



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

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:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	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
Arm title	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.

Arm title	Insulin glargine
------------------	------------------

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 pre-trial 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
----------	-------------------

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.

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

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

Reporting group description:

Subjects received IGlax 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; IGlax). 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 IGlax 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 IGlax 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
-----------------------	------------------

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

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 pre-trial 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.
-----------------	---

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

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 IGlar) 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 ^[1]
P-value	< 0.001 ^[2]
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 IGlar 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 (H0): $HR \geq 1.3$ against the alternative hypothesis (Ha): $HR < 1.3$ was less than 2.5%.

[2] - p value : Refers to one-sided test of $HR \geq 1.3$ (against Ha: $HR < 1.3$).

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 ^[3]
P-value	< 0.001 ^[4]
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)
-----------------	---

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

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 ^[5]
P-value	< 0.001 ^[6]
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

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

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

Dictionary used

Dictionary name	MedDRA
Dictionary version	19

Reporting groups

Reporting group title	IDeg
-----------------------	------

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

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 pre-trial 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
Pheochromocytoma		
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	
Blood and lymphatic system disorders			
Anaemia			
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	
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
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	
Coombs negative haemolytic anaemia			
subjects affected / exposed	0 / 3818 (0.00%)	1 / 3819 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Evans 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	
Haemolytic anaemia			
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	
Haemorrhagic anaemia			
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	
Hypochromic anaemia			

subjects affected / exposed	0 / 3818 (0.00%)	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 %

Non-serious adverse events	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:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported