



## Clinical trial results:

### A trial comparing cardiovascular safety of insulin degludec versus insulin glargine in subjects with type 2 diabetes at high risk of cardiovascular events

#### Summary

EudraCT number	2013-002371-17
Trial protocol	GB PL GR IT ES HR
Global end of trial date	16 October 2016

#### Results information

Result version number	v1 (current)
This version publication date	02 November 2017
First version publication date	02 November 2017

#### Trial information

##### Trial identification

Sponsor protocol code	EX1250-4080
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01959529
WHO universal trial number (UTN)	U1111-1141-7614
Other trial identifiers	Japanese trial registration number: JapicCTI-142464, CTN: 25-3375

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	24 March 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 October 2016
Global end of trial reached?	Yes
Global end of trial date	16 October 2016
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The main objective of the trial was to confirm the cardiovascular safety of insulin degludec (IDeg) compared to that of insulin glargine (IGlar).

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki Amended 2013 and ICH Good Clinical Practice (1996) and with FDA 21 CFR 312.120 in the United States.

Background therapy:

Subjects continued their pre-trial medication except for the basal insulin, which was replaced by any of the investigational medicinal products (IMPs; IDeg or IGlar). The pre-trial bolus insulin was allowed and could be replaced with insulin aspart (IAsp) at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IDeg once daily (OD)/IGlar OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin twice daily (BID), the total basal component was calculated, reduced by 20-30% and switched to IDeg OD/ IGlar OD, and the bolus component was calculated and switched to IAsp. The trial was event driven for with a realised observation period up to 33 months.

Evidence for comparator: -

Actual start date of recruitment	29 October 2013
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	Argentina: 120
Country: Number of subjects enrolled	Brazil: 303
Country: Number of subjects enrolled	Canada: 70
Country: Number of subjects enrolled	Algeria: 63
Country: Number of subjects enrolled	Spain: 60
Country: Number of subjects enrolled	United Kingdom: 80
Country: Number of subjects enrolled	Greece: 90
Country: Number of subjects enrolled	Croatia: 46
Country: Number of subjects enrolled	India: 357
Country: Number of subjects enrolled	Italy: 140
Country: Number of subjects enrolled	Japan: 61
Country: Number of subjects enrolled	Korea, Republic of: 61
Country: Number of subjects enrolled	Mexico: 162
Country: Number of subjects enrolled	Malaysia: 102
Country: Number of subjects enrolled	Poland: 135

Country: Number of subjects enrolled	Romania: 84
Country: Number of subjects enrolled	Russian Federation: 240
Country: Number of subjects enrolled	Thailand: 68
Country: Number of subjects enrolled	United States: 5201
Country: Number of subjects enrolled	South Africa: 194
Worldwide total number of subjects	7637
EEA total number of subjects	635

Notes:

<b>Subjects enrolled per age group</b>	
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)	3682
From 65 to 84 years	3917
85 years and over	38

## Subject disposition

### Recruitment

Recruitment details:

The trial was conducted at 438 sites in 20 countries as follows: Algeria: 6; Argentina: 4; Brazil: 10; Canada: 6; Croatia: 5; Greece: 6; India: 26; Italy: 10; Japan: 8; Republic of Korea: 4; Malaysia: 8; Mexico: 7; Poland: 8; Romania: 4; Russian Federation: 20; South Africa: 15; Spain: 6; Thailand: 6; United Kingdom: 8; United States: 271.

### Pre-assignment

Screening details:

Not applicable

### Period 1

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

Blinding implementation details:

The trial was double-blinded and subjects were randomised 1:1 to receive IDeg or IGLar. Both treatments were provided in identical 10 mL blinded vials.

### Arms

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

Arm description:

Subjects received IDeg 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pre-trial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IDeg). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IDeg OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IDeg OD, and the bolus component was calculated and switched to IAsp. The trial was event driven for with a realised observation period up to 33 months.

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

Dosage and administration details:

IDeg 100 units/mL OD was self administered by subjects S.C. in thigh, upper arm or the abdominal wall between dinner and bedtime.

<b>Arm title</b>	Insulin glargine
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Arm description:

Subjects received IGLar 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pretrial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IGLar). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IGLar OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IGLar OD, and the bolus component was calculated and switched to IAsp. The trial was event driven with a realized treatment period up to 33 months.

Arm type	Active comparator
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Investigational medicinal product name	Insulin glargine
Investigational medicinal product code	
Other name	Lantus®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

IGlar 100 units/mL OD was self administered by subjects S.C. in thigh, upper arm or the abdominal wall between dinner and bedtime.

<b>Number of subjects in period 1</b>	Insulin degludec	Insulin glargine
Started	3818	3819
Exposed	3809	3806
Completed	3742	3747
Not completed	76	72
Adverse event (not hypoglycaemia)	-	1
Lack of glycaemic control	1	1
Unspecified	70	68
Lost to follow-up	4	1
Hypoglycaemia	1	1

## Baseline characteristics

### Reporting groups

Reporting group title	Insulin degludec
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#### Reporting group description:

Subjects received IDeg 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pre-trial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IDeg). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IDeg OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IDeg OD, and the bolus component was calculated and switched to IAsp. The trial was event driven for with a realised observation period up to 33 months.

Reporting group title	Insulin glargine
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#### Reporting group description:

Subjects received IGl 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pre-trial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IGl). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IGl OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IGl OD, and the bolus component was calculated and switched to IAsp. The trial was event driven with a realized treatment period up to 33 months.

Reporting group values	Insulin degludec	Insulin glargine	Total
Number of subjects	3818	3819	7637
Age Categorical Units: Subjects			
Adults (18-64 years)	1835	1847	3682
From 65-84 years	1969	1948	3917
85 years and over	14	24	38
Age Continuous Units: years			
arithmetic mean	64.9	65.0	
standard deviation	± 7.3	± 7.5	-
Gender Categorical Units: Subjects			
Female	1422	1437	2859
Male	2396	2382	4778
HbA1c Units: percentage of HbA1c			
arithmetic mean	8.44	8.41	
standard deviation	± 1.63	± 1.67	-

## End points

### End points reporting groups

Reporting group title	Insulin degludec
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#### Reporting group description:

Subjects received IDeg 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pre-trial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IDeg). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IDeg OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IDeg OD, and the bolus component was calculated and switched to IAsp. The trial was event driven for with a realised observation period up to 33 months.

Reporting group title	Insulin glargine
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#### Reporting group description:

Subjects received IGlar 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pretrial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IGlar). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IGlar OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IGlar OD, and the bolus component was calculated and switched to IAsp. The trial was event driven with a realized treatment period up to 33 months.

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

End point title	Time from randomisation to first occurrence of a major adverse cardiovascular event (MACE): cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke.
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#### End point description:

Time from randomisation to first occurrence of an EAC-confirmed 3-component major adverse cardiovascular event (MACE): cardiovascular death, non-fatal myocardial infarction, or nonfatal stroke. Events with event adjudication committee (EAC)-confirmed onset date between randomisation and individual end of trial were included in the analyses. The number of subjects experiencing first EAC-confirmed MACE, date between randomisation to the end of trial, both days included were presented. The trial was event driven and planned to last up to a maximum of 60.5 months. The actual trial duration (time from first subject first visit to last subject last visit) was 35.6 months. The maximum trial duration for a single subject was 33.1 months. The analysis was based on the FAS, which included all randomised subjects.

End point type	Primary
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#### End point timeframe:

From randomisation to individual end of trial date (maximum patient year observation: 2.75 years)

End point values	Insulin degludec	Insulin glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3818	3819		
Units: Number of subjects				
First EAC-confirmed MACE	325	356		
Myocardial infarction (non-fatal)	143	163		

Stroke (non-fatal)	68	74		
Cardiovascular death	114	119		

## Statistical analyses

Statistical analysis title	Statistical analysis
Statistical analysis description: The hazard ratio (HR) (IDeg vs IGlär) was based on Cox regression with investigational medicinal product as only factor for primary analysis.	
Comparison groups	Insulin glargine v Insulin degludec
Number of subjects included in analysis	7637
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[1]</sup>
P-value	< 0.001 <sup>[2]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.908
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.781
upper limit	1.055

Notes:

[1] - Non-inferiority of IDeg to IGlär was considered confirmed if the upper limit of the two-sided 95% confidence interval for the HR was below 1.3 or equivalent if the p-value for the one-sided test of null hypothesis (H<sub>0</sub>): HR ≥ 1.3 against the alternative hypothesis (H<sub>a</sub>): HR < 1.3 was less than 2.5%.

[2] - p value : Refers to one-sided test of HR ≥ 1.3 (against H<sub>a</sub>: HR < 1.3).

## Secondary: Number of EAC-confirmed severe hypoglycaemic episodes

End point title	Number of EAC-confirmed severe hypoglycaemic episodes
End point description: Number of severe hypoglycaemic episodes from week 0 to the last assessment (up to 35.6 months). The episode of severe hypoglycaemia is an episode requiring assistance of another person to actively administer carbohydrate, glucagon, or take other corrective actions. The trial was event driven and planned to last up to a maximum of 60.5 months. The actual trial duration (time from first subject first visit to last subject last visit) was 35.6 months. The maximum trial duration for a single subject was 33.1 months. The analysis was based on the FAS, which included all randomised subjects.	
End point type	Secondary
End point timeframe: From randomisation to individual end of trial (maximum patient year observation: 2.75 years)	

End point values	Insulin degludec	Insulin glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3818	3819		
Units: Number of severe episodes	280	472		



## Statistical analyses

Statistical analysis title	Statistical analysis
Statistical analysis description: The model included treatment (IDeg vs IGLar) as a fixed factor and was fitted using the FAS.	
Comparison groups	Insulin degludec v Insulin glargine
Number of subjects included in analysis	7637
Analysis specification	Pre-specified
Analysis type	superiority <sup>[3]</sup>
P-value	< 0.001 <sup>[4]</sup>
Method	Negative binomial regression
Parameter estimate	Rate Ratio
Point estimate	0.601
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.476
upper limit	0.759

Notes:

[3] - Superiority was considered confirmed if the upper limit of the two-sided 95% confidence interval for the rate ratio (RR) was below 1.0 or equivalent if the p-value for the one-sided test of H0: RR ≥ 1.0 against Ha: RR < 1.0, was less than 2.5%.

[4] - p-value : Refers to one-sided test of RR ≥ 1.0 (against Ha: RR < 1.0)

## Secondary: Occurrence of at least one EAC confirmed severe hypoglycaemic episode within a subject (yes/no)

End point title	Occurrence of at least one EAC confirmed severe hypoglycaemic episode within a subject (yes/no)
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End point description:

Occurrence of at least one EAC-confirmed severe hypoglycaemic episode within a subject from week 0 to the last assessment (up to 35.6 months). The episode of severe hypoglycaemia is an episode requiring assistance of another person to actively administer carbohydrate, glucagon, or take other corrective actions. The analysis was based on the FAS, which included all randomised subjects.

End point type	Secondary
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End point timeframe:

From randomisation to individual end of trial date (maximum patient year observation: 2.75 years)

End point values	Insulin degludec	Insulin glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3818	3819		
Units: Number of subjects	187	252		

## Statistical analyses

Statistical analysis title	Statistical analysis
Statistical analysis description: The model was logistic regression with log-link function. The model included treatment (IDeg vs IGlar) as a fixed factor and was fitted using the FAS.	
Comparison groups	Insulin degludec v Insulin glargine
Number of subjects included in analysis	7637
Analysis specification	Pre-specified
Analysis type	superiority <sup>[5]</sup>
P-value	< 0.001 <sup>[6]</sup>
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.729
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.866

Notes:

[5] - Superiority of IDeg to IGlar was considered confirmed if the upper limit of the two-sided 95% confidence interval for the odds ratio (OR) was below 1.0 or equivalent if the p-value for the one-sided test of H0: OR ≥ 1.0 against Ha: OR < 1.0, was less than 2.5%.

[6] - p-value: Refers to one-sided test of OR ≥ 1.0 (against Ha: OR < 1.0)

## Secondary: Change in Glycosylated haemoglobin (HbA1c)

End point title	Change in Glycosylated haemoglobin (HbA1c)
End point description: Mean change in HbA1c from week 0 to month 24. The analysis was based on the FAS. The number of subjects analysed are the number of subjects with the available data after 24 months.	
End point type	Secondary
End point timeframe: Randomisation to 24 months	

End point values	Insulin degludec	Insulin glargine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2431	2404		
Units: percentage of HbA1c				
arithmetic mean (standard deviation)	-0.86 (± 1.51)	-0.84 (± 1.57)		

## Statistical analyses

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No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

The AEs were considered from randomisation visit (week 0) to follow up visit (end of treatment plus at least 30 days). The trial was event driven and planned to last up to a maximum of 60.5 months.  
Maximum trial duration for single subject: 33.1 months

Adverse event reporting additional description:

Safety was summarised using the FAS, which included all randomised subjects. Number of deaths causally related to treatment' is the data considered to present under 'total number of deaths resulting from adverse events.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	19
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### Reporting groups

Reporting group title	IDeg
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Reporting group description:

Subjects received IDeg 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pre-trial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IDeg). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IDeg OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IDeg OD, and the bolus component was calculated and switched to IAsp. The trial was event driven for with a realised observation period up to 33 months.

Reporting group title	IGlar
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Reporting group description:

Subjects received IGlar 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pretrial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IGlar). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IGlar OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IGlar OD, and the bolus component was calculated and switched to IAsp. The trial was event driven with a realized treatment period up to 33 months.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Systematic collection of AEs was limited to SAEs, AEs leading to permanent discontinuation of IMP, medication errors leading to SAEs, and AEs related technical complaints and were summarised. Non-serious AEs not fulfilling the above criteria were not systematically collected.

Serious adverse events	IDeg	IGlar	
Total subjects affected by serious adverse events			
subjects affected / exposed	1473 / 3818 (38.58%)	1517 / 3819 (39.72%)	
number of deaths (all causes)	202	221	
number of deaths resulting from adverse events	6	12	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute lymphocytic leukaemia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma gastric			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	2 / 3818 (0.05%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal adenoma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal neoplasm			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adult T-cell lymphoma/leukaemia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
B-cell lymphoma			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell lymphoma stage III			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of bladder			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of thyroid gland			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign ovarian tumour			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct adenocarcinoma			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer recurrent			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer stage 0, with cancer in situ			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma stage I			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone cancer			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Breast cancer			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Breast cancer stage I			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage II			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage IV			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve fibroelastoma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			



subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Choroid melanoma			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	3 / 3818 (0.08%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Colon cancer metastatic			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Colon cancer stage III			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer metastatic			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma recurrent			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Endometrial adenocarcinoma			
subjects affected / exposed	3 / 3818 (0.08%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibroma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder adenocarcinoma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder cancer metastatic			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal cancer metastatic			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal tract adenoma			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Hepatic cancer metastatic			

subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatic neoplasm			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	3 / 3818 (0.08%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 3	1 / 4	
deaths causally related to treatment / all	0 / 1	1 / 3	
Intraductal proliferative breast lesion			
subjects affected / exposed	3 / 3818 (0.08%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	2 / 3818 (0.05%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Leiomyoma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung adenocarcinoma metastatic			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Lung adenocarcinoma stage II			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung cancer metastatic			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung neoplasm malignant			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lymphoma			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant melanoma			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma in situ			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant peritoneal neoplasm			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Meningioma benign			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma malignant			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to bone			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to central nervous system			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to liver			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Metastases to lung			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to lymph nodes			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic neoplasm			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic renal cell carcinoma			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucinous endometrial carcinoma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma metastatic			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer metastatic			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Non-small cell lung cancer stage I			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal adenocarcinoma			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ovarian cancer recurrent			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer stage IV			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	3 / 3818 (0.08%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Pancreatic carcinoma metastatic			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	1 / 2	0 / 0	
Pancreatic carcinoma stage IV			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Papillary cystadenoma lymphomatosum			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Parathyroid tumour benign			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile squamous cell carcinoma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phaeochromocytoma			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary tumour benign			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			



subjects affected / exposed	11 / 3818 (0.29%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 11	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Prostate cancer metastatic			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage I			
subjects affected / exposed	0 / 3818 (0.00%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage II			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Rectal adenoma			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer metastatic			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			

subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer metastatic			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland cancer			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Small cell lung cancer extensive stage			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer metastatic			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Soft tissue sarcoma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Squamous cell carcinoma			

subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Squamous cell carcinoma of lung			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular seminoma (pure) stage I			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testis cancer			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour of ampulla of Vater			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric cancer			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	4 / 3818 (0.10%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aneurysm			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiopathy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic aneurysm			
subjects affected / exposed	3 / 3818 (0.08%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			

subjects affected / exposed	3 / 3818 (0.08%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arterial haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	3 / 3818 (0.08%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Blood pressure inadequately controlled			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	13 / 3818 (0.34%)	10 / 3819 (0.26%)	
occurrences causally related to treatment / all	0 / 13	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry gangrene			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Embolism arterial			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism venous			

subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential hypertension			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypertension			
subjects affected / exposed	17 / 3818 (0.45%)	23 / 3819 (0.60%)	
occurrences causally related to treatment / all	0 / 19	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypertensive crisis			
subjects affected / exposed	8 / 3818 (0.21%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	3 / 3818 (0.08%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	14 / 3818 (0.37%)	14 / 3819 (0.37%)	
occurrences causally related to treatment / all	0 / 14	0 / 15	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent claudication			

subjects affected / exposed	2 / 3818 (0.05%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic limb pain			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Leriche syndrome			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphocele			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant hypertension			
subjects affected / exposed	3 / 3818 (0.08%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microangiopathy			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive shock			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	6 / 3818 (0.16%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	0 / 6	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			

subjects affected / exposed	13 / 3818 (0.34%)	12 / 3819 (0.31%)	
occurrences causally related to treatment / all	0 / 13	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery aneurysm			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	4 / 3818 (0.10%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	2 / 3818 (0.05%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	3 / 3818 (0.08%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peripheral vascular disorder			
subjects affected / exposed	11 / 3818 (0.29%)	14 / 3819 (0.37%)	
occurrences causally related to treatment / all	0 / 12	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral venous disease			



subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reperfusion injury			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian steal syndrome			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior vena cava stenosis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporal arteritis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	4 / 3818 (0.10%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular insufficiency			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Abdominal hernia repair			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal panniculectomy			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amputation			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioplasty			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm repair			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stent insertion			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve replacement			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula operation			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ablation			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker battery replacement			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker insertion			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker replacement			
subjects affected / exposed	0 / 3818 (0.00%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract operation			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colectomy			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colostomy closure			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary arterial stent insertion			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery bypass			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal switch			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrectomy			
subjects affected / exposed	4 / 3818 (0.10%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric bypass			
subjects affected / exposed	3 / 3818 (0.08%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia repair			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip arthroplasty			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hysterectomy			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable defibrillator insertion			

subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable defibrillator replacement			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia repair			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc operation			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-ocular injection			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jejunostomy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint arthroplasty			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee arthroplasty			
subjects affected / exposed	4 / 3818 (0.10%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee operation			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leg amputation			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic surgery			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagectomy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff repair			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Roux loop conversion			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal decompression			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fusion surgery			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal laminectomy			

subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroidectomy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral prostatectomy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia repair			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 3818 (0.08%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac complication associated with device			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Catheter site haematoma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			

subjects affected / exposed	2 / 3818 (0.05%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	16 / 3818 (0.42%)	21 / 3819 (0.55%)	
occurrences causally related to treatment / all	0 / 16	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyst			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	27 / 3818 (0.71%)	21 / 3819 (0.55%)	
occurrences causally related to treatment / all	0 / 27	2 / 21	
deaths causally related to treatment / all	0 / 27	2 / 21	
Fatigue			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body reaction			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised oedema			



subjects affected / exposed	4 / 3818 (0.10%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	1 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Impaired healing			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Local swelling			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Non-cardiac chest pain			
subjects affected / exposed	47 / 3818 (1.23%)	54 / 3819 (1.41%)	
occurrences causally related to treatment / all	0 / 48	0 / 63	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema			
subjects affected / exposed	0 / 3818 (0.00%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema due to cardiac disease			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			

subjects affected / exposed	4 / 3818 (0.10%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyp			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 3	
Sudden death			
subjects affected / exposed	1 / 3818 (0.03%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 8	
Surgical failure			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			

subjects affected / exposed	2 / 3818 (0.05%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent restenosis			
subjects affected / exposed	3 / 3818 (0.08%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal transplant failure			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			

Social stay hospitalisation			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	9 / 3818 (0.24%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast enlargement			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical cyst			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix haemorrhage uterine			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Endometrial hyperplasia			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectocele			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine mass			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			

Acquired diaphragmatic eventration subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema subjects affected / exposed	6 / 3818 (0.16%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute respiratory distress syndrome subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute respiratory failure subjects affected / exposed	24 / 3818 (0.63%)	31 / 3819 (0.81%)	
occurrences causally related to treatment / all	0 / 26	0 / 35	
deaths causally related to treatment / all	0 / 8	0 / 8	
Asthma subjects affected / exposed	6 / 3818 (0.16%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma-chronic obstructive pulmonary disease overlap syndrome subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis subjects affected / exposed	1 / 3818 (0.03%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bronchial hyperreactivity subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			

subjects affected / exposed	42 / 3818 (1.10%)	56 / 3819 (1.47%)	
occurrences causally related to treatment / all	0 / 54	0 / 70	
deaths causally related to treatment / all	0 / 3	0 / 5	
Chronic respiratory failure			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	11 / 3818 (0.29%)	17 / 3819 (0.45%)	
occurrences causally related to treatment / all	0 / 11	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	4 / 3818 (0.10%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			

subjects affected / exposed	3 / 3818 (0.08%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 0	
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Laryngeal stenosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal polyps			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal septum deviation			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiogenic pulmonary oedema			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive airways disorder			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal oedema			



subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pickwickian syndrome			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	1 / 3818 (0.03%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pleurisy			
subjects affected / exposed	0 / 3818 (0.00%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumothorax			
subjects affected / exposed	3 / 3818 (0.08%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pneumothorax spontaneous			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	15 / 3818 (0.39%)	10 / 3819 (0.26%)	
occurrences causally related to treatment / all	0 / 15	2 / 10	
deaths causally related to treatment / all	0 / 5	1 / 1	
Pulmonary fibrosis			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary hypertension			
subjects affected / exposed	6 / 3818 (0.16%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 1	
Pulmonary mass			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	6 / 3818 (0.16%)	9 / 3819 (0.24%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary sarcoidosis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary veno-occlusive disease			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory distress			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	22 / 3818 (0.58%)	18 / 3819 (0.47%)	
occurrences causally related to treatment / all	1 / 23	0 / 19	
deaths causally related to treatment / all	0 / 3	0 / 4	
Respiratory tract inflammation			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	0 / 3818 (0.00%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 0	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute stress disorder			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Affective disorder			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aggression			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agitation			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	3 / 3818 (0.08%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Confusional state			
subjects affected / exposed	3 / 3818 (0.08%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	2 / 3818 (0.05%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			

subjects affected / exposed	5 / 3818 (0.13%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression suicidal			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination, visual			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional self-injury			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	7 / 3818 (0.18%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paranoia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Personality change due to a general medical condition			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post stroke depression			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic stress disorder			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizoaffective disorder			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizoaffective disorder bipolar type			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizophrenia			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	5 / 3818 (0.13%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	0 / 3818 (0.00%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			

subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device fastener issue			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device inappropriate shock delivery			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device lead damage			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lead dislodgement			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			

subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Alcoholic liver disease			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct obstruction			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dyskinesia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	8 / 3818 (0.21%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	6 / 3818 (0.16%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 6	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			



subjects affected / exposed	3 / 3818 (0.08%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	8 / 3818 (0.21%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic hepatic failure			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dilatation intrahepatic duct acquired			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	3 / 3818 (0.08%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hepatic failure			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic lesion			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis chronic active			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatorenal failure			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatorenal syndrome			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ischaemic hepatitis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Jaundice			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sphincter of Oddi dysfunction			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Steatohepatitis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Arteriogram coronary			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy lung			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose decreased			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose increased			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood magnesium decreased			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium decreased			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium increased			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure increased			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac monitoring			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheterisation cardiac			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulation time prolonged			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram ST segment abnormal			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram ST segment elevation			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram ST-T change			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical observation			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			

Accident at work			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	2 / 3818 (0.05%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	2 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaesthetic complication			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaesthetic complication pulmonary			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal bite			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			

subjects affected / exposed	2 / 3818 (0.05%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brachial plexus injury			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns third degree			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve replacement complication			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery restenosis			

subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary vascular graft occlusion			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Drug administration error			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extra dose administered			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye injury			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	54 / 3818 (1.41%)	55 / 3819 (1.44%)	
occurrences causally related to treatment / all	3 / 57	0 / 59	
deaths causally related to treatment / all	0 / 1	0 / 1	
Femoral neck fracture			



subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	3 / 3818 (0.08%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 3	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	2 / 3818 (0.05%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal anastomotic leak			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal injury			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stoma complication			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrostomy tube site complication			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Humerus fracture			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ilium fracture			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated incisional hernia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site haemorrhage			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional overdose			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laceration			
subjects affected / exposed	3 / 3818 (0.08%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle strain			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 3818 (0.00%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax traumatic			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post concussion syndrome			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			

subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	5 / 3818 (0.13%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Post procedural myocardial infarction			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative fever			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative ileus			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative respiratory failure			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative thoracic procedure complication			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound complication			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural complication			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural hypotension			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural intestinal perforation			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary contusion			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	4 / 3818 (0.10%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	20 / 3818 (0.52%)	18 / 3819 (0.47%)	
occurrences causally related to treatment / all	0 / 21	0 / 18	
deaths causally related to treatment / all	0 / 4	0 / 2	
Seroma			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stab wound			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stoma site reaction			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress fracture			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	5 / 3818 (0.13%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subdural haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			

subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transfusion-related acute lung injury			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric injury			



subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular procedure complication			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrong drug administered			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (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			
Congenital ureterocele			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Factor V deficiency			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal arteriovenous malformation			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic arteriovenous malformation			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteogenesis imperfecta			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	11 / 3818 (0.29%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	2 / 12	1 / 8	
deaths causally related to treatment / all	1 / 1	1 / 1	
Acute left ventricular failure			
subjects affected / exposed	7 / 3818 (0.18%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	
Acute myocardial infarction			
subjects affected / exposed	98 / 3818 (2.57%)	115 / 3819 (3.01%)	
occurrences causally related to treatment / all	4 / 111	6 / 123	
deaths causally related to treatment / all	0 / 6	0 / 14	
Angina pectoris			

subjects affected / exposed	36 / 3818 (0.94%)	48 / 3819 (1.26%)	
occurrences causally related to treatment / all	0 / 37	2 / 53	
deaths causally related to treatment / all	0 / 1	0 / 1	
Angina unstable			
subjects affected / exposed	87 / 3818 (2.28%)	79 / 3819 (2.07%)	
occurrences causally related to treatment / all	8 / 94	3 / 93	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic valve disease			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	7 / 3818 (0.18%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	1 / 3818 (0.03%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 2	
Arteriosclerosis coronary artery			
subjects affected / exposed	4 / 3818 (0.10%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 5	
Arteriospasm coronary			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	47 / 3818 (1.23%)	56 / 3819 (1.47%)	
occurrences causally related to treatment / all	0 / 55	0 / 75	
deaths causally related to treatment / all	0 / 3	0 / 2	
Atrial flutter			

subjects affected / exposed	11 / 3818 (0.29%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	0 / 3818 (0.00%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	6 / 3818 (0.16%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block first degree			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular dissociation			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	8 / 3818 (0.21%)	9 / 3819 (0.24%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block left			

subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block right			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac arrest			
subjects affected / exposed	26 / 3818 (0.68%)	20 / 3819 (0.52%)	
occurrences causally related to treatment / all	0 / 26	3 / 21	
deaths causally related to treatment / all	0 / 24	3 / 16	
Cardiac discomfort			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorder			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac failure			
subjects affected / exposed	24 / 3818 (0.63%)	30 / 3819 (0.79%)	
occurrences causally related to treatment / all	1 / 26	0 / 33	
deaths causally related to treatment / all	0 / 3	0 / 4	
Cardiac failure acute			
subjects affected / exposed	7 / 3818 (0.18%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	0 / 7	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 2	
Cardiac failure chronic			
subjects affected / exposed	8 / 3818 (0.21%)	10 / 3819 (0.26%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure congestive			

subjects affected / exposed	134 / 3818 (3.51%)	143 / 3819 (3.74%)	
occurrences causally related to treatment / all	2 / 177	5 / 206	
deaths causally related to treatment / all	0 / 13	2 / 12	
Cardiac hypertrophy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ventricular thrombosis			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	12 / 3818 (0.31%)	9 / 3819 (0.24%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 12	0 / 8	
Cardiogenic shock			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiomegaly			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy			
subjects affected / exposed	4 / 3818 (0.10%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 3	
Cardiopulmonary failure			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Cardiorenal syndrome			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular disorder			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chordae tendinae rupture			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic left ventricular failure			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive cardiomyopathy			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cor pulmonale acute			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	80 / 3818 (2.10%)	89 / 3819 (2.33%)	
occurrences causally related to treatment / all	4 / 85	1 / 91	
deaths causally related to treatment / all	1 / 5	0 / 4	
Coronary artery dissection			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery embolism			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery insufficiency			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	12 / 3818 (0.31%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 12	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	12 / 3818 (0.31%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 12	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary ostial stenosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diastolic dysfunction			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart valve incompetence			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive cardiomyopathy			



subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive heart disease			
subjects affected / exposed	1 / 3818 (0.03%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Intracardiac thrombus			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	3 / 3818 (0.08%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Left ventricular dysfunction			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	6 / 3818 (0.16%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular hypertrophy			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Long QT syndrome			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			

subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	48 / 3818 (1.26%)	66 / 3819 (1.73%)	
occurrences causally related to treatment / all	0 / 51	3 / 68	
deaths causally related to treatment / all	0 / 15	0 / 16	
Myocardial ischaemia			
subjects affected / exposed	7 / 3818 (0.18%)	9 / 3819 (0.24%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Nodal arrhythmia			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prinzmetal angina			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulseless electrical activity			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Restrictive cardiomyopathy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Silent myocardial infarction			
subjects affected / exposed	4 / 3818 (0.10%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	1 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus arrest			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus bradycardia			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	6 / 3818 (0.16%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	1 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	4 / 3818 (0.10%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systolic dysfunction			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tachycardia			
subjects affected / exposed	1 / 3818 (0.03%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trifascicular block			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			

subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	6 / 3818 (0.16%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 7	1 / 5	
deaths causally related to treatment / all	0 / 4	0 / 1	
Ventricular hypokinesia			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	8 / 3818 (0.21%)	12 / 3819 (0.31%)	
occurrences causally related to treatment / all	0 / 9	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance disorder			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			

subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Brain stem haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Brain stem infarction			
subjects affected / exposed	2 / 3818 (0.05%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	1 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem stroke			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery disease			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	0 / 3818 (0.00%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	15 / 3818 (0.39%)	14 / 3819 (0.37%)	
occurrences causally related to treatment / all	0 / 15	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cerebral arteriosclerosis			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	3 / 3818 (0.08%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 3	
Cerebral infarction			
subjects affected / exposed	5 / 3818 (0.13%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebral ischaemia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral small vessel ischaemic disease			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	11 / 3818 (0.29%)	22 / 3819 (0.58%)	
occurrences causally related to treatment / all	0 / 11	2 / 23	
deaths causally related to treatment / all	0 / 5	0 / 6	
Cervical myelopathy			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cranial nerve paralysis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			

subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia Alzheimer's type			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetic mononeuropathy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathy			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	7 / 3818 (0.18%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	1 / 7	0 / 4	
deaths causally related to treatment / all	1 / 1	0 / 0	
Dysarthria			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic cerebral infarction			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	4 / 3818 (0.10%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Encephalopathy			



subjects affected / exposed	6 / 3818 (0.16%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Epidural lipomatosis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential tremor			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 3	
Haemorrhagic cerebral infarction			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemorrhagic stroke			

subjects affected / exposed	3 / 3818 (0.08%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemorrhagic transformation stroke			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	4 / 3818 (0.10%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	3 / 3818 (0.08%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiplegic migraine			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			
subjects affected / exposed	2 / 3818 (0.05%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hyperglycaemic seizure			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive encephalopathy			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic coma			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic seizure			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	5 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic unconsciousness			
subjects affected / exposed	27 / 3818 (0.71%)	29 / 3819 (0.76%)	
occurrences causally related to treatment / all	19 / 29	23 / 33	
deaths causally related to treatment / all	0 / 0	1 / 1	
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
IIIrd nerve paralysis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intensive care unit acquired weakness			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intracranial pressure increased			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ischaemic cerebral infarction			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	43 / 3818 (1.13%)	45 / 3819 (1.18%)	
occurrences causally related to treatment / all	3 / 44	3 / 50	
deaths causally related to treatment / all	0 / 2	0 / 2	
Lacunar infarction			
subjects affected / exposed	5 / 3818 (0.13%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lacunar stroke			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	4 / 3818 (0.10%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	1 / 4	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			

subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Memory impairment			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	7 / 3818 (0.18%)	9 / 3819 (0.24%)	
occurrences causally related to treatment / all	0 / 7	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Migraine			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine-triggered seizure			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mononeuropathy multiplex			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Motor neurone disease			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple sclerosis relapse			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myasthenia gravis			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve root compression			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normal pressure hydrocephalus			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease			
subjects affected / exposed	1 / 3818 (0.03%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-injection delirium sedation syndrome			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			

subjects affected / exposed	3 / 3818 (0.08%)	12 / 3819 (0.31%)	
occurrences causally related to treatment / all	0 / 3	1 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radicular pain			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reversible ischaemic neurological deficit			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	6 / 3818 (0.16%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Senile dementia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitic myelopathy			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Syncope			
subjects affected / exposed	25 / 3818 (0.65%)	24 / 3819 (0.63%)	
occurrences causally related to treatment / all	3 / 27	0 / 29	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamic infarction			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamus haemorrhage			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Thrombotic stroke			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic encephalopathy			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			



subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	28 / 3818 (0.73%)	42 / 3819 (1.10%)	
occurrences causally related to treatment / all	1 / 29	2 / 44	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulnar nerve palsy			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIth nerve paralysis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vascular headache			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual field defect			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed	11 / 3818 (0.29%)	34 / 3819 (0.89%)	
occurrences causally related to treatment / all	0 / 12	0 / 40	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Autoimmune haemolytic anaemia</b>			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Coagulopathy</b>			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Coombs negative haemolytic anaemia</b>			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Evans syndrome</b>			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Haemolytic anaemia</b>			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Haemorrhagic anaemia</b>			
subjects affected / exposed	7 / 3818 (0.18%)	9 / 3819 (0.24%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Hypochromic anaemia</b>			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	3 / 3818 (0.08%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	3 / 3818 (0.08%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrogenic anaemia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness neurosensory			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inner ear disorder			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniere's disease			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	5 / 3818 (0.13%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Blindness			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			

subjects affected / exposed	9 / 3818 (0.24%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	1 / 13	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract diabetic			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	4 / 3818 (0.10%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular fibrosis			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurotrophic keratopathy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pterygium			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein occlusion			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy proliferative			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			

subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia obstructive			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal mass			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	10 / 3818 (0.26%)	10 / 3819 (0.26%)	
occurrences causally related to treatment / all	0 / 10	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	3 / 3818 (0.08%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acid peptic disease			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute abdomen			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Alcoholic pancreatitis			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendix disorder			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Barrett's oesophagus			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	6 / 3818 (0.16%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	3 / 3818 (0.08%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	4 / 3818 (0.10%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			



subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gastroparesis			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	11 / 3818 (0.29%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 14	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diverticular perforation			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	5 / 3818 (0.13%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal stenosis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			

subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal vascular ectasia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	0 / 3818 (0.00%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocoele			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epigastric discomfort			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive duodenitis			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric antral vascular ectasia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric perforation			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	2 / 3818 (0.05%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer perforation			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	8 / 3818 (0.21%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroduodenitis haemorrhagic			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	10 / 3818 (0.26%)	15 / 3819 (0.39%)	
occurrences causally related to treatment / all	0 / 10	0 / 16	
deaths causally related to treatment / all	0 / 2	0 / 0	
Gastrointestinal polyp haemorrhage			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal ulcer haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	6 / 3818 (0.16%)	9 / 3819 (0.24%)	
occurrences causally related to treatment / all	1 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	1 / 3818 (0.03%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			

subjects affected / exposed	4 / 3818 (0.10%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	4 / 3818 (0.10%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	3 / 3818 (0.08%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intestinal obstruction			
subjects affected / exposed	4 / 3818 (0.10%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			

subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intra-abdominal haematoma			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable bowel syndrome			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal ulcer haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	4 / 3818 (0.10%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	3 / 3818 (0.08%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric haematoma			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic colitis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal rupture			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer haemorrhage			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic mass			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			

subjects affected / exposed	7 / 3818 (0.18%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	6 / 3818 (0.16%)	11 / 3819 (0.29%)	
occurrences causally related to treatment / all	0 / 7	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer perforation			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontal disease			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumatosis intestinalis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal ulcer haemorrhage			



subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland calculus			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland mass			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	9 / 3818 (0.24%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spigelian hernia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3818 (0.00%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			

subjects affected / exposed	5 / 3818 (0.13%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	1 / 5	1 / 7	
deaths causally related to treatment / all	1 / 1	0 / 1	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	3 / 3818 (0.08%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	2 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Decubitus ulcer			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dermal cyst			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	10 / 3818 (0.26%)	11 / 3819 (0.29%)	
occurrences causally related to treatment / all	0 / 10	2 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathic ulcer			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hidradenitis			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperhidrosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hypersensitivity vasculitis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic ulcer			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pemphigoid			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin necrosis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Skin ulcer			
subjects affected / exposed	13 / 3818 (0.34%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 13	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Skin ulcer haemorrhage			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stasis dermatitis			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	70 / 3818 (1.83%)	95 / 3819 (2.49%)	
occurrences causally related to treatment / all	0 / 79	2 / 110	
deaths causally related to treatment / all	0 / 9	0 / 6	
Acute prerenal failure			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anuria			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Azotaemia			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bladder neck obstruction			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder outlet obstruction			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	16 / 3818 (0.42%)	26 / 3819 (0.68%)	
occurrences causally related to treatment / all	3 / 18	0 / 30	
deaths causally related to treatment / all	1 / 1	0 / 1	
Cystitis noninfective			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic nephropathy			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	12 / 3818 (0.31%)	9 / 3819 (0.24%)	
occurrences causally related to treatment / all	1 / 12	0 / 9	
deaths causally related to treatment / all	0 / 2	0 / 3	
Glomerulonephritis rapidly progressive			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			

subjects affected / exposed	2 / 3818 (0.05%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	2 / 3818 (0.05%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	11 / 3818 (0.29%)	9 / 3819 (0.24%)	
occurrences causally related to treatment / all	0 / 11	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nephropathy toxic			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrosclerosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stenosis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	14 / 3818 (0.37%)	17 / 3819 (0.45%)	
occurrences causally related to treatment / all	0 / 14	0 / 17	
deaths causally related to treatment / all	0 / 2	0 / 2	
Renal impairment			
subjects affected / exposed	3 / 3818 (0.08%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal mass			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular necrosis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stag horn calculus			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			

subjects affected / exposed	3 / 3818 (0.08%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary hesitation			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	9 / 3818 (0.24%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 9	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic goitre			



subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic nodular goitre			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Ankle deformity			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	5 / 3818 (0.13%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	3 / 3818 (0.08%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back disorder			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	7 / 3818 (0.18%)	12 / 3819 (0.31%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			

subjects affected / exposed	0 / 3818 (0.00%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	5 / 3818 (0.13%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dactylitis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enthesopathy			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intervertebral disc degeneration			
subjects affected / exposed	4 / 3818 (0.10%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	9 / 3818 (0.24%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint effusion			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	12 / 3818 (0.31%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 13	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			

subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	4 / 3818 (0.10%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	3 / 3818 (0.08%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	3 / 3818 (0.08%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myopathy			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	32 / 3818 (0.84%)	30 / 3819 (0.79%)	
occurrences causally related to treatment / all	0 / 35	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteopenia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	3 / 3818 (0.08%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudarthrosis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	4 / 3818 (0.10%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Rotator cuff syndrome			

subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue necrosis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			
subjects affected / exposed	4 / 3818 (0.10%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	3 / 3818 (0.08%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon disorder			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			

subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal sepsis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall infection			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	0 / 3818 (0.00%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess rupture			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess soft tissue			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute endocarditis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	4 / 3818 (0.10%)	6 / 3819 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerotic gangrene			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	4 / 3818 (0.10%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial pyelonephritis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			



subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Beta haemolytic streptococcal infection			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	16 / 3818 (0.42%)	21 / 3819 (0.55%)	
occurrences causally related to treatment / all	0 / 17	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis bacterial			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis viral			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site infection			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	52 / 3818 (1.36%)	61 / 3819 (1.60%)	
occurrences causally related to treatment / all	1 / 64	1 / 72	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cellulitis orbital			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis staphylococcal			

subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis streptococcal			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest wall abscess			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	8 / 3818 (0.21%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic abscess			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivitis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			

subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dermatitis infected			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	3 / 3818 (0.08%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			
subjects affected / exposed	4 / 3818 (0.10%)	8 / 3819 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated cryptococcosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	11 / 3818 (0.29%)	14 / 3819 (0.37%)	
occurrences causally related to treatment / all	0 / 13	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysentery			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema infected			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Endocarditis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottitis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
External ear cellulitis			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural abscess			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gangrene			
subjects affected / exposed	5 / 3818 (0.13%)	13 / 3819 (0.34%)	
occurrences causally related to treatment / all	0 / 5	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gas gangrene			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	13 / 3818 (0.34%)	12 / 3819 (0.31%)	
occurrences causally related to treatment / all	0 / 13	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis Escherichia coli			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	2 / 3818 (0.05%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft infection			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin abscess			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
H1N1 influenza			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter gastritis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site infection			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected bite			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected dermal cyst			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected seroma			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			

subjects affected / exposed	3 / 3818 (0.08%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious colitis			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	5 / 3818 (0.13%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Infusion site infection			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral discitis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint abscess			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Labyrinthitis			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Localised infection			
subjects affected / exposed	4 / 3818 (0.10%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	2 / 3818 (0.05%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lyme disease			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis aseptic			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis viral			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucormycosis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising fasciitis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal candidiasis			



subjects affected / exposed	0 / 3818 (0.00%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	20 / 3818 (0.52%)	22 / 3819 (0.58%)	
occurrences causally related to treatment / all	0 / 26	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis acute			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis chronic			
subjects affected / exposed	3 / 3818 (0.08%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis externa			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media chronic			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraspinal abscess			

subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paronychia			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal abscess			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirectal abscess			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal abscess			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis bacterial			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pilonidal cyst			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	90 / 3818 (2.36%)	90 / 3819 (2.36%)	
occurrences causally related to treatment / all	1 / 99	1 / 102	
deaths causally related to treatment / all	0 / 8	0 / 4	
Pneumonia bacterial			
subjects affected / exposed	2 / 3818 (0.05%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia klebsiella			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pseudomonal			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia staphylococcal			

subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia streptococcal			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural cellulitis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	8 / 3818 (0.21%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural sepsis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative abscess			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	11 / 3818 (0.29%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 12	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate infection			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis Escherichia coli			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	2 / 3818 (0.05%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pyelonephritis			
subjects affected / exposed	2 / 3818 (0.05%)	11 / 3819 (0.29%)	
occurrences causally related to treatment / all	0 / 2	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	4 / 3818 (0.10%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyuria			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal abscess			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal abscess			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection viral			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salpingitis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	36 / 3818 (0.94%)	31 / 3819 (0.81%)	
occurrences causally related to treatment / all	1 / 37	1 / 31	
deaths causally related to treatment / all	0 / 7	0 / 5	
Sepsis pasteurella			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sepsis syndrome			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic arthritis staphylococcal			

subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic embolus			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	11 / 3818 (0.29%)	12 / 3819 (0.31%)	
occurrences causally related to treatment / all	0 / 11	0 / 13	
deaths causally related to treatment / all	0 / 8	0 / 5	
Sialoadenitis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue infection			
subjects affected / exposed	2 / 3818 (0.05%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal abscess			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			

subjects affected / exposed	3 / 3818 (0.08%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Staphylococcal sepsis			
subjects affected / exposed	2 / 3818 (0.05%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Streptococcal bacteraemia			
subjects affected / exposed	0 / 3818 (0.00%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			
subjects affected / exposed	3 / 3818 (0.08%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdiaphragmatic abscess			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			



subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	5 / 3818 (0.13%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	34 / 3818 (0.89%)	30 / 3819 (0.79%)	
occurrences causally related to treatment / all	0 / 37	0 / 37	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 3818 (0.00%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	10 / 3818 (0.26%)	9 / 3819 (0.24%)	
occurrences causally related to treatment / all	0 / 11	0 / 9	
deaths causally related to treatment / all	0 / 2	0 / 1	
Viraemia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	1 / 3818 (0.03%)	3 / 3819 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral pericarditis			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval abscess			

subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	2 / 3818 (0.05%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	23 / 3818 (0.60%)	16 / 3819 (0.42%)	
occurrences causally related to treatment / all	0 / 23	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	1 / 3818 (0.03%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	1 / 1	0 / 4	
deaths causally related to treatment / all	1 / 1	0 / 3	
Diabetes mellitus inadequate control			
subjects affected / exposed	5 / 3818 (0.13%)	4 / 3819 (0.10%)	
occurrences causally related to treatment / all	2 / 5	0 / 4	
deaths causally related to treatment / all	1 / 1	0 / 0	
Diabetic complication			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	5 / 3818 (0.13%)	14 / 3819 (0.37%)	
occurrences causally related to treatment / all	0 / 5	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetic metabolic decompensation			

subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	2 / 3818 (0.05%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid overload			
subjects affected / exposed	4 / 3818 (0.10%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gout			
subjects affected / exposed	4 / 3818 (0.10%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 4	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperammonaemia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	11 / 3818 (0.29%)	16 / 3819 (0.42%)	
occurrences causally related to treatment / all	1 / 12	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	18 / 3818 (0.47%)	22 / 3819 (0.58%)	
occurrences causally related to treatment / all	0 / 21	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypernatraemia			

subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	64 / 3818 (1.68%)	49 / 3819 (1.28%)	
occurrences causally related to treatment / all	57 / 77	38 / 66	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	3 / 3818 (0.08%)	5 / 3819 (0.13%)	
occurrences causally related to treatment / all	1 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	1 / 3818 (0.03%)	0 / 3819 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	8 / 3818 (0.21%)	7 / 3819 (0.18%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypovolaemia			
subjects affected / exposed	2 / 3818 (0.05%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	1 / 3818 (0.03%)	2 / 3819 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	3 / 3818 (0.08%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Obesity			

subjects affected / exposed	3 / 3818 (0.08%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudohyponatraemia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 3818 (0.03%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	

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

<b>Non-serious adverse events</b>	IDeg	IGlar	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 3818 (0.00%)	0 / 3819 (0.00%)	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 April 2014	The following changes were made: 1. Clarification on how to document and evaluate eligibility and treatment continuation. 2. Additional secondary endpoints, and statistical considerations, with reference to the SAP. 3. Storage conditions for open (in-use) IMP was omitted 4. The process for external evaluation of hypoglycaemia was clarified. 5. Update of the reference for the Helsinki Declaration. 6. Minor corrections, clarifications and updates.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported