

**Clinical trial results:****A Multi-Center, Prospective, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of AMR101 on Cardiovascular Health and Mortality in Hypertriglyceridemic Patients with Cardiovascular Disease or at High Risk for Cardiovascular Disease: REDUCE-IT (Reduction of Cardiovascular Events with EPA – Intervention Trial)****Summary**

EudraCT number	2011-004726-10
Trial protocol	NL PL
Global end of trial date	31 May 2018

Results information

Result version number	v1 (current)
This version publication date	01 March 2022
First version publication date	01 March 2022

Trial information**Trial identification**

Sponsor protocol code	AMR-01-01-0019
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01492361
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Amarin Pharma, Inc.
Sponsor organisation address	440 Route 22 Suite 300, Bridgewater, United States, 08807
Public contact	Alex Giaquinto, Amarin Pharma, Inc., +1 908719-1315, alex.giaquinto@amarincorp.com
Scientific contact	Alex Giaquinto, Amarin Pharma, Inc., +1 908719-1315, alex.giaquinto@amarincorp.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 September 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 May 2018
Global end of trial reached?	Yes
Global end of trial date	31 May 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is, in patients at low-density lipoprotein cholesterol (LDL-C) goal while on statin therapy, with established cardiovascular disease (CVD) or at high risk for CVD, and hypertriglyceridemia (fasting triglycerides [TG] ≥ 200 mg/dL and < 500 mg/dL [≥ 2.26 mmol/L and < 5.64 mmol/L]), to evaluate the effect of 4 g/day AMR101 on the time from randomization to first occurrence of any component of the composite of the following major cardiovascular (CV) events:

- CV death;
- Nonfatal myocardial infarction (MI), (including silent MI; electrocardiograms [ECGs] will be performed annually for the detection of silent MIs);
- Nonfatal stroke;
- Coronary revascularization; or
- Unstable angina determined to be caused by myocardial ischemia by invasive/non-invasive testing and requiring emergent hospitalization.

Protection of trial subjects:

A data monitoring committee (DMC) was instituted for REDUCE-IT to ensure ongoing patient safety and to oversee and review the pre-specified interim analyses. Recommendations for study continuation at the interim analyses were guided by an interim decision-making process pre-specified in the interim statistical analysis plan; formal efficacy analyses were performed as well as safety evaluations at all safety data reviews. The DMC was specifically charged with monitoring the event rates in the active and placebo groups to assess any possible contribution of the placebo selection to the results. Members of the DMC did not otherwise participate in the study. The committee included two cardiologists (electrophysiologists) and one independent statistician, along with a second supporting, but non-voting independent statistician.

Background therapy:

Stable dose of low, moderate, or high intensity statin (\pm ezetimibe) for at least 4 weeks prior to screening

Evidence for comparator: -

Actual start date of recruitment	21 November 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 189
Country: Number of subjects enrolled	Canada: 250
Country: Number of subjects enrolled	India: 262
Country: Number of subjects enrolled	New Zealand: 134
Country: Number of subjects enrolled	Romania: 202
Country: Number of subjects enrolled	Russian Federation: 709

Country: Number of subjects enrolled	Ukraine: 836
Country: Number of subjects enrolled	United States: 3146
Country: Number of subjects enrolled	South Africa: 414
Country: Number of subjects enrolled	Netherlands: 1678
Country: Number of subjects enrolled	Poland: 359
Worldwide total number of subjects	8179
EEA total number of subjects	2239

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)	4416
From 65 to 84 years	3734
85 years and over	29

Subject disposition

Recruitment

Recruitment details:

473 sites enrolled or followed patients in 11 countries (United States, the Netherlands, Ukraine, Russian Federation, South Africa, Poland, India, Canada, Romania, Australia, and New Zealand). The first patient was screened in November 2011 and the last patient was randomized in August 2016.

Pre-assignment

Screening details:

Screened Subjects: 19,212; Reason for Screen Fail: Incl./Excl. criteria not met, 10,429; Withdrawal of Consent, 340; Adverse Event, 13; CV Risk Category 2 Closed, 4; Lost to Follow-up, 108; Death, 5, Enrollment closed, 3; Other, 135. (4 patients presented 2 screen failure reasons)

Period 1

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

Blinding implementation details:

Treatment was assigned using a computer-generated randomization scheme via Interactive Web Response System. Study medication and placebo were similar in appearance. Patients, investigators, Sponsor, study administrators, and support staff were blinded. Sponsor data analysts were blinded.

Arms

Are arms mutually exclusive?	Yes
Arm title	AMR101

Arm description:

4 1-g icosapent ethyl capsules daily (2 capsules BID)

Arm type	Experimental
Investigational medicinal product name	icosapent ethyl
Investigational medicinal product code	AMR101
Other name	ethyl-EPA, Ethyl-Eicosapentaenoate, Vazkepa, Vascepa
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

4 g/day administered as 4 1-g capsules taken orally, 2 capsules BID, with food

Arm title	Placebo
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Arm description:

matching placebo

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	matching placebo
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

4 g BID

Number of subjects in period 1	AMR101	Placebo
Started	4089	4090
Death before the final visit	265 ^[1]	295 ^[2]
Completed	3684	3630
Not completed	405	460
Consent withdrawn by subject	281	297
Investigator judgement	12	12
Other	49	62
Incomplete final visit	63	89

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of death before the final visit is the actual value from the study

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of death before the final visit is the actual value from the study

Baseline characteristics

Reporting groups

Reporting group title	AMR101
Reporting group description: 4 1-g icosapent ethyl capsules daily (2 capsules BID)	
Reporting group title	Placebo
Reporting group description: matching placebo	

Reporting group values	AMR101	Placebo	Total
Number of subjects	4089	4090	8179
Age categorical			
Units: Subjects			
Adults (18-64 years)	2232	2184	4416
From 65-84 years	1846	1888	3734
85 years and over	11	18	29
Age continuous			
Men and women ≥ 45 years of age with established CVD, or ≥ 50 years of age with diabetes in combination with ≥ 1 additional risk factor for CVD were eligible for enrollment			
Units: years			
median	64.0	64.0	
inter-quartile range (Q1-Q3)	57.0 to 69.0	57.0 to 69.0	-
Gender categorical			
Units: Subjects			
Female	1162	1195	2357
Male	2927	2895	5822
Cardiovascular risk stratum			
CV Risk Category 1 (Secondary Prevention Cohort): patients with established CVD defined in the inclusion criteria CV Risk Category 2 (Primary Prevention Cohort): patients with diabetes and at least one additional risk factor for CVD, but no established CVD			
Units: Subjects			
Secondary Prevention Cohort	2892	2893	5785
Primary Prevention Cohort	1197	1197	2394

Subject analysis sets

Subject analysis set title	Intent-to-Treat population
Subject analysis set type	Intention-to-treat
Subject analysis set description: The Intent-to-Treat (ITT) population was defined as all patients who were randomized via the IWRS. The Safety population was the same as the ITT population.	

Reporting group values	Intent-to-Treat population		
Number of subjects	8179		
Age categorical			
Units: Subjects			
Adults (18-64 years)	4416		
From 65-84 years	3734		

85 years and over	29		
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Age continuous			
Men and women ≥ 45 years of age with established CVD, or ≥ 50 years of age with diabetes in combination with ≥ 1 additional risk factor for CVD were eligible for enrollment			
Units: years			
median	64.0		
inter-quartile range (Q1-Q3)	57.0 to 69.0		
Gender categorical			
Units: Subjects			
Female	2357		
Male	5822		
Cardiovascular risk stratum			
CV Risk Category 1 (Secondary Prevention Cohort): patients with established CVD defined in the inclusion criteria			
CV Risk Category 2 (Primary Prevention Cohort): patients with diabetes and at least one additional risk factor for CVD, but no established CVD			
Units: Subjects			
Secondary Prevention Cohort	5785		
Primary Prevention Cohort	2394		

End points

End points reporting groups

Reporting group title	AMR101
Reporting group description:	
4 1-g icosapent ethyl capsules daily (2 capsules BID)	
Reporting group title	Placebo
Reporting group description:	
matching placebo	
Subject analysis set title	Intent-to-Treat population
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
The Intent-to-Treat (ITT) population was defined as all patients who were randomized via the IWRS. The Safety population was the same as the ITT population.	

Primary: Composite of CV Death, Nonfatal MI (Including Silent MI), Nonfatal Stroke, Coronary Revascularization, and Unstable Angina Determined to be Caused by Myocardial Ischemia by Invasive / Non-invasive Testing and Requiring Emergent Hospitalization

End point title	Composite of CV Death, Nonfatal MI (Including Silent MI), Nonfatal Stroke, Coronary Revascularization, and Unstable Angina Determined to be Caused by Myocardial Ischemia by Invasive / Non-invasive Testing and Requiring Emergent Hospitalization		
End point description:	Time from randomization to the first occurrence of any component of the composite of the following clinical events: CV death, nonfatal MI (including silent MI), nonfatal stroke, coronary revascularization, and unstable angina determined to be caused by myocardial ischemia by invasive / non-invasive testing and requiring emergent hospitalization.		
End point type	Primary		
End point timeframe:	4-6 years		

End point values	AMR101	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4089	4090		
Units: Subjects	705	901		

Statistical analyses

Statistical analysis title	Log-rank test & Cox proportional model		
Statistical analysis description:			
Stratified by CV risk category, use of ezetimibe, and geographical region			
Comparison groups	Placebo v AMR101		

Number of subjects included in analysis	8179
Analysis specification	Pre-specified
Analysis type	superiority ^[1]
P-value	< 0.00001 ^[2]
Method	Log-rank test & Cox proportional model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	0.83

Notes:

[1] - The purpose of this study is to evaluate whether AMR101, combined with a statin therapy, will be superior to the statin therapy alone, when used as a prevention in reducing long-term clinical events in patients with mixed dyslipidemia at high risk for cardiovascular (CV) events.

[2] - The 2-sided alpha level for the primary analysis was adjusted to 0.0437 from 0.05 to account for the two interim analyses based on a group sequential design with O'Brien-Fleming boundaries generated using the Lan-DeMets alpha-spending function.

Secondary: Composite of CV death, nonfatal MI (including silent MI), or nonfatal stroke.

End point title	Composite of CV death, nonfatal MI (including silent MI), or nonfatal stroke.
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End point description:

Key secondary outcome measure is the time from randomization to the first occurrence of the composite of CV death, nonfatal MI (including silent MI), or nonfatal stroke.

End point type	Secondary
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End point timeframe:

4-6 years

End point values	AMR101	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4089	4090		
Units: Subjects	459	606		

Statistical analyses

Statistical analysis title	Log-rank test & Cox proportional model
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Statistical analysis description:

Stratified by CV risk category, use of ezetimibe, and geographical region.

Comparison groups	AMR101 v Placebo
Number of subjects included in analysis	8179
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.00001 ^[3]
Method	Log-rank test & Cox proportional model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.83

Notes:

[3] - Because the primary endpoint was statistically significant, prespecified secondary end points were tested in a hierarchical fashion, in the order listed below, at the final alpha level of 0.0437.

Secondary: Composite of CV Death or Nonfatal MI (Including Silent MI).

End point title	Composite of CV Death or Nonfatal MI (Including Silent MI).
End point description: Time from randomization to the first occurrence of the composite of CV death or nonfatal MI (including silent MI).	
End point type	Secondary
End point timeframe: 4-6 years	

End point values	AMR101	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4089	4090		
Units: Subjects	392	507		

Statistical analyses

Statistical analysis title	Log-rank test & Cox proportional model
Statistical analysis description: Stratified by CV risk category, use of ezetimibe, and geographical region.	
Comparison groups	AMR101 v Placebo
Number of subjects included in analysis	8179
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Log-rank test & Cox proportional model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	0.86

Secondary: Fatal or Nonfatal MI (Including Silent MI).

End point title	Fatal or Nonfatal MI (Including Silent MI).
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End point description:

Time from randomization to the first occurrence of fatal or nonfatal MI (including silent MI).

End point type Secondary

End point timeframe:

4-6 years

End point values	AMR101	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4089	4090		
Units: Subjects	250	355		

Statistical analyses

Statistical analysis title Log-rank test & Cox proportional model

Statistical analysis description:

Stratified by CV risk category, use of ezetimibe, and geographical region.

Comparison groups AMR101 v Placebo

Number of subjects included in analysis 8179

Analysis specification Pre-specified

Analysis type superiority

P-value < 0.0001

Method Log-rank test & Cox proportional model

Parameter estimate Hazard ratio (HR)

Point estimate 0.69

Confidence interval

level 95 %

sides 2-sided

lower limit 0.58

upper limit 0.81

Secondary: Non-elective Coronary Revascularization Represented as the Composite of Emergent or Urgent Classifications.

End point title Non-elective Coronary Revascularization Represented as the Composite of Emergent or Urgent Classifications.

End point description:

Time from randomization to the first occurrence of non-elective coronary revascularization represented as the composite of emergent or urgent classifications.

End point type Secondary

End point timeframe:

4-6 years

End point values	AMR101	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4089	4090		
Units: Subjects	216	321		

Statistical analyses

Statistical analysis title	Log-rank test & Cox proportional model
Statistical analysis description: Stratified by CV risk category, use of ezetimibe, and geographical region.	
Comparison groups	AMR101 v Placebo
Number of subjects included in analysis	8179
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Log-rank test & Cox proportional model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	0.78

Secondary: CV Death

End point title	CV Death
End point description: Time from randomization to the occurrence of CV death	
End point type	Secondary
End point timeframe: 4-6 years	

End point values	AMR101	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4089	4090		
Units: Subjects	174	213		

Statistical analyses

Statistical analysis title	Log-rank test & Cox proportional model
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Statistical analysis description:

Stratified by CV risk category, use of ezetimibe, and geographical region.

Comparison groups	AMR101 v Placebo
Number of subjects included in analysis	8179
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0315
Method	Log-rank test & Cox proportional model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	0.98

Secondary: Unstable Angina Determined to be Caused by Myocardial Ischemia by Invasive / Non-invasive Testing and Requiring Emergent Hospitalization.

End point title	Unstable Angina Determined to be Caused by Myocardial Ischemia by Invasive / Non-invasive Testing and Requiring Emergent Hospitalization.
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End point description:

Time from randomization to the first occurrence of unstable angina determined to be caused by myocardial ischemia by invasive / non-invasive testing and requiring emergent hospitalization.

End point type	Secondary
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End point timeframe:

4-6 years

End point values	AMR101	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4089	4090		
Units: Subjects	108	157		

Statistical analyses

Statistical analysis title	Log-rank test & Cox proportional model
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Statistical analysis description:

Stratified by CV risk category, use of ezetimibe, and geographical region.

Comparison groups	AMR101 v Placebo
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Number of subjects included in analysis	8179
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0018
Method	Log-rank test & Cox proportional model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	0.87

Secondary: Fatal or Nonfatal Stroke.

End point title	Fatal or Nonfatal Stroke.
End point description:	Time from randomization to the first occurrence of fatal or nonfatal stroke.
End point type	Secondary
End point timeframe:	4-6 years

End point values	AMR101	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4089	4090		
Units: Subjects	98	134		

Statistical analyses

Statistical analysis title	Log-rank test & Cox proportional model
Statistical analysis description:	Stratified by CV risk category, use of ezetimibe, and geographical region.
Comparison groups	AMR101 v Placebo
Number of subjects included in analysis	8179
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0129
Method	Log-rank test & Cox proportional model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.72

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	0.93

Secondary: Total Mortality, Nonfatal MI (Including Silent MI), or Nonfatal Stroke.

End point title	Total Mortality, Nonfatal MI (Including Silent MI), or Nonfatal Stroke.
End point description:	Time from randomization to the first occurrence of the composite of total mortality, nonfatal MI (including silent MI), or nonfatal stroke.
End point type	Secondary
End point timeframe:	4-6 years

End point values	AMR101	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4089	4090		
Units: Subjects	549	690		

Statistical analyses

Statistical analysis title	Log-rank test & Cox proportional model
Statistical analysis description:	Stratified by CV risk category, use of ezetimibe, and geographical region.
Comparison groups	AMR101 v Placebo
Number of subjects included in analysis	8179
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Log-rank test & Cox proportional model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	0.86

Secondary: Total Mortality.

End point title	Total Mortality.
End point description:	Time from randomization to the first occurrence of the composite of total mortality, nonfatal MI (including silent MI), or nonfatal stroke.
End point type	Secondary
End point timeframe:	4-6 years

End point values	AMR101	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4089	4090		
Units: Subjects	274	310		

Statistical analyses

Statistical analysis title	Log-rank test & Cox proportional model
Statistical analysis description:	Stratified by CV risk category, use of ezetimibe, and geographical region.
Comparison groups	AMR101 v Placebo
Number of subjects included in analysis	8179
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0915
Method	Log-rank test & Cox proportional model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.02

Adverse events

Adverse events information

Timeframe for reporting adverse events:

4-6 years

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.1
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Reporting groups

Reporting group title	AMR101
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Reporting group description: -

Reporting group title	Placebo
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Reporting group description: -

Serious adverse events	AMR101	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1252 / 4089 (30.62%)	1254 / 4090 (30.66%)	
number of deaths (all causes)	274	310	
number of deaths resulting from adverse events	94	102	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	1 / 4089 (0.02%)	3 / 4090 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Adenocarcinoma			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma gastric			

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	6 / 4089 (0.15%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 2
Adenoid cystic carcinoma		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal adenoma		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal neoplasm		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal cancer		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal squamous cell carcinoma		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basal cell carcinoma		

subjects affected / exposed	3 / 4089 (0.07%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of thyroid gland		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	8 / 4089 (0.20%)	9 / 4090 (0.22%)
occurrences causally related to treatment / all	1 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Bladder cancer recurrent		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage III		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		
subjects affected / exposed	3 / 4089 (0.07%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	5 / 4089 (0.12%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Bone cancer		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm		

subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Breast cancer		
subjects affected / exposed	14 / 4089 (0.34%)	8 / 4090 (0.20%)
occurrences causally related to treatment / all	0 / 15	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer male		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer metastatic		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Breast cancer recurrent		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer stage I		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cancer pain		
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Central nervous system neoplasm		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma		

subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Cervix neoplasm		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholesteatoma		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	1 / 4089 (0.02%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	10 / 4089 (0.24%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Colon cancer metastatic		

subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Colon cancer recurrent			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon neoplasm			
subjects affected / exposed	1 / 4089 (0.02%)	3 / 4090 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenocarcinoma			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Colorectal cancer metastatic			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
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			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal neoplasm			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
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	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Endometrial cancer		
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer metastatic		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer stage I		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extranodal marginal zone B-cell lymphoma (MALT type)		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric adenoma		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		
subjects affected / exposed	4 / 4089 (0.10%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Gastric cancer recurrent		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastric neoplasm		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal cancer		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal tumour		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal tract adenoma		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer		
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatic cancer metastatic		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatocellular carcinoma		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal proliferative breast lesion		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		

subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Iris melanoma		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large cell lung cancer metastatic		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Large intestine benign neoplasm		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Leiomyosarcoma		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lip and/or oral cavity cancer		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
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	4 / 4089 (0.10%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Lung adenocarcinoma stage II		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung adenocarcinoma stage IV		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung cancer metastatic		
subjects affected / exposed	8 / 4089 (0.20%)	9 / 4090 (0.22%)
occurrences causally related to treatment / all	0 / 9	0 / 9
deaths causally related to treatment / all	0 / 7	0 / 7
Lung carcinoma cell type unspecified recurrent		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung neoplasm malignant		
subjects affected / exposed	8 / 4089 (0.20%)	14 / 4090 (0.34%)
occurrences causally related to treatment / all	0 / 9	0 / 14
deaths causally related to treatment / all	0 / 3	0 / 5
Lymphocytic leukaemia		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant glioma		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		

subjects affected / exposed	7 / 4089 (0.17%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Malignant melanoma in situ		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant mesenteric neoplasm		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to abdominal cavity		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to bone		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to central nervous system		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Metastases to chest wall		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to kidney		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to liver		
subjects affected / exposed	4 / 4089 (0.10%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to lung		
subjects affected / exposed	3 / 4089 (0.07%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lymph nodes		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to peritoneum		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastasis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic carcinoma of the bladder		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic gastric cancer		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic neoplasm		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic renal cell carcinoma			
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic squamous cell carcinoma			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Mucinous adenocarcinoma of appendix			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucoepidermoid carcinoma of salivary gland			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nasal neoplasm			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neuroendocrine carcinoma of the skin			

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroma		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nodular melanoma		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-Hodgkin's lymphoma		
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		
subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2
Non-small cell lung cancer metastatic		
subjects affected / exposed	3 / 4089 (0.07%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer stage III		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer stage IV		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Oesophageal cancer metastatic		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Oesophageal neoplasm		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal cancer		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian adenoma		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer metastatic		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ovarian epithelial cancer		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian epithelial cancer metastatic		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ovarian granulosa-theca cell tumour		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian neoplasm		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	6 / 4089 (0.15%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 4
Pancreatic carcinoma metastatic		
subjects affected / exposed	5 / 4089 (0.12%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Pancreatic neoplasm		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid tumour benign		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Penile cancer		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Pleural mesothelioma		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Prostate cancer		
subjects affected / exposed	26 / 4089 (0.64%)	26 / 4090 (0.64%)
occurrences causally related to treatment / all	0 / 27	1 / 26
deaths causally related to treatment / all	0 / 1	0 / 1
Prostate cancer metastatic		
subjects affected / exposed	5 / 4089 (0.12%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 1
Prostate cancer recurrent		
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage IV		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		

subjects affected / exposed	2 / 4089 (0.05%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Rectal neoplasm		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Refractory anaemia with ringed sideroblasts		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Refractory cytopenia with unilineage dysplasia		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	6 / 4089 (0.15%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 0
Renal cancer metastatic		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Renal cell carcinoma		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal cancer		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland adenoma		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Schwannoma		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer metastatic		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestine carcinoma		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		
subjects affected / exposed	4 / 4089 (0.10%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		

subjects affected / exposed	4 / 4089 (0.10%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 0
Squamous cell carcinoma of pharynx		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of skin		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Testis cancer		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Throat cancer		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
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 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer metastatic		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Tongue cancer metastatic		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsil cancer		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell cancer of the renal pelvis and ureter			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	2 / 4089 (0.05%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma recurrent			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour ulceration			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral cancer			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			

subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Angiodysplasia		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic aneurysm		
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Aortic aneurysm rupture		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Aortic stenosis		
subjects affected / exposed	4 / 4089 (0.10%)	10 / 4090 (0.24%)
occurrences causally related to treatment / all	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure fluctuation		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	5 / 4089 (0.12%)	8 / 4090 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism arterial		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extravasation blood		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	12 / 4089 (0.29%)	16 / 4090 (0.39%)
occurrences causally related to treatment / all	0 / 12	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	15 / 4089 (0.37%)	11 / 4090 (0.27%)
occurrences causally related to treatment / all	0 / 15	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		

subjects affected / exposed	9 / 4089 (0.22%)	11 / 4090 (0.27%)
occurrences causally related to treatment / all	0 / 9	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Iliac artery occlusion		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jugular vein thrombosis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leriche syndrome		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
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	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	4 / 4089 (0.10%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		

subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Peripheral embolism		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	1 / 4089 (0.02%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renovascular hypertension		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Shock haemorrhagic		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Temporal arteritis		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vena cava thrombosis			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Aortic valve replacement			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Artificial urinary sphincter implant			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ablation			

subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endotracheal intubation			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric bypass			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip arthroplasty			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hospitalisation			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.05%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee arthroplasty			
subjects affected / exposed	3 / 4089 (0.07%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal polypectomy			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung lobectomy			

subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polypectomy			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff repair			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shoulder operation			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal operation			
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stem cell transplant			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral bladder resection			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral prostatectomy			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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			
Adverse drug reaction			

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Asthenia		
subjects affected / exposed	6 / 4089 (0.15%)	8 / 4090 (0.20%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Catheter site haemorrhage		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
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	1 / 4089 (0.02%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Chest pain		
subjects affected / exposed	66 / 4089 (1.61%)	66 / 4090 (1.61%)
occurrences causally related to treatment / all	0 / 75	0 / 68
deaths causally related to treatment / all	0 / 0	0 / 0
Chills		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Complication associated with device		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Death		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Drowning		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Exercise tolerance decreased		
subjects affected / exposed	0 / 4089 (0.00%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Fatigue		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gait disturbance		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
General physical health deterioration		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Generalised oedema		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired healing		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated hernia		

subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		
subjects affected / exposed	5 / 4089 (0.12%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple organ dysfunction syndrome		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Non-cardiac chest pain		
subjects affected / exposed	49 / 4089 (1.20%)	52 / 4090 (1.27%)
occurrences causally related to treatment / all	1 / 52	0 / 58
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	3 / 4089 (0.07%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pain		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic mass		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral swelling		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyp		

subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	4 / 4089 (0.10%)	5 / 4090 (0.12%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suprapubic pain			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swelling			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	1 / 4089 (0.02%)	7 / 4090 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 2	
Ulcer			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcer haemorrhage			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent restenosis			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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			
Allergy to arthropod sting			

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
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 / 4089 (0.02%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypersensitivity			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Adnexa uteri mass			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	18 / 4089 (0.44%)	11 / 4090 (0.27%)	
occurrences causally related to treatment / all	0 / 18	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hypoplasia			

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Female genital tract fistula		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Genital haemorrhage		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Menorrhagia		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cyst		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cyst ruptured		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic prolapse		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peyronie's disease		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatism		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	6 / 4089 (0.15%)	3 / 4090 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seminal vesicular cyst			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular cyst			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			

subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute respiratory distress syndrome		
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Acute respiratory failure		
subjects affected / exposed	19 / 4089 (0.46%)	18 / 4090 (0.44%)
occurrences causally related to treatment / all	1 / 21	0 / 20
deaths causally related to treatment / all	0 / 2	0 / 4
Aspiration		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Asthma		
subjects affected / exposed	9 / 4089 (0.22%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Atelectasis		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial fistula		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial hyperreactivity		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		

subjects affected / exposed	0 / 4089 (0.00%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
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	33 / 4089 (0.81%)	34 / 4090 (0.83%)
occurrences causally related to treatment / all	0 / 44	0 / 74
deaths causally related to treatment / all	0 / 1	0 / 2
Dyspnoea		
subjects affected / exposed	16 / 4089 (0.39%)	13 / 4090 (0.32%)
occurrences causally related to treatment / all	0 / 18	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea exertional		
subjects affected / exposed	4 / 4089 (0.10%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	7 / 4089 (0.17%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	1 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemothorax		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hiccups		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercapnia		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	3 / 4089 (0.07%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.02%)	1 / 4090 (0.02%)
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	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal turbinate hypertrophy		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal mass		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	7 / 4089 (0.17%)	11 / 4090 (0.27%)
occurrences causally related to treatment / all	0 / 7	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuritic pain		
subjects affected / exposed	1 / 4089 (0.02%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumomediastinum		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	7 / 4089 (0.17%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonitis		

subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	3 / 4089 (0.07%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	14 / 4089 (0.34%)	22 / 4090 (0.54%)
occurrences causally related to treatment / all	0 / 16	0 / 22
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary fibrosis		
subjects affected / exposed	4 / 4089 (0.10%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	2 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary hypertension		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mass		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	3 / 4089 (0.07%)	7 / 4090 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory acidosis		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory arrest		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	16 / 4089 (0.39%)	15 / 4090 (0.37%)	
occurrences causally related to treatment / all	0 / 17	0 / 17	
deaths causally related to treatment / all	0 / 4	0 / 3	
Rhinitis allergic			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status asthmaticus			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal mass			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Wheezing			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aggression		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Agitated depression		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Alcohol abuse		
subjects affected / exposed	1 / 4089 (0.02%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Alcohol withdrawal syndrome		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholism		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar disorder		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Completed suicide		

subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Confusional state		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	5 / 4089 (0.12%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium tremens		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mania		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes		
subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Panic attack		

subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizoaffective disorder			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizophrenia			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device breakage			
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (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 / 4089 (0.02%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Alcoholic liver disease			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	3 / 4089 (0.07%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dilatation			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	4 / 4089 (0.10%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			

subjects affected / exposed	9 / 4089 (0.22%)	7 / 4090 (0.17%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	15 / 4089 (0.37%)	7 / 4090 (0.17%)
occurrences causally related to treatment / all	0 / 15	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis chronic		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	15 / 4089 (0.37%)	18 / 4090 (0.44%)
occurrences causally related to treatment / all	0 / 15	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Cholestasis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cryptogenic cirrhosis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder disorder		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder enlargement		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder polyp		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatic steatosis			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic hepatitis			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	3 / 4089 (0.07%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level above therapeutic			

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriogram coronary		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Biopsy pleura		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood glucose increased		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure difference of extremities		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
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 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac murmur		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction abnormal		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction decreased		

subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram T wave abnormal		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza A virus test positive		
subjects affected / exposed	0 / 4089 (0.00%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza virus test positive		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lipase increased		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic specific antigen increased		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transaminases increased		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Weight decreased		

subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
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	4 / 4089 (0.10%)	5 / 4090 (0.12%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Avulsion fracture			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Axillary nerve injury			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back injury			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone fragmentation			

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain contusion		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Carbon monoxide poisoning		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cartilage injury		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chest injury		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Clavicle fracture		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Compression fracture		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		

subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	1 / 4089 (0.02%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dislocation of sternum		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	16 / 4089 (0.39%)	15 / 4090 (0.37%)
occurrences causally related to treatment / all	0 / 17	0 / 17
deaths causally related to treatment / all	0 / 1	0 / 0
Femoral neck fracture		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	4 / 4089 (0.10%)	10 / 4090 (0.24%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body in gastrointestinal tract		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fractured sacrum		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stoma complication		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hand fracture		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	5 / 4089 (0.12%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Heat stroke		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	8 / 4089 (0.20%)	8 / 4090 (0.20%)
occurrences causally related to treatment / all	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	3 / 4089 (0.07%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated incisional hernia		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	6 / 4089 (0.15%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw fracture		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		
subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Laceration		
subjects affected / exposed	3 / 4089 (0.07%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament injury		

subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	4 / 4089 (0.10%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	3 / 4089 (0.07%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle injury		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle rupture		

subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle strain		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal injury		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Overdose		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Periprosthetic fracture		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Poisoning deliberate		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post laminectomy syndrome		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural discharge		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematuria		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	5 / 4089 (0.12%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	1 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural pulmonary embolism		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural swelling		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative adhesion		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative fever		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative hernia		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative ileus		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative renal failure		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative thrombosis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural hypertension		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		
subjects affected / exposed	0 / 4089 (0.00%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pubis fracture		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation injury		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation oesophagitis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	5 / 4089 (0.12%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	3 / 4089 (0.07%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Sciatic nerve injury		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fractured base		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column injury		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		

subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stomal hernia		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stress fracture		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	9 / 4089 (0.22%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haemorrhage		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		

subjects affected / exposed	4 / 4089 (0.10%)	4 / 4090 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma			
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Traumatic liver injury			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic renal injury			

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric anastomosis complication			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral injury			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Hypertrophic cardiomyopathy			

subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreas divisum			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	6 / 4089 (0.15%)	4 / 4090 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	1 / 4089 (0.02%)	4 / 4090 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Angina pectoris			
subjects affected / exposed	48 / 4089 (1.17%)	48 / 4090 (1.17%)	
occurrences causally related to treatment / all	0 / 53	0 / 50	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	41 / 4089 (1.00%)	53 / 4090 (1.30%)	
occurrences causally related to treatment / all	0 / 43	0 / 55	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease mixed			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			

subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve stenosis		
subjects affected / exposed	10 / 4089 (0.24%)	7 / 4090 (0.17%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia		
subjects affected / exposed	3 / 4089 (0.07%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Arteriospasm coronary		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		
subjects affected / exposed	21 / 4089 (0.51%)	17 / 4090 (0.42%)
occurrences causally related to treatment / all	0 / 22	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial flutter		
subjects affected / exposed	1 / 4089 (0.02%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	4 / 4089 (0.10%)	9 / 4090 (0.22%)
occurrences causally related to treatment / all	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 4
Cardiac failure		
subjects affected / exposed	7 / 4089 (0.17%)	8 / 4090 (0.20%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure acute		
subjects affected / exposed	3 / 4089 (0.07%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Cardiac failure chronic		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac failure congestive		
subjects affected / exposed	19 / 4089 (0.46%)	13 / 4090 (0.32%)
occurrences causally related to treatment / all	0 / 19	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac tamponade		

subjects affected / exposed	0 / 4089 (0.00%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve disease		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac ventricular thrombosis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	0 / 4089 (0.00%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 2
Cardiogenic shock		
subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiomyopathy		
subjects affected / exposed	4 / 4089 (0.10%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Congestive cardiomyopathy		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cor pulmonale chronic		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	9 / 4089 (0.22%)	16 / 4090 (0.39%)
occurrences causally related to treatment / all	0 / 9	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery dissection		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery occlusion		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive heart disease		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.07%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Microvascular coronary artery diseases		

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subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
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	4 / 4089 (0.10%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial infarction		
subjects affected / exposed	4 / 4089 (0.10%)	12 / 4090 (0.29%)
occurrences causally related to treatment / all	0 / 4	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 5
Myocardial ischaemia		
subjects affected / exposed	4 / 4089 (0.10%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial haemorrhage		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuropericarditis		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Silent myocardial infarction		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular extrasystoles		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia paroxysmal		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular arrhythmia		
subjects affected / exposed	3 / 4089 (0.07%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular fibrillation		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular parasystole		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Acute disseminated encephalomyelitis			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Altered state of consciousness			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aphasia			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
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	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery disease		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery occlusion		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carpal tunnel syndrome		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral infarction		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrospinal fluid leakage		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	3 / 4089 (0.07%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Cervical radiculopathy		

subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Demyelinating polyneuropathy		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	11 / 4089 (0.27%)	10 / 4090 (0.24%)
occurrences causally related to treatment / all	0 / 12	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Dural arteriovenous fistula		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		

subjects affected / exposed	7 / 4089 (0.17%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paralysis		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic transformation stroke		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		
subjects affected / exposed	3 / 4089 (0.07%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 3	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	0 / 4089 (0.00%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocephalus		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive encephalopathy		

subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic coma		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hypoglycaemic encephalopathy		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic unconsciousness		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
IIIrd nerve paralysis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial aneurysm		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial mass		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	1 / 4089 (0.02%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple sclerosis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple sclerosis relapse		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve compression		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgia		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neurodegenerative disorder		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Neurological symptom		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		

subjects affected / exposed	6 / 4089 (0.15%)	6 / 4090 (0.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudoradicular syndrome			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Quadriplegia			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radicular syndrome			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reversible ischaemic neurological deficit			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	3 / 4089 (0.07%)	4 / 4090 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sensory ganglionitis			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Speech disorder			

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord herniation		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
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	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	28 / 4089 (0.68%)	31 / 4090 (0.76%)
occurrences causally related to treatment / all	1 / 31	0 / 36
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient global amnesia		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		
subjects affected / exposed	8 / 4089 (0.20%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Trigeminal nerve disorder		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Trigeminal neuralgia		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unresponsive to stimuli			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vasogenic cerebral oedema			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord paralysis			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	22 / 4089 (0.54%)	20 / 4090 (0.49%)	
occurrences causally related to treatment / all	0 / 22	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			

subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic anaemia		
subjects affected / exposed	4 / 4089 (0.10%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Immune thrombocytopenic purpura		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
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	4 / 4089 (0.10%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoid tissue hyperplasia		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenia		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normocytic anaemia		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pernicious anaemia			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenomegaly			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	3 / 4089 (0.07%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Thrombotic microangiopathy			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inner ear disorder			

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	5 / 4089 (0.12%)	8 / 4090 (0.20%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	2 / 4089 (0.05%)	5 / 4090 (0.12%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	4 / 4089 (0.10%)	5 / 4090 (0.12%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chalazion			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye swelling			

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid ptosis			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	3 / 4089 (0.07%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein thrombosis			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
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	3 / 4089 (0.07%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal hernia obstructive		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain		
subjects affected / exposed	7 / 4089 (0.17%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	5 / 4089 (0.12%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendix disorder		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic gastritis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		

subjects affected / exposed	6 / 4089 (0.15%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	5 / 4089 (0.12%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	6 / 4089 (0.15%)	8 / 4090 (0.20%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's disease		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	5 / 4089 (0.12%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		

subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	3 / 4089 (0.07%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal perforation		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Duodenal ulcer		
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis haemorrhagic		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenogastric reflux		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterovesical fistula		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epigastric discomfort		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faeces discoloured		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric antral vascular ectasia		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	1 / 4089 (0.02%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric perforation		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	5 / 4089 (0.12%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer perforation		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastritis		
subjects affected / exposed	0 / 4089 (0.00%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia haemorrhagic		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	26 / 4089 (0.64%)	20 / 4090 (0.49%)
occurrences causally related to treatment / all	1 / 28	1 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal inflammation		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal obstruction		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal pain		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroesophageal reflux disease		
subjects affected / exposed	4 / 4089 (0.10%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	3 / 4089 (0.07%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		

subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	3 / 4089 (0.07%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	2 / 4089 (0.05%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	4 / 4089 (0.10%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired gastric emptying		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	11 / 4089 (0.27%)	8 / 4090 (0.20%)
occurrences causally related to treatment / all	0 / 11	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ischaemia		
subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Intestinal obstruction		

subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal perforation		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haemorrhage		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.00%)	1 / 4090 (0.02%)
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	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	4 / 4089 (0.10%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	5 / 4089 (0.12%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-Weiss syndrome		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	3 / 4089 (0.07%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric arterial occlusion		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mouth haemorrhage		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	4 / 4089 (0.10%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive pancreatitis		
subjects affected / exposed	2 / 4089 (0.05%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal food impaction		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal haemorrhage		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal pain		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic cyst		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic mass		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	3 / 4089 (0.07%)	7 / 4090 (0.17%)
occurrences causally related to treatment / all	0 / 3	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	4 / 4089 (0.10%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	1 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis chronic		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis haemorrhagic		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Peptic ulcer		

subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal adhesions		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal disorder		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngo-oesophageal diverticulum		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Portal hypertensive gastropathy		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proctitis ulcerative		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	10 / 4089 (0.24%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 11	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal prolapse		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal fibrosis		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haematoma		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haemorrhage		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	16 / 4089 (0.39%)	12 / 4090 (0.29%)
occurrences causally related to treatment / all	0 / 19	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Strangulated umbilical hernia		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subileus		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis mesenteric vessel		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.02%)	10 / 4090 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	3 / 4089 (0.07%)	3 / 4090 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	7 / 4089 (0.17%)	4 / 4090 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal cyst			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	2 / 4089 (0.05%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ulcer			

subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ecchymosis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Granuloma annulare		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Panniculitis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Photosensitivity reaction		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rash erythematous		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin ulcer		
subjects affected / exposed	5 / 4089 (0.12%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Urticaria		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	47 / 4089 (1.15%)	34 / 4090 (0.83%)	
occurrences causally related to treatment / all	1 / 52	0 / 41	
deaths causally related to treatment / all	0 / 2	0 / 0	
Acute prerenal failure			
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder dysfunction			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck obstruction			
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder outlet obstruction			
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder prolapse			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder stenosis			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	0 / 4089 (0.00%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		
subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		
subjects affected / exposed	6 / 4089 (0.15%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis haemorrhagic		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysuria		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	8 / 4089 (0.20%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertonic bladder		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incontinence		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	13 / 4089 (0.32%)	12 / 4090 (0.29%)
occurrences causally related to treatment / all	0 / 14	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery fibromuscular dysplasia		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		

subjects affected / exposed	4 / 4089 (0.10%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal disorder		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	11 / 4089 (0.27%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
Renal haemorrhage		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		
subjects affected / exposed	5 / 4089 (0.12%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal injury		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stag horn calculus		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stress urinary incontinence		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric dilatation		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric stenosis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		
subjects affected / exposed	6 / 4089 (0.15%)	7 / 4090 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral meatus stenosis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stenosis		
subjects affected / exposed	3 / 4089 (0.07%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder haemorrhage		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder polyp		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary incontinence		

subjects affected / exposed	0 / 4089 (0.00%)	4 / 4090 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	5 / 4089 (0.12%)	4 / 4090 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Addison's disease			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	0 / 4089 (0.00%)	4 / 4090 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			

subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic nodular goitre			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
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			
Arthralgia			
subjects affected / exposed	7 / 4089 (0.17%)	9 / 4090 (0.22%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	6 / 4089 (0.15%)	6 / 4090 (0.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back disorder			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
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	17 / 4089 (0.42%)	11 / 4090 (0.27%)	
occurrences causally related to treatment / all	0 / 18	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			

subjects affected / exposed	1 / 4089 (0.02%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Coccydynia		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		
subjects affected / exposed	0 / 4089 (0.00%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Flank pain		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
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	2 / 4089 (0.05%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty tophus		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemarthrosis		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc compression		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc disorder		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	16 / 4089 (0.39%)	7 / 4090 (0.17%)
occurrences causally related to treatment / all	0 / 16	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Joint range of motion decreased		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Knee deformity		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	10 / 4089 (0.24%)	10 / 4090 (0.24%)
occurrences causally related to treatment / all	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Mandibular mass		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mobility decreased		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle spasms		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	6 / 4089 (0.15%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		
subjects affected / exposed	5 / 4089 (0.12%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
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	1 / 4089 (0.02%)	0 / 4090 (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	81 / 4089 (1.98%)	73 / 4090 (1.78%)
occurrences causally related to treatment / all	0 / 89	0 / 81
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondrosis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	5 / 4089 (0.12%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in jaw		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pathological fracture		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudarthrosis		

subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatic fever		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	0 / 4089 (0.00%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	10 / 4089 (0.24%)	12 / 4090 (0.29%)
occurrences causally related to treatment / all	0 / 11	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue mass		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column stenosis		
subjects affected / exposed	11 / 4089 (0.27%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 12	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	3 / 4089 (0.07%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		

subjects affected / exposed	3 / 4089 (0.07%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sympathetic posterior cervical syndrome			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic lupus erythematosus			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall abscess		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess intestinal		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess limb		
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acquired immunodeficiency syndrome		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	2 / 4089 (0.05%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	9 / 4089 (0.22%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		

subjects affected / exposed	4 / 4089 (0.10%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis infective		
subjects affected / exposed	3 / 4089 (0.07%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	3 / 4089 (0.07%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial sepsis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary abscess		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Breast abscess		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiolitis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	11 / 4089 (0.27%)	10 / 4090 (0.24%)
occurrences causally related to treatment / all	0 / 11	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis bacterial		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis viral		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis infective		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter gastroenteritis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Catheter site cellulitis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	36 / 4089 (0.88%)	28 / 4090 (0.68%)
occurrences causally related to treatment / all	0 / 38	0 / 39
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis streptococcal		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	3 / 4089 (0.07%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis bacterial		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis escherichia		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus infection		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.27%)	9 / 4090 (0.22%)
occurrences causally related to treatment / all	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	1 / 4089 (0.02%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal bacteraemia		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
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 / 4089 (0.02%)	0 / 4090 (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	13 / 4089 (0.32%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 16	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gas gangrene		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	16 / 4089 (0.39%)	16 / 4090 (0.39%)
occurrences causally related to treatment / all	0 / 16	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis rotavirus		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	5 / 4089 (0.12%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal bacterial overgrowth		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Genital infection fungal		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Graft infection		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.00%)	1 / 4090 (0.02%)
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	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis C		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis viral		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site infection		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site abscess		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious colitis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of bronchiectasis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		

subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	2 / 4089 (0.05%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Intervertebral discitis		
subjects affected / exposed	3 / 4089 (0.07%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint abscess		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Keratitis bacterial		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella infection		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngitis		
subjects affected / exposed	3 / 4089 (0.07%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Latent tuberculosis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Listeriosis		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	3 / 4089 (0.07%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	1 / 4089 (0.02%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection viral		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mastitis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis bacterial		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mycobacterial infection		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising fasciitis		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenic sepsis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oral candidiasis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
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 / 4089 (0.00%)	2 / 4090 (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	12 / 4089 (0.29%)	7 / 4090 (0.17%)
occurrences causally related to treatment / all	0 / 14	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis acute		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media acute		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parainfluenzae virus infection		

subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parasitic gastroenteritis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parotitis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic abscess		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perirectal abscess		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis bacterial		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal abscess		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngolaryngeal abscess		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pilonidal cyst		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumococcal sepsis		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	105 / 4089 (2.57%)	118 / 4090 (2.89%)
occurrences causally related to treatment / all	0 / 128	0 / 137
deaths causally related to treatment / all	0 / 9	0 / 4
Pneumonia bacterial		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia influenzal		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pseudomonal		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia respiratory syncytial viral		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia staphylococcal		

subjects affected / exposed	1 / 4089 (0.02%)	2 / 4090 (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 / 4089 (0.05%)	0 / 4090 (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 / 4089 (0.00%)	1 / 4090 (0.02%)
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	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	8 / 4089 (0.20%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pseudomonas infection		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelocystitis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	7 / 4089 (0.17%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	2 / 4089 (0.05%)	4 / 4090 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal abscess		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus infection		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection viral		

subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rhinovirus infection		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rotavirus infection		
subjects affected / exposed	0 / 4089 (0.00%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	25 / 4089 (0.61%)	31 / 4090 (0.76%)
occurrences causally related to treatment / all	0 / 29	0 / 34
deaths causally related to treatment / all	0 / 2	0 / 4
Sepsis syndrome		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
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	12 / 4089 (0.29%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 13	0 / 3
deaths causally related to treatment / all	0 / 4	0 / 2
Shunt infection		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sialoadenitis		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin infection		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		
subjects affected / exposed	3 / 4089 (0.07%)	2 / 4090 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal bacteraemia		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal infection		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal sepsis		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subacute endocarditis		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic candida		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tick-borne fever		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (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 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	1 / 4089 (0.02%)	5 / 4090 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Urinary tract infection		
subjects affected / exposed	25 / 4089 (0.61%)	22 / 4090 (0.54%)
occurrences causally related to treatment / all	0 / 32	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	11 / 4089 (0.27%)	9 / 4090 (0.22%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 2
Viral infection		
subjects affected / exposed	1 / 4089 (0.02%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Viral sepsis		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cellulitis			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound abscess			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	4 / 4089 (0.10%)	2 / 4090 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection staphylococcal			
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			

subjects affected / exposed	16 / 4089 (0.39%)	11 / 4090 (0.27%)
occurrences causally related to treatment / all	0 / 16	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus		
subjects affected / exposed	11 / 4089 (0.27%)	8 / 4090 (0.20%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	5 / 4089 (0.12%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	4 / 4089 (0.10%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Failure to thrive		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	2 / 4089 (0.05%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		

subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	10 / 4089 (0.24%)	8 / 4090 (0.20%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	3 / 4089 (0.07%)	6 / 4090 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypernatraemia		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperosmolar state		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	15 / 4089 (0.37%)	14 / 4090 (0.34%)
occurrences causally related to treatment / all	0 / 15	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		

subjects affected / exposed	3 / 4089 (0.07%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	1 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	5 / 4089 (0.12%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypophosphataemia		
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	2 / 4089 (0.05%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency		
subjects affected / exposed	0 / 4089 (0.00%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic acidosis		
subjects affected / exposed	1 / 4089 (0.02%)	1 / 4090 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		
subjects affected / exposed	2 / 4089 (0.05%)	3 / 4090 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity		

subjects affected / exposed	9 / 4089 (0.22%)	5 / 4090 (0.12%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock hypoglycaemic			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour lysis syndrome			
subjects affected / exposed	1 / 4089 (0.02%)	0 / 4090 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	2 / 4089 (0.05%)	4 / 4090 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	AMR101	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3268 / 4089 (79.92%)	3248 / 4090 (79.41%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	312 / 4089 (7.63%)	333 / 4090 (8.14%)	
occurrences (all)	340	375	
Nervous system disorders			
Dizziness			
subjects affected / exposed	227 / 4089 (5.55%)	238 / 4090 (5.82%)	
occurrences (all)	264	278	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	178 / 4089 (4.35%)	224 / 4090 (5.48%)	
occurrences (all)	201	244	
General disorders and administration site conditions			

Chest pain subjects affected / exposed occurrences (all)	226 / 4089 (5.53%) 265	240 / 4090 (5.87%) 305	
Fatigue subjects affected / exposed occurrences (all)	227 / 4089 (5.55%) 239	195 / 4090 (4.77%) 206	
Oedema peripheral subjects affected / exposed occurrences (all)	264 / 4089 (6.46%) 296	201 / 4090 (4.91%) 242	
Eye disorders Cataract subjects affected / exposed occurrences (all)	230 / 4089 (5.62%) 312	205 / 4090 (5.01%) 272	
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all)	216 / 4089 (5.28%) 231	142 / 4090 (3.47%) 147	
Diarrhoea subjects affected / exposed occurrences (all)	363 / 4089 (8.88%) 452	450 / 4090 (11.00%) 565	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	241 / 4089 (5.89%) 275	241 / 4090 (5.89%) 284	
Dyspnoea subjects affected / exposed occurrences (all)	243 / 4089 (5.94%) 280	233 / 4090 (5.70%) 282	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	309 / 4089 (7.56%) 389	306 / 4090 (7.48%) 361	
Back pain subjects affected / exposed occurrences (all)	322 / 4089 (7.87%) 361	303 / 4090 (7.41%) 339	
Pain in extremity			

subjects affected / exposed occurrences (all)	232 / 4089 (5.67%) 285	239 / 4090 (5.84%) 282	
Infections and infestations			
Bronchitis			
subjects affected / exposed occurrences (all)	295 / 4089 (7.21%) 361	292 / 4090 (7.14%) 377	
Influenza			
subjects affected / exposed occurrences (all)	261 / 4089 (6.38%) 314	267 / 4090 (6.53%) 331	
Nasopharyngitis			
subjects affected / exposed occurrences (all)	314 / 4089 (7.68%) 406	300 / 4090 (7.33%) 370	
Upper respiratory tract infection			
subjects affected / exposed occurrences (all)	311 / 4089 (7.61%) 417	315 / 4090 (7.70%) 416	
Urinary tract infection			
subjects affected / exposed occurrences (all)	240 / 4089 (5.87%) 356	246 / 4090 (6.01%) 361	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 May 2013	Fasting TG level at screening increased from 135 mg/dL (reflecting a 10% variability allowance from the target of 150 mg/dL) to 200 mg/dL (without a variability allowance).
08 July 2016	The composite of hard major adverse coronary event (MACE) endpoints (CV death, non-fatal MI, non-fatal stroke) was designated as the "key secondary endpoint" and secondary endpoints were streamlined and re-ordered to further elucidate primary and key secondary findings. Added an additional interim analysis to occur after approximately 80% of the total primary endpoint events are reached. Updated cardiovascular endpoint definitions per new version of Standardized Definitions for Endpoint Events in Cardiovascular Trials.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/28294373>

<http://www.ncbi.nlm.nih.gov/pubmed/30898607>

<http://www.ncbi.nlm.nih.gov/pubmed/31707829>

<http://www.ncbi.nlm.nih.gov/pubmed/30415628>

<http://www.ncbi.nlm.nih.gov/pubmed/34620410>

<http://www.ncbi.nlm.nih.gov/pubmed/34706555>

<http://www.ncbi.nlm.nih.gov/pubmed/34710343>

<http://www.ncbi.nlm.nih.gov/pubmed/35027114>

<http://www.ncbi.nlm.nih.gov/pubmed/33010162>

<http://www.ncbi.nlm.nih.gov/pubmed/33148016>

<http://www.ncbi.nlm.nih.gov/pubmed/31439224>