



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
-----------------------	-------------

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
Arm title	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.

Arm title	Placebo
------------------	---------

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
----------	---------

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.

Number of subjects in period 1	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
-----------------------	-------------

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
-----------------------	---------

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
-----------------------	-------------

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
-----------------------	---------

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).
-----------------	---

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
----------------	---------

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
----------------------------	----------------------

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
-------------------	-----------------------

Number of subjects included in analysis	9340
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.001 [1]
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 (α -level 0.025) test for non-inferiority (hazard ratio ≥ 1.3).

Statistical analysis title	Superiority test
-----------------------------------	------------------

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 ≥ 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 [2]
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 (α -level 0.025) test for superiority (hazard ratio ≥ 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
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	18.0
--------------------	------

Reporting groups

Reporting group title	Liraglutide
-----------------------	-------------

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
-----------------------	---------

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
Phlebosclerosis		
subjects affected / exposed	1 / 4668 (0.02%)	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
Sternal 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
Subcutaneous 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
Subdural haematoma		
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
Subdural haemorrhage		
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
Tendon rupture		
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
Thermal burn		
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
Tibia fracture		
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
Toxicity to various agents		

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
Embolic 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
Embolic 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
Polyarthritis		

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
Mastitis		
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mastoiditis		
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
Mediastinitis		
subjects affected / exposed	0 / 4668 (0.00%)	1 / 4672 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis		
subjects affected / exposed	1 / 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
Meningitis pneumococcal		
subjects affected / exposed	1 / 4668 (0.02%)	0 / 4672 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metapneumovirus 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
Nasopharyngitis		
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
Necrotising fasciitis		

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 %

Non-serious adverse events	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 ≥ 50 ng/L (changed from ≥ 100 ng/L). 2) Calcitonin values ≥ 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>

