.17%)	12 / 4672 (0.26%)	
occurrences causally related to treatment / all	9 / 9	19 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	4 / 4668 (0.09%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	5 / 5	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral circulatory failure			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Peripheral ischaemia			



subjects affected / exposed	13 / 4668 (0.28%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	14 / 14	12 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	10 / 4668 (0.21%)	8 / 4672 (0.17%)	
occurrences causally related to treatment / all	11 / 11	9 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral venous disease			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phleboscrosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	5 / 4668 (0.11%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	5 / 5	0 / 0	
deaths causally related to treatment / all	3 / 3	0 / 0	
Steal syndrome			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian artery stenosis			

subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subgaleal haematoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thromboangiitis obliterans			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis necrotising			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Surgical and medical procedures			
Abdominal panniculectomy			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominoplasty			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioplasty			
subjects affected / exposed	7 / 4668 (0.15%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	8 / 8	12 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle operation			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm repair			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic bypass			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic surgery			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial repair			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial stent insertion			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial therapeutic procedure			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula operation			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atherectomy			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ablation			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker battery replacement			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker removal			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker replacement			

subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac resynchronisation therapy			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary bypass			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular event prophylaxis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid angioplasty			
subjects affected / exposed	5 / 4668 (0.11%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	5 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery bypass			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stent insertion			
subjects affected / exposed	6 / 4668 (0.13%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	6 / 6	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid endarterectomy			
subjects affected / exposed	19 / 4668 (0.41%)	14 / 4672 (0.30%)	
occurrences causally related to treatment / all	23 / 23	14 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid revascularisation			

subjects affected / exposed	6 / 4668 (0.13%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	6 / 6	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract operation			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral revascularisation			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystectomy			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colostomy closure			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary angioplasty			
subjects affected / exposed	46 / 4668 (0.99%)	39 / 4672 (0.83%)	
occurrences causally related to treatment / all	56 / 56	42 / 42	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary arterial stent insertion			
subjects affected / exposed	110 / 4668 (2.36%)	112 / 4672 (2.40%)	
occurrences causally related to treatment / all	117 / 117	136 / 136	
deaths causally related to treatment / all	0 / 0	1 / 1	
Coronary artery bypass			
subjects affected / exposed	84 / 4668 (1.80%)	102 / 4672 (2.18%)	
occurrences causally related to treatment / all	86 / 86	105 / 105	
deaths causally related to treatment / all	2 / 2	1 / 1	
Coronary revascularisation			

subjects affected / exposed	120 / 4668 (2.57%)	132 / 4672 (2.83%)	
occurrences causally related to treatment / all	144 / 144	157 / 157	
deaths causally related to treatment / all	3 / 3	0 / 0	
Deep brain stimulation			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endarterectomy			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric banding			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric bypass			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroplasty			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip arthroplasty			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hospitalisation			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable defibrillator insertion			

subjects affected / exposed	2 / 4668 (0.04%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable defibrillator replacement			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia repair			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic heart disease prophylaxis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint arthroplasty			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee arthroplasty			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee operation			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma excision			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device battery replacement			



subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device change			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve replacement			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity surgery			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroidectomy			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic floor repair			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Percutaneous coronary intervention			
subjects affected / exposed	59 / 4668 (1.26%)	57 / 4672 (1.22%)	
occurrences causally related to treatment / all	71 / 71	66 / 66	
deaths causally related to treatment / all	1 / 1	0 / 0	
Peripheral artery angioplasty			
subjects affected / exposed	20 / 4668 (0.43%)	27 / 4672 (0.58%)	
occurrences causally related to treatment / all	25 / 25	29 / 29	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery bypass			

subjects affected / exposed	11 / 4668 (0.24%)	14 / 4672 (0.30%)	
occurrences causally related to treatment / all	12 / 12	19 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stent insertion			
subjects affected / exposed	7 / 4668 (0.15%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	10 / 10	10 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral endarterectomy			
subjects affected / exposed	6 / 4668 (0.13%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	7 / 7	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral revascularisation			
subjects affected / exposed	29 / 4668 (0.62%)	36 / 4672 (0.77%)	
occurrences causally related to treatment / all	33 / 33	47 / 47	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prophylaxis against dehydration			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rehabilitation therapy			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stent placement			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal revascularisation surgery			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin graft			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal decompression			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stent placement			
subjects affected / exposed	3 / 4668 (0.06%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	3 / 3	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombectomy			
subjects affected / exposed	0 / 4668 (0.00%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	0 / 0	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular operation			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent insertion			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist surgery			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Adhesion			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adverse drug reaction			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	9 / 4668 (0.19%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	10 / 10	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			
subjects affected / exposed	4 / 4668 (0.09%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	4 / 4	6 / 6	
deaths causally related to treatment / all	4 / 4	6 / 6	
Catheter site haemorrhage			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	3 / 4668 (0.06%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	3 / 3	6 / 6	
deaths causally related to treatment / all	0 / 0	1 / 1	
Chest pain			
subjects affected / exposed	53 / 4668 (1.14%)	49 / 4672 (1.05%)	
occurrences causally related to treatment / all	56 / 56	52 / 52	
deaths causally related to treatment / all	1 / 1	2 / 2	
Chills			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyst			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	55 / 4668 (1.18%)	47 / 4672 (1.01%)	
occurrences causally related to treatment / all	55 / 55	47 / 47	
deaths causally related to treatment / all	55 / 55	47 / 47	
Decreased activity			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device battery issue			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	2 / 4668 (0.04%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	3 / 3	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device leakage			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	2 / 4668 (0.04%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	3 / 3	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drowning			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Drug interaction			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug withdrawal syndrome			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Gait disturbance			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	2 / 2	
Generalised oedema			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	1 / 1	0 / 0	
Granuloma			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			

subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ill-defined disorder			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing			
subjects affected / exposed	4 / 4668 (0.09%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	4 / 4	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Incarcerated hernia			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Local swelling			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mass			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device complication			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metaplasia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal inflammation			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ failure			
subjects affected / exposed	7 / 4668 (0.15%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	7 / 7	9 / 9	
deaths causally related to treatment / all	6 / 6	9 / 9	
Necrosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	45 / 4668 (0.96%)	63 / 4672 (1.35%)	
occurrences causally related to treatment / all	52 / 52	73 / 73	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			



subjects affected / exposed	6 / 4668 (0.13%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	6 / 6	10 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyp			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	5 / 4668 (0.11%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	6 / 6	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stent-graft endoleak			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	4 / 4668 (0.09%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	4 / 4	6 / 6	
deaths causally related to treatment / all	4 / 4	6 / 6	
Sudden death			
subjects affected / exposed	11 / 4668 (0.24%)	17 / 4672 (0.36%)	
occurrences causally related to treatment / all	11 / 11	17 / 17	
deaths causally related to treatment / all	11 / 11	17 / 17	
Systemic inflammatory response syndrome			

subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis in device			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Amyloidosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contrast media allergy			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	4 / 4668 (0.09%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	4 / 4	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			

Social stay hospitalisation			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Walking disability			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired phimosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	25 / 4668 (0.54%)	23 / 4672 (0.49%)	
occurrences causally related to treatment / all	25 / 25	23 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast mass			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical polyp			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Endometrial hyperplasia			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erectile dysfunction			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital prolapse			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematospermia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peyronie's disease			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic dysplasia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			

subjects affected / exposed	7 / 4668 (0.15%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	7 / 7	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular cyst			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular mass			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular necrosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	1 / 4668 (0.02%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	1 / 1	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal fistula			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			

subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute interstitial pneumonitis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	13 / 4668 (0.28%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	15 / 15	13 / 13	
deaths causally related to treatment / all	1 / 1	3 / 3	
Acute respiratory distress syndrome			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	1 / 1	1 / 1	
Acute respiratory failure			
subjects affected / exposed	22 / 4668 (0.47%)	18 / 4672 (0.39%)	
occurrences causally related to treatment / all	23 / 23	21 / 21	
deaths causally related to treatment / all	5 / 5	2 / 2	
Asphyxia			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	2 / 2	
Aspiration			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Asthma			

subjects affected / exposed	12 / 4668 (0.26%)	14 / 4672 (0.30%)	
occurrences causally related to treatment / all	14 / 14	23 / 23	
deaths causally related to treatment / all	0 / 0	1 / 1	
Asthmatic crisis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial hyperreactivity			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis chronic			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumopathy			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Bronchospasm			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	6 / 6	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Chronic obstructive pulmonary disease			

subjects affected / exposed	50 / 4668 (1.07%)	59 / 4672 (1.26%)	
occurrences causally related to treatment / all	68 / 68	82 / 82	
deaths causally related to treatment / all	3 / 3	7 / 7	
Chronic respiratory failure			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dependence on respirator			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	20 / 4668 (0.43%)	32 / 4672 (0.68%)	
occurrences causally related to treatment / all	21 / 21	36 / 36	
deaths causally related to treatment / all	2 / 2	7 / 7	
Dyspnoea exertional			
subjects affected / exposed	6 / 4668 (0.13%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	6 / 6	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
Epistaxis			
subjects affected / exposed	8 / 4668 (0.17%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	8 / 8	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			



subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatopulmonary syndrome			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercapnia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	5 / 4668 (0.11%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	5 / 5	3 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal dysplasia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal oedema			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal stenosis			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infiltration			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Nasal polyps			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal septum deviation			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngeal polyp			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Non-cardiogenic pulmonary oedema			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive airways disorder			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organising pneumonia			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paranasal cyst			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal cyst			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal inflammation			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	4 / 4668 (0.09%)	15 / 4672 (0.32%)	
occurrences causally related to treatment / all	4 / 4	18 / 18	
deaths causally related to treatment / all	1 / 1	1 / 1	
Pleurisy			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	7 / 4668 (0.15%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	7 / 7	7 / 7	
deaths causally related to treatment / all	2 / 2	2 / 2	
Pneumonitis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			

subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary cavitation			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	21 / 4668 (0.45%)	24 / 4672 (0.51%)	
occurrences causally related to treatment / all	21 / 21	26 / 26	
deaths causally related to treatment / all	2 / 2	5 / 5	
Pulmonary fibrosis			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	4 / 4	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pulmonary hypertension			
subjects affected / exposed	3 / 4668 (0.06%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	3 / 3	5 / 5	
deaths causally related to treatment / all	1 / 1	1 / 1	
Pulmonary mass			
subjects affected / exposed	3 / 4668 (0.06%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	3 / 3	8 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	17 / 4668 (0.36%)	21 / 4672 (0.45%)	
occurrences causally related to treatment / all	22 / 22	25 / 25	
deaths causally related to treatment / all	6 / 6	0 / 0	
Pulmonary sarcoidosis			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory arrest			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Respiratory distress			
subjects affected / exposed	5 / 4668 (0.11%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	5 / 5	0 / 0	
deaths causally related to treatment / all	3 / 3	0 / 0	
Respiratory failure			
subjects affected / exposed	18 / 4668 (0.39%)	19 / 4672 (0.41%)	
occurrences causally related to treatment / all	20 / 20	21 / 21	
deaths causally related to treatment / all	5 / 5	10 / 10	
Restrictive pulmonary disease			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis allergic			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis hypertrophic			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus polyp			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			

subjects affected / exposed	9 / 4668 (0.19%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	9 / 9	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status asthmaticus			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper airway obstruction			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord polyp			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	3 / 4668 (0.06%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	5 / 5	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			

subjects affected / exposed	1 / 4668 (0.02%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	1 / 1	4 / 4	
deaths causally related to treatment / all	1 / 1	4 / 4	
Confusional state			
subjects affected / exposed	0 / 4668 (0.00%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	0 / 0	9 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
Depression			
subjects affected / exposed	9 / 4668 (0.19%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	11 / 11	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disorientation			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	1 / 4668 (0.02%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	1 / 1	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mania			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental disorder			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			

subjects affected / exposed	3 / 4668 (0.06%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	3 / 3	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Personality disorder			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somatisation disorder			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	4 / 4668 (0.09%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	4 / 4	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Bile duct stenosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary cirrhosis			



subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	5 / 4668 (0.11%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	5 / 5	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary fistula			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Cholangitis			
subjects affected / exposed	2 / 4668 (0.04%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	3 / 3	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	4 / 4668 (0.09%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	11 / 4668 (0.24%)	12 / 4672 (0.26%)	
occurrences causally related to treatment / all	11 / 11	12 / 12	
deaths causally related to treatment / all	1 / 1	0 / 0	
Cholecystitis acute			
subjects affected / exposed	35 / 4668 (0.75%)	18 / 4672 (0.39%)	
occurrences causally related to treatment / all	35 / 35	19 / 19	
deaths causally related to treatment / all	1 / 1	1 / 1	
Cholecystitis chronic			
subjects affected / exposed	8 / 4668 (0.17%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	8 / 8	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			

subjects affected / exposed	44 / 4668 (0.94%)	30 / 4672 (0.64%)	
occurrences causally related to treatment / all	45 / 45	30 / 30	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic hepatic failure			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	2 / 2	
Chronic hepatitis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cirrhosis alcoholic			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Cryptogenic cirrhosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder disorder			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder perforation			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder polyp			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	4 / 4668 (0.09%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	4 / 4	6 / 6	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hepatic cyst			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hepatic lesion			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic steatosis			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hepatitis acute			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatomegaly			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatorenal syndrome			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Ischaemic hepatitis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal hypertension			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Ammonia increased			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amylase increased			
subjects affected / exposed	5 / 4668 (0.11%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	5 / 5	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiogram peripheral			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriogram coronary			
subjects affected / exposed	0 / 4668 (0.00%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	0 / 0	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood alcohol increased			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood calcitonin increased			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	6 / 4668 (0.13%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	6 / 6	3 / 3	
deaths causally related to treatment / all	1 / 1	0 / 0	
Blood glucose fluctuation			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose increased			
subjects affected / exposed	8 / 4668 (0.17%)	8 / 4672 (0.17%)	
occurrences causally related to treatment / all	8 / 8	11 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood iron decreased			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood magnesium decreased			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium decreased			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium increased			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure decreased			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure increased			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure systolic increased			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood urea increased			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood urine present			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac murmur			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac stress test abnormal			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular evaluation			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheterisation cardiac			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonoscopy			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonoscopy normal			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Culture urine positive			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ECG signs of myocardial ischaemia			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerular filtration rate decreased			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glycosylated haemoglobin increased			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			



subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate decreased			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate increased			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Imaging procedure			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory marker increased			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio decreased			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	3 / 4668 (0.06%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	3 / 3	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular end-diastolic pressure increased			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipase increased			
subjects affected / exposed	11 / 4668 (0.24%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	11 / 11	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial necrosis marker increased			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic enzymes increased			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic specific antigen increased			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Red blood cell sedimentation rate increased			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal function test			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Serum ferritin decreased			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transplant evaluation			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urine albumin/creatinine ratio increased			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight increased			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accident			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			

subjects affected / exposed	5 / 4668 (0.11%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	5 / 5	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Afferent loop syndrome			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	2 / 4668 (0.04%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	2 / 2	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial restenosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula site complication			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula thrombosis			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asbestosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder injury			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain herniation			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns second degree			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbon monoxide poisoning			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Cardiac valve replacement complication			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve rupture			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery restenosis			

subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract operation complication			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract traumatic			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Complications of transplanted kidney			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	1 / 4668 (0.02%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	1 / 1	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery reocclusion			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery restenosis			
subjects affected / exposed	5 / 4668 (0.11%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	5 / 5	10 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary vascular graft occlusion			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delayed recovery from anaesthesia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dialysis related complication			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electric shock			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			

subjects affected / exposed	84 / 4668 (1.80%)	81 / 4672 (1.73%)	
occurrences causally related to treatment / all	94 / 94	83 / 83	
deaths causally related to treatment / all	3 / 3	4 / 4	
Fat embolism			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	3 / 4668 (0.06%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	3 / 3	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	6 / 4668 (0.13%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	6 / 6	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Foot fracture			
subjects affected / exposed	1 / 4668 (0.02%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	1 / 1	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture displacement			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Frostbite			



subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gun shot wound			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Hand fracture			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	4 / 4668 (0.09%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	4 / 4	4 / 4	
deaths causally related to treatment / all	1 / 1	0 / 0	
Heat exhaustion			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	5 / 4668 (0.11%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	6 / 6	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Human bite			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			

subjects affected / exposed	4 / 4668 (0.09%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	4 / 4	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incorrect dose administered			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation of wound			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional overdose			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw fracture			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	4 / 4668 (0.09%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	5 / 5	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laceration			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb traumatic amputation			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	3 / 4668 (0.06%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	3 / 3	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle rupture			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle strain			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial reocclusion			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery restenosis			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post laminectomy syndrome			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural fistula			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			

subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematuria			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural hypothyroidism			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural myocardial infarction			
subjects affected / exposed	0 / 4668 (0.00%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	0 / 0	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural pulmonary embolism			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Post procedural stroke			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic pain			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative fever			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative hernia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative respiratory failure			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative thoracic procedure complication			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Postoperative thrombosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound complication			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural hypotension			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural intestinal perforation			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation pneumonitis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Radius fracture			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory fume inhalation disorder			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Rib fracture			
subjects affected / exposed	2 / 4668 (0.04%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	2 / 2	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	20 / 4668 (0.43%)	16 / 4672 (0.34%)	
occurrences causally related to treatment / all	23 / 23	16 / 16	
deaths causally related to treatment / all	3 / 3	3 / 3	
Scapula fracture			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seroma			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shunt occlusion			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skeletal injury			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue injury			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord injury thoracic			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic rupture			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stab wound			



subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Sternal fracture</b>			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Subcutaneous haematoma</b>			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Subdural haematoma</b>			
subjects affected / exposed	5 / 4668 (0.11%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	6 / 6	10 / 10	
deaths causally related to treatment / all	0 / 0	3 / 3	
<b>Subdural haemorrhage</b>			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tendon rupture</b>			
subjects affected / exposed	3 / 4668 (0.06%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	3 / 3	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Thermal burn</b>			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tibia fracture</b>			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Toxicity to various agents</b>			

subjects affected / exposed	4 / 4668 (0.09%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	4 / 4	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheostomy malfunction			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic arthritis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic arthrosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic ulcer			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention postoperative			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft occlusion			
subjects affected / exposed	3 / 4668 (0.06%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	3 / 3	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft thrombosis			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	3 / 3	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	4 / 4	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound decomposition			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haemorrhage			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Wound necrosis			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrong drug administered			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Arteriovenous malformation			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial septal defect			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Buried penis syndrome			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coarctation of the aorta			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital cystic kidney disease			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermoid cyst			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hamartoma			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial lipoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreas divisum			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheo-oesophageal fistula			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			

subjects affected / exposed	37 / 4668 (0.79%)	54 / 4672 (1.16%)	
occurrences causally related to treatment / all	41 / 41	59 / 59	
deaths causally related to treatment / all	2 / 2	1 / 1	
Acute left ventricular failure			
subjects affected / exposed	2 / 4668 (0.04%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	2 / 2	7 / 7	
deaths causally related to treatment / all	1 / 1	1 / 1	
Acute myocardial infarction			
subjects affected / exposed	155 / 4668 (3.32%)	187 / 4672 (4.00%)	
occurrences causally related to treatment / all	176 / 176	211 / 211	
deaths causally related to treatment / all	17 / 17	26 / 26	
Adams-Stokes syndrome			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	93 / 4668 (1.99%)	93 / 4672 (1.99%)	
occurrences causally related to treatment / all	105 / 105	106 / 106	
deaths causally related to treatment / all	2 / 2	1 / 1	
Angina unstable			
subjects affected / exposed	144 / 4668 (3.08%)	151 / 4672 (3.23%)	
occurrences causally related to treatment / all	179 / 179	180 / 180	
deaths causally related to treatment / all	2 / 2	1 / 1	
Aortic valve calcification			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	2 / 2	
Aortic valve sclerosis			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	6 / 4668 (0.13%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	6 / 6	10 / 10	
deaths causally related to treatment / all	1 / 1	0 / 0	
Arrhythmia			
subjects affected / exposed	10 / 4668 (0.21%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	11 / 11	5 / 5	
deaths causally related to treatment / all	3 / 3	0 / 0	
Arrhythmia supraventricular			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	7 / 4668 (0.15%)	12 / 4672 (0.26%)	
occurrences causally related to treatment / all	7 / 7	12 / 12	
deaths causally related to treatment / all	1 / 1	2 / 2	
Atrial fibrillation			
subjects affected / exposed	89 / 4668 (1.91%)	97 / 4672 (2.08%)	
occurrences causally related to treatment / all	113 / 113	112 / 112	
deaths causally related to treatment / all	1 / 1	4 / 4	
Atrial flutter			
subjects affected / exposed	17 / 4668 (0.36%)	16 / 4672 (0.34%)	
occurrences causally related to treatment / all	20 / 20	18 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	1 / 4668 (0.02%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	1 / 1	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			

subjects affected / exposed	1 / 4668 (0.02%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	1 / 1	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	10 / 4668 (0.21%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	10 / 10	9 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block first degree			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular dissociation			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	5 / 4668 (0.11%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	5 / 5	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	11 / 4668 (0.24%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	11 / 11	11 / 11	
deaths causally related to treatment / all	0 / 0	1 / 1	
Bundle branch block left			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block right			



subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac aneurysm			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	1 / 1	1 / 1	
Cardiac arrest			
subjects affected / exposed	20 / 4668 (0.43%)	31 / 4672 (0.66%)	
occurrences causally related to treatment / all	20 / 20	31 / 31	
deaths causally related to treatment / all	12 / 12	22 / 22	
Cardiac discomfort			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorder			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	115 / 4668 (2.46%)	137 / 4672 (2.93%)	
occurrences causally related to treatment / all	138 / 138	201 / 201	
deaths causally related to treatment / all	16 / 16	21 / 21	
Cardiac failure acute			
subjects affected / exposed	9 / 4668 (0.19%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	11 / 11	12 / 12	
deaths causally related to treatment / all	2 / 2	2 / 2	
Cardiac failure chronic			
subjects affected / exposed	28 / 4668 (0.60%)	25 / 4672 (0.54%)	
occurrences causally related to treatment / all	28 / 28	29 / 29	
deaths causally related to treatment / all	2 / 2	3 / 3	
Cardiac failure congestive			

subjects affected / exposed	121 / 4668 (2.59%)	129 / 4672 (2.76%)	
occurrences causally related to treatment / all	180 / 180	176 / 176	
deaths causally related to treatment / all	8 / 8	18 / 18	
Cardiac valve disease			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ventricular thrombosis			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cardio-respiratory arrest			
subjects affected / exposed	15 / 4668 (0.32%)	13 / 4672 (0.28%)	
occurrences causally related to treatment / all	15 / 15	15 / 15	
deaths causally related to treatment / all	12 / 12	13 / 13	
Cardiogenic shock			
subjects affected / exposed	4 / 4668 (0.09%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	4 / 4	11 / 11	
deaths causally related to treatment / all	3 / 3	8 / 8	
Cardiomegaly			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cardiomyopathy			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	4 / 4	
deaths causally related to treatment / all	0 / 0	2 / 2	
Cardiopulmonary failure			
subjects affected / exposed	3 / 4668 (0.06%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	3 / 3	6 / 6	
deaths causally related to treatment / all	3 / 3	4 / 4	
Cardiorenal syndrome			

subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular disorder			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	2 / 2	
Cardiovascular insufficiency			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	2 / 2	0 / 0	
Chordae tendinae rupture			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive cardiomyopathy			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cor pulmonale			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale acute			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale chronic			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			

subjects affected / exposed	73 / 4668 (1.56%)	87 / 4672 (1.86%)	
occurrences causally related to treatment / all	77 / 77	89 / 89	
deaths causally related to treatment / all	4 / 4	4 / 4	
Coronary artery insufficiency			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	16 / 4668 (0.34%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	16 / 16	10 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	20 / 4668 (0.43%)	35 / 4672 (0.75%)	
occurrences causally related to treatment / all	20 / 20	36 / 36	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary ostial stenosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dilatation atrial			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrasystoles			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive cardiomyopathy			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive heart disease			

subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	1 / 1	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	3 / 4668 (0.06%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	3 / 3	9 / 9	
deaths causally related to treatment / all	1 / 1	1 / 1	
Left ventricular dysfunction			
subjects affected / exposed	5 / 4668 (0.11%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	5 / 5	10 / 10	
deaths causally related to treatment / all	0 / 0	1 / 1	
Left ventricular failure			
subjects affected / exposed	3 / 4668 (0.06%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	3 / 3	7 / 7	
deaths causally related to treatment / all	0 / 0	1 / 1	
Left ventricular hypertrophy			
subjects affected / exposed	3 / 4668 (0.06%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	3 / 3	3 / 3	
deaths causally related to treatment / all	1 / 1	0 / 0	
Microvascular coronary artery disease			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve calcification			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	3 / 4668 (0.06%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	3 / 3	10 / 10	
deaths causally related to treatment / all	0 / 0	3 / 3	
Mitral valve stenosis			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial fibrosis			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	68 / 4668 (1.46%)	84 / 4672 (1.80%)	
occurrences causally related to treatment / all	71 / 71	89 / 89	
deaths causally related to treatment / all	18 / 18	31 / 31	
Myocardial ischaemia			
subjects affected / exposed	27 / 4668 (0.58%)	33 / 4672 (0.71%)	
occurrences causally related to treatment / all	27 / 27	35 / 35	
deaths causally related to treatment / all	1 / 1	8 / 8	
Myocarditis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal rhythm			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	3 / 4668 (0.06%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	3 / 3	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial cyst			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			

subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial haemorrhage			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 4668 (0.02%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	1 / 1	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis uraemic			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumopericardium			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postural orthostatic tachycardia syndrome			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhythm idioventricular			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Silent myocardial infarction			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus arrest			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus bradycardia			
subjects affected / exposed	0 / 4668 (0.00%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	0 / 0	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	10 / 4668 (0.21%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	10 / 10	9 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Supraventricular extrasystoles			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	9 / 4668 (0.19%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	9 / 9	9 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systolic dysfunction			



subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	4 / 4668 (0.09%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	4 / 4	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence			
subjects affected / exposed	0 / 4668 (0.00%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	2 / 2	
Ventricular arrhythmia			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Ventricular dyssynchrony			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	5 / 4668 (0.11%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	5 / 5	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	4 / 4668 (0.09%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	4 / 4	6 / 6	
deaths causally related to treatment / all	1 / 1	1 / 1	
Ventricular hypokinesia			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachyarrhythmia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	18 / 4668 (0.39%)	8 / 4672 (0.17%)	
occurrences causally related to treatment / all	29 / 29	11 / 11	
deaths causally related to treatment / all	1 / 1	0 / 0	
Wolff-Parkinson-White syndrome			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autonomic nervous system imbalance			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia haemorrhage			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Basal ganglia stroke			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	2 / 2	
Brain oedema			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Brain stem infarction			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid arteriosclerosis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery aneurysm			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery disease			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	3 / 4668 (0.06%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	3 / 3	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			

subjects affected / exposed	28 / 4668 (0.60%)	16 / 4672 (0.34%)	
occurrences causally related to treatment / all	30 / 30	18 / 18	
deaths causally related to treatment / all	0 / 0	1 / 1	
Carpal tunnel syndrome			
subjects affected / exposed	6 / 4668 (0.13%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	7 / 7	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda equina syndrome			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar haematoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cerebellar infarction			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar ischaemia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cerebral haemorrhage			
subjects affected / exposed	4 / 4668 (0.09%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	4 / 4	5 / 5	
deaths causally related to treatment / all	1 / 1	1 / 1	
Cerebral hypoperfusion			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	14 / 4668 (0.30%)	20 / 4672 (0.43%)	
occurrences causally related to treatment / all	14 / 14	21 / 21	
deaths causally related to treatment / all	2 / 2	3 / 3	
Cerebral ischaemia			
subjects affected / exposed	3 / 4668 (0.06%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	3 / 3	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral small vessel ischaemic disease			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	52 / 4668 (1.11%)	65 / 4672 (1.39%)	
occurrences causally related to treatment / all	56 / 56	68 / 68	
deaths causally related to treatment / all	8 / 8	11 / 11	
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical myelopathy			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic inflammatory demyelinating polyradiculoneuropathy			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	4 / 4668 (0.09%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	4 / 4	4 / 4	
deaths causally related to treatment / all	0 / 0	1 / 1	
Coma			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	2 / 2	
Dementia			
subjects affected / exposed	3 / 4668 (0.06%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	3 / 3	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia Alzheimer's type			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia with Lewy bodies			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressed level of consciousness			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic mononeuropathy			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathy			

subjects affected / exposed	9 / 4668 (0.19%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	10 / 10	12 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	12 / 4668 (0.26%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	12 / 12	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyskinesia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolitic cerebral infarction			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolitic stroke			
subjects affected / exposed	5 / 4668 (0.11%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	6 / 6	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Epilepsy			
subjects affected / exposed	4 / 4668 (0.09%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	5 / 5	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			

subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	6 / 4668 (0.13%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	6 / 6	4 / 4	
deaths causally related to treatment / all	1 / 1	2 / 2	
Haemorrhagic cerebral infarction			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	10 / 4668 (0.21%)	13 / 4672 (0.28%)	
occurrences causally related to treatment / all	10 / 10	13 / 13	
deaths causally related to treatment / all	3 / 3	7 / 7	
Headache			
subjects affected / exposed	2 / 4668 (0.04%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	2 / 2	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiplegia			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			



subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hydrocephalus			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperaesthesia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive encephalopathy			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic coma			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic seizure			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic unconsciousness			
subjects affected / exposed	21 / 4668 (0.45%)	28 / 4672 (0.60%)	
occurrences causally related to treatment / all	24 / 24	28 / 28	
deaths causally related to treatment / all	0 / 0	1 / 1	
Hypoxic-ischaemic encephalopathy			

subjects affected / exposed	2 / 4668 (0.04%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	1 / 1	2 / 2	
IIIrd nerve disorder			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intercostal neuralgia			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Internal carotid artery kinking			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cerebral infarction			
subjects affected / exposed	2 / 4668 (0.04%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	3 / 3	4 / 4	
deaths causally related to treatment / all	0 / 0	1 / 1	
Ischaemic stroke			
subjects affected / exposed	50 / 4668 (1.07%)	54 / 4672 (1.16%)	
occurrences causally related to treatment / all	54 / 54	59 / 59	
deaths causally related to treatment / all	3 / 3	7 / 7	
Lacunar infarction			
subjects affected / exposed	6 / 4668 (0.13%)	8 / 4672 (0.17%)	
occurrences causally related to treatment / all	7 / 7	8 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	5 / 4668 (0.11%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	6 / 6	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			
subjects affected / exposed	4 / 4668 (0.09%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	4 / 4	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Memory impairment			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	6 / 4668 (0.13%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	6 / 6	0 / 0	
deaths causally related to treatment / all	2 / 2	0 / 0	
Migraine			
subjects affected / exposed	0 / 4668 (0.00%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mononeuropathy			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple system atrophy			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Myasthenia gravis			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve compression			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuritis cranial			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normal pressure hydrocephalus			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic intolerance			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraplegia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	1 / 1	0 / 0	
Parkinsonism			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve lesion			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peroneal nerve palsy			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Petit mal epilepsy			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			

subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post herpetic neuralgia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic headache			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	6 / 4668 (0.13%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	7 / 7	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Restless legs syndrome			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reversible ischaemic neurological deficit			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	4 / 4668 (0.09%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	4 / 4	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			

subjects affected / exposed	7 / 4668 (0.15%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	7 / 7	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure like phenomena			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Serotonin syndrome			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal claudication			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	4 / 4668 (0.09%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	4 / 4	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	39 / 4668 (0.84%)	26 / 4672 (0.56%)	
occurrences causally related to treatment / all	43 / 43	27 / 27	
deaths causally related to treatment / all	1 / 1	0 / 0	
Tension headache			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamic infarction			

subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic cerebral infarction			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic stroke			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	2 / 2	0 / 0	
Toxic encephalopathy			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	52 / 4668 (1.11%)	68 / 4672 (1.46%)	
occurrences causally related to treatment / all	57 / 57	73 / 73	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unresponsive to stimuli			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uraemic encephalopathy			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
VIIth nerve paralysis			
subjects affected / exposed	3 / 4668 (0.06%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	3 / 3	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			



subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Vertebral artery stenosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord paralysis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	31 / 4668 (0.66%)	21 / 4672 (0.45%)	
occurrences causally related to treatment / all	32 / 32	22 / 22	
deaths causally related to treatment / all	1 / 1	0 / 0	
Anaemia macrocytic			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia megaloblastic			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia vitamin B12 deficiency			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic anaemia			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic anaemia			
subjects affected / exposed	1 / 4668 (0.02%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	1 / 1	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypochromic anaemia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenic purpura			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	9 / 4668 (0.19%)	13 / 4672 (0.28%)	
occurrences causally related to treatment / all	9 / 9	13 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic anaemia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Paratracheal lymphadenopathy			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic embolism			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			

subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenomegaly			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Aural polyp			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness bilateral			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eustachian tube dysfunction			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	6 / 4668 (0.13%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	6 / 6	10 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angle closure glaucoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphakia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune uveitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blepharitis			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	24 / 4668 (0.51%)	32 / 4672 (0.68%)	
occurrences causally related to treatment / all	29 / 29	35 / 35	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal erosion			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic blindness			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinal oedema			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	9 / 4668 (0.19%)	15 / 4672 (0.32%)	
occurrences causally related to treatment / all	9 / 9	15 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye haemorrhage			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid ptosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iridocyclitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iritis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular fibrosis			
subjects affected / exposed	2 / 4668 (0.04%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	2 / 2	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular oedema			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular rupture			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open angle glaucoma			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic nerve infarction			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papilloedema			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal aneurysm			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery embolism			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal degeneration			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			



subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal infarction			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vascular occlusion			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein occlusion			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein thrombosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy			
subjects affected / exposed	2 / 4668 (0.04%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy haemorrhagic			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy proliferative			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative keratitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous adhesions			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	6 / 4668 (0.13%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	6 / 6	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			

subjects affected / exposed	2 / 4668 (0.04%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal incarcerated hernia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal mass			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	20 / 4668 (0.43%)	15 / 4672 (0.32%)	
occurrences causally related to treatment / all	20 / 20	16 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	5 / 4668 (0.11%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	6 / 6	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal strangulated hernia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acid peptic disease			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acquired oesophageal web			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal skin tags			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Barrett's oesophagus			
subjects affected / exposed	2 / 4668 (0.04%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiospasm			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Change of bowel habit			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	0 / 4668 (0.00%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			

subjects affected / exposed	9 / 4668 (0.19%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	9 / 9	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic pseudo-obstruction			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	11 / 4668 (0.24%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	11 / 11	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	14 / 4668 (0.30%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	14 / 14	11 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	2 / 4668 (0.04%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	2 / 2	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis intestinal haemorrhagic			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	2 / 4668 (0.04%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	2 / 2	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal perforation			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal polyp			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	8 / 4668 (0.17%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	8 / 8	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	3 / 4668 (0.06%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	3 / 3	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer perforation			

subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	4 / 4668 (0.09%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	4 / 4	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocutaneous fistula			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical fistula			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epigastric discomfort			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive oesophagitis			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecal incontinence			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecalith			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecaloma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric antral vascular ectasia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric polyps			



subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	4 / 4668 (0.09%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	4 / 4	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	5 / 4668 (0.11%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	5 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer perforation			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	15 / 4668 (0.32%)	13 / 4672 (0.28%)	
occurrences causally related to treatment / all	16 / 16	14 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	4 / 4668 (0.09%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	4 / 4	10 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroduodenitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia			

subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorder			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	14 / 4668 (0.30%)	21 / 4672 (0.45%)	
occurrences causally related to treatment / all	17 / 17	27 / 27	
deaths causally related to treatment / all	2 / 2	3 / 3	
Gastrointestinal hypomotility			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal necrosis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal polyp haemorrhage			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal ulcer haemorrhage			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	11 / 4668 (0.24%)	12 / 4672 (0.26%)	
occurrences causally related to treatment / all	11 / 11	12 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	1 / 4668 (0.02%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	1 / 1	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	3 / 4668 (0.06%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	3 / 3	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	0 / 4668 (0.00%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	0 / 0	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	4 / 4668 (0.09%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	4 / 4	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	5 / 4668 (0.11%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	6 / 6	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated hiatus hernia			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory bowel disease			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	12 / 4668 (0.26%)	14 / 4672 (0.30%)	
occurrences causally related to treatment / all	15 / 15	14 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal infarction			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	3 / 4668 (0.06%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	3 / 3	2 / 2	
deaths causally related to treatment / all	2 / 2	1 / 1	
Intestinal obstruction			
subjects affected / exposed	2 / 4668 (0.04%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	2 / 2	9 / 9	
deaths causally related to treatment / all	0 / 0	1 / 1	
Intestinal polyp			

subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable bowel syndrome			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal ulcer			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	16 / 4668 (0.34%)	13 / 4672 (0.28%)	
occurrences causally related to treatment / all	16 / 16	18 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mechanical ileus			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery embolism			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Nausea			
subjects affected / exposed	8 / 4668 (0.17%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	9 / 9	9 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedematous pancreatitis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal achalasia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Oesophagitis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis ulcerative			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic cyst			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic disorder			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic mass			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pancreatic pseudocyst			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	18 / 4668 (0.39%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	20 / 20	11 / 11	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pancreatitis acute			
subjects affected / exposed	14 / 4668 (0.30%)	19 / 4672 (0.41%)	
occurrences causally related to treatment / all	14 / 14	22 / 22	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pancreatitis chronic			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis relapsing			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			
subjects affected / exposed	3 / 4668 (0.06%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	3 / 3	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal adhesions			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal haematoma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctitis ulcerative			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reactive gastropathy			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	6 / 4668 (0.13%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	7 / 7	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			
subjects affected / exposed	3 / 4668 (0.06%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	3 / 3	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal prolapse			



subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reflux gastritis			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haematoma			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Retroperitoneal mass			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland mass			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Short-bowel syndrome			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	10 / 4668 (0.21%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	12 / 12	23 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swollen tongue			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth socket haemorrhage			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	6 / 4668 (0.13%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	6 / 6	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	6 / 4668 (0.13%)	8 / 4672 (0.17%)	
occurrences causally related to treatment / all	6 / 6	8 / 8	
deaths causally related to treatment / all	1 / 1	0 / 0	
Volvulus			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	8 / 8	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	17 / 4668 (0.36%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	20 / 20	11 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Actinic elastosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Actinic keratosis			
subjects affected / exposed	4 / 4668 (0.09%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	5 / 5	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alopecia areata			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	6 / 4668 (0.13%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	8 / 8	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic pigmented purpura			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic spontaneous urticaria			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Dermatitis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis contact			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	66 / 4668 (1.41%)	80 / 4672 (1.71%)	
occurrences causally related to treatment / all	88 / 88	94 / 94	
deaths causally related to treatment / all	0 / 0	3 / 3	
Diabetic neuropathic ulcer			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ulcer			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	4 / 4	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage subcutaneous			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keloid scar			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lichen sclerosus			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lividity			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melanocytic hyperplasia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nail bed inflammation			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrobiosis lipoidica diabetorum			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurodermatitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic ulcer			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parapsoriasis			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pemphigoid			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin lesion			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			

subjects affected / exposed	10 / 4668 (0.21%)	15 / 4672 (0.32%)	
occurrences causally related to treatment / all	10 / 10	15 / 15	
deaths causally related to treatment / all	1 / 1	0 / 0	
Skin necrosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stasis dermatitis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic epidermal necrolysis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria papular			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	108 / 4668 (2.31%)	94 / 4672 (2.01%)	
occurrences causally related to treatment / all	124 / 124	105 / 105	
deaths causally related to treatment / all	10 / 10	8 / 8	
Acute prerenal failure			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Azotaemia			
subjects affected / exposed	3 / 4668 (0.06%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	3 / 3	2 / 2	
deaths causally related to treatment / all	1 / 1	0 / 0	
Bladder diverticulum			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder dysplasia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder hypertrophy			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck obstruction			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder outlet obstruction			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder prolapse			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder stenosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus ureteric			

subjects affected / exposed	10 / 4668 (0.21%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	10 / 10	9 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	52 / 4668 (1.11%)	52 / 4672 (1.11%)	
occurrences causally related to treatment / all	60 / 60	55 / 55	
deaths causally related to treatment / all	11 / 11	8 / 8	
Diabetic nephropathy			
subjects affected / exposed	6 / 4668 (0.13%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	7 / 7	11 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibrillary glomerulonephritis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Focal segmental glomerulosclerosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis membranous			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulosclerosis			



subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	7 / 4668 (0.15%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	7 / 7	2 / 2	
deaths causally related to treatment / all	1 / 1	0 / 0	
Haemorrhage urinary tract			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	5 / 4668 (0.11%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	6 / 6	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesangioproliferative glomerulonephritis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microalbuminuria			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephritis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Nephrolithiasis			
subjects affected / exposed	26 / 4668 (0.56%)	21 / 4672 (0.45%)	
occurrences causally related to treatment / all	27 / 27	22 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			

subjects affected / exposed	6 / 4668 (0.13%)	13 / 4672 (0.28%)	
occurrences causally related to treatment / all	6 / 6	15 / 15	
deaths causally related to treatment / all	0 / 0	1 / 1	
Nephropathy toxic			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nocturia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive uropathy			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvi-ureteric obstruction			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyuria			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proteinuria			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery arteriosclerosis			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery occlusion			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stenosis			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	5 / 4668 (0.11%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	5 / 5	11 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	20 / 4668 (0.43%)	31 / 4672 (0.66%)	
occurrences causally related to treatment / all	21 / 21	33 / 33	
deaths causally related to treatment / all	4 / 4	6 / 6	
Renal impairment			
subjects affected / exposed	14 / 4668 (0.30%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	14 / 14	10 / 10	
deaths causally related to treatment / all	1 / 1	0 / 0	
Renal haemorrhage			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Renal infarct			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal injury			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal pain			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular necrosis			
subjects affected / exposed	1 / 4668 (0.02%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	1 / 1	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Single functional kidney			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
Ureteral necrosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteral polyp			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric obstruction			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	4 / 4668 (0.09%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	4 / 4	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder polyp			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Urinary incontinence			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	8 / 4668 (0.17%)	12 / 4672 (0.26%)	
occurrences causally related to treatment / all	8 / 8	13 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Autoimmune thyroiditis			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cushing's syndrome			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	8 / 4668 (0.17%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	8 / 8	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercorticism			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism primary			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaldosteronism			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	6 / 4668 (0.13%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	6 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid C-cell hyperplasia			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroiditis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroiditis subacute			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic nodular goitre			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Acquired claw toe			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	10 / 4668 (0.21%)	13 / 4672 (0.28%)	
occurrences causally related to treatment / all	10 / 10	14 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	16 / 4668 (0.34%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	17 / 17	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis reactive			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back disorder			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	14 / 4668 (0.30%)	20 / 4672 (0.43%)	
occurrences causally related to treatment / all	14 / 14	21 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment syndrome			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diastasis recti abdominis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dupuytren's contracture			



subjects affected / exposed	4 / 4668 (0.09%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibromyalgia			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture nonunion			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin pain			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (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 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	4 / 4668 (0.09%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	4 / 4	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc displacement			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	13 / 4668 (0.28%)	23 / 4672 (0.49%)	
occurrences causally related to treatment / all	14 / 14	27 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint swelling			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	11 / 4668 (0.24%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	12 / 12	9 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscal degeneration			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mobility decreased			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle haemorrhage			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	7 / 4668 (0.15%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	7 / 7	9 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	5 / 4668 (0.11%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	5 / 5	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myositis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic arthropathy			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis deformans			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			

subjects affected / exposed	75 / 4668 (1.61%)	64 / 4672 (1.37%)	
occurrences causally related to treatment / all	80 / 80	69 / 69	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteolysis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporotic fracture			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	7 / 4668 (0.15%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	7 / 7	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periarthritis			
subjects affected / exposed	5 / 4668 (0.11%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	5 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthrititis			

subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	1 / 4668 (0.02%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	1 / 1	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	5 / 4668 (0.11%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	5 / 5	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sacroiliitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			
subjects affected / exposed	7 / 4668 (0.15%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	7 / 7	10 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal instability			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			

subjects affected / exposed	9 / 4668 (0.19%)	8 / 4672 (0.17%)	
occurrences causally related to treatment / all	9 / 9	8 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigger finger			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulnocarpal abutment syndrome			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			

subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	1 / 4668 (0.02%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	5 / 4668 (0.11%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	5 / 5	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess of salivary gland			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatitis B			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	8 / 4668 (0.17%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	8 / 8	11 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerotic gangrene			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical pneumonia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			



subjects affected / exposed	5 / 4668 (0.11%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	5 / 5	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial food poisoning			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Biliary sepsis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract infection			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast abscess			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Bronchitis			

subjects affected / exposed	15 / 4668 (0.32%)	24 / 4672 (0.51%)	
occurrences causally related to treatment / all	15 / 15	25 / 25	
deaths causally related to treatment / all	0 / 0	2 / 2	
Bronchopneumonia			
subjects affected / exposed	11 / 4668 (0.24%)	19 / 4672 (0.41%)	
occurrences causally related to treatment / all	13 / 13	21 / 21	
deaths causally related to treatment / all	2 / 2	4 / 4	
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbuncle			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve abscess			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	37 / 4668 (0.79%)	54 / 4672 (1.16%)	
occurrences causally related to treatment / all	50 / 50	61 / 61	
deaths causally related to treatment / all	0 / 0	2 / 2	
Cellulitis gangrenous			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis of male external genital organ			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicitis			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholera			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Citrobacter sepsis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium colitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	6 / 4668 (0.13%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	6 / 6	3 / 3	
deaths causally related to treatment / all	1 / 1	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cystitis			
subjects affected / exposed	7 / 4668 (0.15%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	7 / 7	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryocystitis			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	5 / 4668 (0.11%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	5 / 5	5 / 5	
deaths causally related to treatment / all	0 / 0	1 / 1	
Device related sepsis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			
subjects affected / exposed	11 / 4668 (0.24%)	9 / 4672 (0.19%)	
occurrences causally related to treatment / all	12 / 12	11 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	7 / 4668 (0.15%)	13 / 4672 (0.28%)	
occurrences causally related to treatment / all	8 / 8	13 / 13	
deaths causally related to treatment / all	1 / 1	0 / 0	
Dysentery			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear infection			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	3 / 4668 (0.06%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	3 / 3	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis enterococcal			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis staphylococcal			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endophthalmitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter pneumonia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal infection			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis ureaplasma			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	10 / 4668 (0.21%)	14 / 4672 (0.30%)	
occurrences causally related to treatment / all	11 / 11	16 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia pyelonephritis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural abscess			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye infection			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder abscess			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder empyema			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	10 / 4668 (0.21%)	12 / 4672 (0.26%)	
occurrences causally related to treatment / all	13 / 13	14 / 14	
deaths causally related to treatment / all	1 / 1	2 / 2	
Gas gangrene			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis bacterial			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	33 / 4668 (0.71%)	31 / 4672 (0.66%)	
occurrences causally related to treatment / all	34 / 34	31 / 31	
deaths causally related to treatment / all	0 / 0	1 / 1	
Gastroenteritis bacterial			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis norovirus			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis salmonella			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	9 / 4668 (0.19%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	9 / 9	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal viral infection			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingivitis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin abscess			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma infection			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter gastritis			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter infection			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes virus infection			



subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Human ehrlichiosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileal gangrene			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Incision site infection			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected bites			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected dermal cyst			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	2 / 4668 (0.04%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	2 / 2	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			

subjects affected / exposed	0 / 4668 (0.00%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	0 / 0	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious colitis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (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	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	4 / 4	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Influenza			
subjects affected / exposed	3 / 4668 (0.06%)	8 / 4672 (0.17%)	
occurrences causally related to treatment / all	3 / 3	8 / 8	
deaths causally related to treatment / all	0 / 0	1 / 1	
Intervertebral discitis			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney infection			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella bacteraemia			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Legionella infection			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	1 / 1	0 / 0	
Lobar pneumonia			
subjects affected / exposed	15 / 4668 (0.32%)	15 / 4672 (0.32%)	
occurrences causally related to treatment / all	16 / 16	15 / 15	
deaths causally related to treatment / all	2 / 2	0 / 0	
Localised infection			
subjects affected / exposed	7 / 4668 (0.15%)	8 / 4672 (0.17%)	
occurrences causally related to treatment / all	9 / 9	8 / 8	
deaths causally related to treatment / all	0 / 0	1 / 1	
Lower respiratory tract infection			
subjects affected / exposed	15 / 4668 (0.32%)	15 / 4672 (0.32%)	
occurrences causally related to treatment / all	16 / 16	15 / 15	
deaths causally related to treatment / all	0 / 0	1 / 1	
Lung infection			

subjects affected / exposed	2 / 4668 (0.04%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	0 / 0	1 / 1	
<b>Mastitis</b>			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Mastoiditis</b>			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Mediastinitis</b>			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Meningitis</b>			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
<b>Meningitis pneumococcal</b>			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Metapneumovirus infection</b>			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nasopharyngitis</b>			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Necrotising fasciitis</b>			

subjects affected / exposed	4 / 4668 (0.09%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal candidiasis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			
subjects affected / exposed	2 / 4668 (0.04%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	2 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	21 / 4668 (0.45%)	23 / 4672 (0.49%)	
occurrences causally related to treatment / all	27 / 27	30 / 30	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis acute			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (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	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis externa			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media chronic			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreas infection			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae virus infection			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotitis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile infection			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perichondritis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			

subjects affected / exposed	5 / 4668 (0.11%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	6 / 6	9 / 9	
deaths causally related to treatment / all	1 / 1	0 / 0	
Peritonitis bacterial			
subjects affected / exposed	3 / 4668 (0.06%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	3 / 3	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Peritonsillar abscess			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pilonidal cyst			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasmodium falciparum infection			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal sepsis			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	133 / 4668 (2.85%)	141 / 4672 (3.02%)	
occurrences causally related to treatment / all	154 / 154	157 / 157	
deaths causally related to treatment / all	20 / 20	15 / 15	
Pneumonia bacterial			

subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	2 / 4668 (0.04%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia legionella			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pseudomonal			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia staphylococcal			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pneumonia viral			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Post procedural cellulitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			



subjects affected / exposed	6 / 4668 (0.13%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	6 / 6	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural sepsis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative abscess			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	9 / 4668 (0.19%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	9 / 9	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic abscess			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomembranous colitis			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoas abscess			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mycosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			

subjects affected / exposed	2 / 4668 (0.04%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	2 / 2	3 / 3	
deaths causally related to treatment / all	2 / 2	1 / 1	
Pulmonary tuberculosis			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	9 / 4668 (0.19%)	10 / 4672 (0.21%)	
occurrences causally related to treatment / all	9 / 9	12 / 12	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pyelonephritis acute			
subjects affected / exposed	6 / 4668 (0.13%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	9 / 9	6 / 6	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pyuria			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal abscess			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	2 / 4668 (0.04%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	2 / 2	10 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection viral			

subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonella sepsis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonellosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal abscess			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	48 / 4668 (1.03%)	34 / 4672 (0.73%)	
occurrences causally related to treatment / all	50 / 50	36 / 36	
deaths causally related to treatment / all	13 / 13	12 / 12	
Sepsis syndrome			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	8 / 4668 (0.17%)	13 / 4672 (0.28%)	
occurrences causally related to treatment / all	9 / 9	13 / 13	
deaths causally related to treatment / all	6 / 6	8 / 8	
Sinusitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue infection			

subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Staphylococcal infection			
subjects affected / exposed	2 / 4668 (0.04%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	0 / 0	1 / 1	
Staphylococcal sepsis			
subjects affected / exposed	4 / 4668 (0.09%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal skin infection			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal bacteraemia			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal infection			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular abscess			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	0 / 4668 (0.00%)	5 / 4672 (0.11%)	
occurrences causally related to treatment / all	0 / 0	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth infection			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheitis			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	4 / 4	
deaths causally related to treatment / all	0 / 0	1 / 1	
Tuberculosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis of genitourinary system			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			

subjects affected / exposed	4 / 4668 (0.09%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	4 / 4	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	47 / 4668 (1.01%)	71 / 4672 (1.52%)	
occurrences causally related to treatment / all	51 / 51	79 / 79	
deaths causally related to treatment / all	1 / 1	2 / 2	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 4668 (0.00%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	8 / 4668 (0.17%)	17 / 4672 (0.36%)	
occurrences causally related to treatment / all	8 / 8	19 / 19	
deaths causally related to treatment / all	1 / 1	1 / 1	
Vaginal abscess			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular neuronitis			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	5 / 4668 (0.11%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	5 / 5	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral myocarditis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral pharyngitis			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral sinusitis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	6 / 4668 (0.13%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	6 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection staphylococcal			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Zygomycosis			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Cell death			

subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	4 / 4668 (0.09%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	4 / 4	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	30 / 4668 (0.64%)	22 / 4672 (0.47%)	
occurrences causally related to treatment / all	30 / 30	22 / 22	
deaths causally related to treatment / all	1 / 1	2 / 2	
Diabetes mellitus			
subjects affected / exposed	3 / 4668 (0.06%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	3 / 3	12 / 12	
deaths causally related to treatment / all	0 / 0	2 / 2	
Diabetes mellitus inadequate control			
subjects affected / exposed	25 / 4668 (0.54%)	43 / 4672 (0.92%)	
occurrences causally related to treatment / all	28 / 28	47 / 47	
deaths causally related to treatment / all	0 / 0	1 / 1	
Diabetic complication			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Diabetic ketoacidosis			
subjects affected / exposed	11 / 4668 (0.24%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	12 / 12	8 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyslipidaemia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			



subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	3 / 4668 (0.06%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Fluid overload			
subjects affected / exposed	8 / 4668 (0.17%)	4 / 4672 (0.09%)	
occurrences causally related to treatment / all	8 / 8	6 / 6	
deaths causally related to treatment / all	1 / 1	0 / 0	
Fluid retention			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	4 / 4668 (0.09%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	8 / 8	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	34 / 4668 (0.73%)	49 / 4672 (1.05%)	
occurrences causally related to treatment / all	35 / 35	52 / 52	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	9 / 4668 (0.19%)	15 / 4672 (0.32%)	
occurrences causally related to treatment / all	10 / 10	15 / 15	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hyperlipidaemia			

subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperosmolar hyperglycaemic state			
subjects affected / exposed	3 / 4668 (0.06%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	3 / 3	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	44 / 4668 (0.94%)	75 / 4672 (1.61%)	
occurrences causally related to treatment / all	60 / 60	92 / 92	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	7 / 4668 (0.15%)	7 / 4672 (0.15%)	
occurrences causally related to treatment / all	8 / 8	7 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	0 / 4668 (0.00%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	4 / 4668 (0.09%)	6 / 4672 (0.13%)	
occurrences causally related to treatment / all	4 / 4	6 / 6	
deaths causally related to treatment / all	0 / 0	1 / 1	
Hypovolaemia			

subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insulin-requiring type 2 diabetes mellitus			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency			
subjects affected / exposed	1 / 4668 (0.02%)	3 / 4672 (0.06%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketoacidosis			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	2 / 4668 (0.04%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Malnutrition			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	1 / 4668 (0.02%)	2 / 4672 (0.04%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	1 / 1	1 / 1	
Metabolic disorder			
subjects affected / exposed	1 / 4668 (0.02%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic syndrome			

subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	8 / 4668 (0.17%)	11 / 4672 (0.24%)	
occurrences causally related to treatment / all	8 / 8	11 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitamin B12 deficiency			
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

<b>Non-serious adverse events</b>	Liraglutide	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	684 / 4668 (14.65%)	210 / 4672 (4.49%)	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	266 / 4668 (5.70%)	102 / 4672 (2.18%)	
occurrences (all)	355	124	
Nausea			
subjects affected / exposed	517 / 4668 (11.08%)	129 / 4672 (2.76%)	
occurrences (all)	655	149	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 January 2011	1) Changes to action in exclusion, randomisation and visit procedures in cases of measured calcitonin values $\geq 50$ ng/L (changed from $\geq 100$ ng/L). 2) Calcitonin values $\geq 20$ ng/L reported as MESI during the trial. 3). Actions taken in case of suspicion of acute hypersensitivity or immune-complex disease. 4) Actions taken in case a subject undergoes a thyroidectomy. Specification of history of concomitant cardiovascular disease. 5) Diabetic foot ulcer included in history of diabetes complication. 6) Definition of immediate and delayed hypersensitivity reaction. 7) Subject information updated accordingly.
08 July 2011	1) Subjects on premixed insulin was now considered eligible for participation in the trial. 2) Definition of diabetes-related blindness included
17 May 2012	1) Possible reintroduction of subjects violating exclusion criteria 2 and/or 3 to support retention. Subjects could be reintroduced to randomised treatment after a wash-out period. 2) Changes to the recording of concomitant medication during hospitalisation. 3) Introduction of 'male partner-consent' in case of a pregnancy
11 April 2013	1) Inclusion criteria 3 updated: Subjects randomised in error due to not meeting the age criterion at screening could be reintroduced on originally randomised treatment as each subject reaches the required age. 2) Updates to the adverse event section and event adjudication process. 3) Liraglutide background section updated based on the Investigator's Brochure. 4) An additional SI/IC form to ensure collection of information on primary outcome
20 June 2014	1) Introducing a staggered close down of sites. 2) Follow-up visit (visit 16) applicable for all randomised subjects. 3) Revision of the statistical considerations to meet regulatory expectations and to align with the Statistical Programming Plan

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/27295427>

<http://www.ncbi.nlm.nih.gov/pubmed/26855018>

<http://www.ncbi.nlm.nih.gov/pubmed/26864124>

<http://www.ncbi.nlm.nih.gov/pubmed/27320184>

<http://www.ncbi.nlm.nih.gov/pubmed/27274772>

<http://www.ncbi.nlm.nih.gov/pubmed/25275271>

<http://www.ncbi.nlm.nih.gov/pubmed/24176437>

<http://www.ncbi.nlm.nih.gov/pubmed/25656058>

