

**Clinical trial results:****A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When Evolocumab (AMG 145) is Used in Combination With Statin Therapy In Patients with Clinically Evident Cardiovascular Disease****Summary**

EudraCT number	2012-001398-97
Trial protocol	FI SK PL GR LT BE IT NL DK AT HU PT ES CZ EE IS GB DE BG
Global end of trial date	SE LV IE NO 11 November 2016

Results information

Result version number	v2 (current)
This version publication date	19 January 2018
First version publication date	26 November 2017

Version creation reason

Trial information**Trial identification**

Sponsor protocol code	20110118
-----------------------	----------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01764633
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Amgen Inc.
Sponsor organisation address	One Amgen Center Drive, Thousand Oaks, CA, United States, 91320
Public contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com
Scientific contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.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	18 January 2017
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	11 November 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to evaluate the effect of treatment with evolocumab, compared with placebo, on the risk for cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization, whichever occurs first, in patients with clinically evident cardiovascular disease.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) regulations/guidelines.

All subjects provided written informed consent before undergoing any study-related procedures, including screening procedures.

The study and all amendments were reviewed by an independent ethics committees (IEC) or institutional review board (IRB) at each center.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 February 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 325
Country: Number of subjects enrolled	China: 1021
Country: Number of subjects enrolled	Hong Kong: 46
Country: Number of subjects enrolled	India: 266
Country: Number of subjects enrolled	Japan: 429
Country: Number of subjects enrolled	Korea, Republic of: 181
Country: Number of subjects enrolled	Malaysia: 65
Country: Number of subjects enrolled	New Zealand: 92
Country: Number of subjects enrolled	Philippines: 294
Country: Number of subjects enrolled	Singapore: 35
Country: Number of subjects enrolled	South Africa: 937
Country: Number of subjects enrolled	Taiwan: 144
Country: Number of subjects enrolled	Austria: 173
Country: Number of subjects enrolled	Belgium: 245
Country: Number of subjects enrolled	Bulgaria: 292
Country: Number of subjects enrolled	Czech Republic: 2221
Country: Number of subjects enrolled	Denmark: 481

Country: Number of subjects enrolled	Estonia: 164
Country: Number of subjects enrolled	Finland: 242
Country: Number of subjects enrolled	France: 354
Country: Number of subjects enrolled	Germany: 738
Country: Number of subjects enrolled	Greece: 271
Country: Number of subjects enrolled	Hungary: 980
Country: Number of subjects enrolled	Iceland: 90
Country: Number of subjects enrolled	Ireland: 55
Country: Number of subjects enrolled	Israel: 239
Country: Number of subjects enrolled	Italy: 393
Country: Number of subjects enrolled	Latvia: 144
Country: Number of subjects enrolled	Lithuania: 131
Country: Number of subjects enrolled	Netherlands: 998
Country: Number of subjects enrolled	Norway: 111
Country: Number of subjects enrolled	Poland: 2467
Country: Number of subjects enrolled	Portugal: 273
Country: Number of subjects enrolled	Romania: 193
Country: Number of subjects enrolled	Russian Federation: 1565
Country: Number of subjects enrolled	Slovakia: 638
Country: Number of subjects enrolled	Spain: 362
Country: Number of subjects enrolled	Sweden: 474
Country: Number of subjects enrolled	Switzerland: 175
Country: Number of subjects enrolled	Turkey: 189
Country: Number of subjects enrolled	Ukraine: 1186
Country: Number of subjects enrolled	United Kingdom: 1491
Country: Number of subjects enrolled	Argentina: 269
Country: Number of subjects enrolled	Brazil: 693
Country: Number of subjects enrolled	Chile: 196
Country: Number of subjects enrolled	Colombia: 377
Country: Number of subjects enrolled	Mexico: 288
Country: Number of subjects enrolled	Canada: 558
Country: Number of subjects enrolled	United States: 4013
Worldwide total number of subjects	27564
EEA total number of subjects	13981

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)	15310
From 65 to 84 years	12225
85 years and over	29

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at 1242 clinical centers in 49 countries in the regions of Europe (62.9%), North America (16.6%), Asia Pacific (13.9%), and Latin America (6.6%) from 08 February 2013 to 05 June 2015.

Pre-assignment

Screening details:

Eligible participants were randomized in a 1:1 ratio to receive either subcutaneous (SC) evolocumab or placebo. Randomization was stratified by the final screening low-density lipoprotein cholesterol (LDL-C) level (< 85 mg/dL vs ≥ 85 mg/dL) and by geographical region.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received placebo subcutaneous injections either once every 2 weeks (Q2W) or once a month (QM) according to their own preference.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered subcutaneously using a spring-based prefilled 1.0 mL autoinjector/pen.

Arm title	Evolocumab
------------------	------------

Arm description:

Participants received evolocumab subcutaneous injections either 140 mg Q2W or 420 mg QM according to their own preference.

Arm type	Experimental
Investigational medicinal product name	Evolocumab
Investigational medicinal product code	AMG 145
Other name	Repatha
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered subcutaneously at 140 mg Q2W or 420 mg QM using a spring-based prefilled 1.0 mL autoinjector/pen.

Number of subjects in period 1	Placebo	Evolocumab
Started	13780	13784
Received Treatment	13756	13769
Completed	13662	13691
Not completed	118	93
Consent withdrawn by subject	105	88
Lost to follow-up	13	5

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: Participants received placebo subcutaneous injections either once every 2 weeks (Q2W) or once a month (QM) according to their own preference.	
Reporting group title	Evolocumab
Reporting group description: Participants received evolocumab subcutaneous injections either 140 mg Q2W or 420 mg QM according to their own preference.	

Reporting group values	Placebo	Evolocumab	Total
Number of subjects	13780	13784	27564
Age, Customized			
Units: Subjects			
< 65 years	7687	7623	15310
≥ 65 years	6093	6161	12254
Age Continuous			
Units: years			
arithmetic mean	62.5	62.5	
standard deviation	± 8.9	± 9.1	-
Sex: Female, Male			
Units: Subjects			
Female	3382	3387	6769
Male	10398	10397	20795
Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaska Native	80	60	140
Asian	1349	1374	2723
Black or African American	352	317	669
Native Hawaiian or Other Pacific Islander	11	15	26
White	11710	11748	23458
Multiple	12	19	31
Other	266	251	517
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1084	1093	2177
Not Hispanic or Latino	12694	12688	25382
Unknown or Not Reported	2	3	5
Final Screening Low-density Lipoprotein Cholesterol			
Units: Subjects			
< 85 mg/dL	4803	4809	9612
≥ 85 mg/dL	8977	8975	17952
Geographical Region			
Units: Subjects			
Europe	8669	8667	17336
North America	2284	2286	4570

Latin America	910	913	1823
Asia Pacific	1917	1918	3835

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received placebo subcutaneous injections either once every 2 weeks (Q2W) or once a month (QM) according to their own preference.	
Reporting group title	Evolocumab
Reporting group description:	
Participants received evolocumab subcutaneous injections either 140 mg Q2W or 420 mg QM according to their own preference.	

Primary: Time to Cardiovascular Death, Myocardial Infarction, Hospitalization for Unstable Angina, Stroke, or Coronary Revascularization

End point title	Time to Cardiovascular Death, Myocardial Infarction, Hospitalization for Unstable Angina, Stroke, or Coronary Revascularization
End point description:	
All deaths and potential endpoint events were adjudicated by an independent external Clinical Events Committee (CEC) led by the Thrombolysis in Myocardial Infarction (TIMI) Study Group, using standardized definitions based on the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials and the Third Universal Definition of Myocardial Infarction". Time to cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization was defined as the time from randomization to the first occurrence of any component of the composite endpoint and was analyzed using Kaplan-Meier (KM) survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on last non-fatal potential endpoint collection date.	
End point type	Primary
End point timeframe:	
Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.	

End point values	Placebo	Evolocumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13780 ^[1]	13784 ^[2]		
Units: percentage of participants				
number (confidence interval 95%)				
KM estimate at 6 months (N = 13276, 13349)	3.11 (2.82 to 3.40)	2.74 (2.47 to 3.01)		
KM estimate at 12 months (N = 12822, 12937)	6.01 (5.61 to 6.41)	5.31 (4.93 to 5.68)		
KM estimate at 18 months (N = 11837, 12034)	8.32 (7.86 to 8.78)	7.25 (6.81 to 7.68)		
KM estimate at 24 months (N = 7589, 7743)	10.66 (10.12 to 11.19)	9.13 (8.63 to 9.63)		
KM estimate at 30 months (N = 3589, 3652)	12.72 (12.08 to 13.35)	10.91 (10.31 to 11.50)		
KM estimate at 36 months (N = 672, 681)	14.64 (13.76 to 15.50)	12.57 (11.70 to 13.42)		

Notes:

[1] - N = the number of subjects at risk

[2] - N = the number of subjects at risk

Statistical analyses

Statistical analysis title	Primary Analysis
-----------------------------------	------------------

Statistical analysis description:

The primary endpoint was compared between treatment groups at a significance level of 0.05. The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

Comparison groups	Placebo v Evolocumab
Number of subjects included in analysis	27564
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 ^[3]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	0.92

Notes:

[3] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to Cardiovascular Death, Myocardial Infarction, or Stroke

End point title	Time to Cardiovascular Death, Myocardial Infarction, or Stroke
-----------------	--

End point description:

All deaths and potential endpoint events were adjudicated by an independent external CEC led by the TIMI Study Group, using standardized definitions based on the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials and the Third Universal Definition of Myocardial Infarction". Time to cardiovascular death, myocardial infarction, or stroke was defined as the time from randomization to the first occurrence of any component of the composite endpoint and was analyzed using Kaplan-Meier (KM) survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on last non-fatal potential endpoint collection date.

End point type	Secondary
----------------	-----------

End point timeframe:

Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.

End point values	Placebo	Evolocumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13780 ^[4]	13784 ^[5]		
Units: percentage of participants				
number (confidence interval 95%)				
KM estimate at 6 months (N = 13447, 13499)	1.86 (1.63 to 2.08)	1.65 (1.44 to 1.86)		
KM estimate at 12 months (N = 13140, 13240)	3.68 (3.36 to 3.99)	3.10 (2.81 to 3.38)		
KM estimate at 18 months (N = 12257, 12422)	5.18 (4.81 to 5.55)	4.29 (3.95 to 4.62)		
KM estimate at 24 months (N = 7923, 8066)	6.83 (6.39 to 7.26)	5.47 (5.08 to 5.86)		
KM estimate at 30 months (N = 3785, 3837)	8.31 (7.78 to 8.84)	6.66 (6.19 to 7.14)		
KM estimate at 36 months (N = 717, 713)	9.93 (9.16 to 10.69)	7.90 (7.17 to 8.63)		

Notes:

[4] - N = the number of subjects at risk

[5] - N = the number of subjects at risk

Statistical analyses

Statistical analysis title	Primary Analysis
-----------------------------------	------------------

Statistical analysis description:

If the primary endpoint reached statistical significance at the 0.05 level, the key secondary endpoint (composite of cardiovascular death, myocardial infarction, and stroke) was tested at a significance level of 0.05.

The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

Comparison groups	Placebo v Evolocumab
Number of subjects included in analysis	27564
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 ^[6]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.88

Notes:

[6] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to Cardiovascular Death

End point title	Time to Cardiovascular Death
------------------------	------------------------------

End point description:

All deaths and potential endpoint events were adjudicated by an independent external CEC led by the TIMI Study Group, using standardized definitions based on the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials and the Third Universal Definition of Myocardial Infarction". Cardiovascular death includes death resulting from an acute myocardial infarction (MI), sudden cardiac death, death due to heart failure (HF), death due to stroke, death due to cardiovascular (CV) procedures, death due to CV hemorrhage, and death due to other CV causes. Time to cardiovascular death was defined as the time from randomization to the date of cardiovascular death

and was analyzed using Kaplan-Meier (KM) survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on the last confirmed survival status date.

End point type	Secondary
End point timeframe:	
Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.	

End point values	Placebo	Evolocumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13780 ^[7]	13784 ^[8]		
Units: percentage of participants				
number (confidence interval 95%)				
KM estimate at 6 months (N = 13688, 13698)	0.40 (0.29 to 0.50)	0.39 (0.29 to 0.50)		
KM estimate at 12 months (N = 13590, 13598)	0.82 (0.67 to 0.97)	0.79 (0.64 to 0.94)		
KM estimate at 18 months (N = 12844, 12869)	1.19 (1.01 to 1.37)	1.20 (1.01 to 1.38)		
KM estimate at 24 months (N = 8427, 8441)	1.57 (1.36 to 1.79)	1.64 (1.42 to 1.85)		
KM estimate at 30 months (N = 4081, 4043)	1.99 (1.72 to 2.26)	2.11 (1.83 to 2.39)		
KM estimate at 36 months (N = 783, 767)	2.39 (1.98 to 2.80)	2.49 (2.09 to 2.88)		

Notes:

[7] - N = the number of subjects at risk

[8] - N = the number of subjects at risk

Statistical analyses

Statistical analysis title	Primary Analysis
Statistical analysis description:	
If the primary and key secondary endpoint reached a statistical significance level of 0.05, then the endpoint of cardiovascular death was tested at a significance level of 0.05.	
The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).	
Comparison groups	Placebo v Evolocumab
Number of subjects included in analysis	27564
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6188 ^[9]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.25

Notes:

[9] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to All Cause Death

End point title	Time to All Cause Death
-----------------	-------------------------

End point description:

Time to all-cause death was defined as the time from randomization to the date of death and was analyzed using Kaplan-Meier (KM) survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on the last confirmed survival status date.

End point type	Secondary
----------------	-----------

End point timeframe:

Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.

End point values	Placebo	Evolocumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13780 ^[10]	13784 ^[11]		
Units: percentage of participants				
number (confidence interval 95%)				
KM estimate at 6 months (N = 13688, 13698)	0.62 (0.49 to 0.75)	0.55 (0.43 to 0.68)		
KM estimate at 12 months (N = 13590, 13598)	1.29 (1.10 to 1.47)	1.26 (1.07 to 1.44)		
KM estimate at 18 months (N = 12844, 12869)	1.96 (1.73 to 2.19)	1.94 (1.71 to 2.17)		
KM estimate at 24 months (N = 8427, 8441)	2.78 (2.49 to 3.06)	2.81 (2.52 to 3.10)		
KM estimate at 30 months (N = 4081, 4043)	3.48 (3.12 to 3.83)	3.63 (3.27 to 3.98)		
KM estimate at 36 months (N = 783, 767)	4.28 (3.74 to 4.82)	4.75 (4.16 to 5.34)		

Notes:

[10] - N = the number of subjects at risk

[11] - N = the number of subjects at risk

Statistical analyses

Statistical analysis title	Primary Analysis
----------------------------	------------------

Statistical analysis description:

If the primary, key secondary and endpoint cardiovascular death reached a statistical significance level of 0.05, then the endpoint of all-cause death was tested at a significance level of 0.04 and remaining secondary endpoints at an overall significant level of 0.01 by applying the Hochberg method.

The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

Comparison groups	Placebo v Evolocumab
-------------------	----------------------

Number of subjects included in analysis	27564
---	-------

Analysis specification	Pre-specified
------------------------	---------------

Analysis type	superiority
---------------	-------------

P-value	= 0.5368 ^[12]
---------	--------------------------

Method	Logrank
--------	---------

Parameter estimate	Hazard ratio (HR)
--------------------	-------------------

Point estimate	1.04
----------------	------

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.19

Notes:

[12] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to First Myocardial Infarction

End point title	Time to First Myocardial Infarction
-----------------	-------------------------------------

End point description:

All deaths and potential endpoint events were adjudicated by an independent external CEC led by the TIMI Study Group, using standardized definitions based on the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials and the Third Universal Definition of Myocardial Infarction". The diagnosis of myocardial infarction required the combination of:

- Evidence of myocardial necrosis (either changes in cardiac biomarkers or post-mortem pathological findings); and
- Supporting information derived from the clinical presentation, electrocardiographic changes, or the results of myocardial or coronary artery Imaging.

Time to first myocardial infarction was defined as the time from randomization to the date of the first MI and was analyzed using Kaplan-Meier survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on last non-fatal potential endpoint collection date.

End point type	Secondary
----------------	-----------

End point timeframe:

Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.

End point values	Placebo	Evolocumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13780 ^[13]	13784 ^[14]		
Units: percentage of participants				
number (confidence interval 95%)				
KM estimate at 6 months (N = 13497, 13536)	1.14 (0.97 to 1.32)	1.06 (0.88 to 1.23)		
KM estimate at 12 months (N = 13226, 13312)	2.39 (2.13 to 2.64)	1.90 (1.67 to 2.13)		
KM estimate at 18 months (N = 12374, 12522)	3.33 (3.03 to 3.63)	2.55 (2.28 to 2.81)		
KM estimate at 24 months (N = 8031, 8137)	4.30 (3.95 to 4.65)	3.21 (2.90 to 3.51)		
KM estimate at 30 months (N = 3839, 3883)	5.25 (4.82 to 5.67)	3.83 (3.47 to 4.19)		
KM estimate at 36 months (N = 733, 726)	6.28 (5.67 to 6.89)	4.41 (3.85 to 4.96)		

Notes:

[13] - N = the number of subjects at risk

[14] - N = the number of subjects at risk

Statistical analyses

Statistical analysis title	Primary Analysis
----------------------------	------------------

Statistical analysis description:

If the primary, key secondary, and endpoint of cardiovascular death reached a statistical significance

level of 0.05, then the endpoint of all-cause death was tested at a significance level of 0.04 and remaining secondary endpoints were tested at an overall significance level of 0.01 by applying the Hochberg method.

The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

Comparison groups	Placebo v Evolocumab
Number of subjects included in analysis	27564
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [15]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.82

Notes:

[15] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to First Stroke

End point title	Time to First Stroke
-----------------	----------------------

End point description:

All deaths and potential endpoint events were adjudicated by an independent external CEC led by the TIMI Study Group, using standardized definitions based on the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials and the Third Universal Definition of Myocardial Infarction". Stroke was defined as an acute episode of focal or global neurological dysfunction caused by brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction. Time to first stroke was defined as the time from randomization to the date of the stroke and was analyzed using Kaplan-Meier (KM) survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on last non-fatal potential endpoint collection date.

End point type	Secondary
----------------	-----------

End point timeframe:

Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.

End point values	Placebo	Evolocumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13780 ^[16]	13784 ^[17]		
Units: percentage of participants				
number (confidence interval 95%)				
KM estimate at 6 months (N = 13587, 13631)	0.50 (0.38 to 0.61)	0.31 (0.22 to 0.41)		
KM estimate at 12 months (N = 13428, 13470)	0.85 (0.69 to 1.00)	0.70 (0.56 to 0.84)		
KM estimate at 18 months (N = 12626, 12703)	1.30 (1.11 to 1.50)	1.05 (0.88 to 1.22)		
KM estimate at 24 months (N = 8240, 8304)	1.80 (1.57 to 2.04)	1.36 (1.16 to 1.56)		
KM estimate at 30 months (N = 3977, 3967)	2.15 (1.88 to 2.43)	1.71 (1.46 to 1.96)		

KM estimate at 36 months (N = 757, 741)	2.60 (2.20 to 3.00)	2.18 (1.76 to 2.59)		
---	---------------------	---------------------	--	--

Notes:

[16] - N = the number of subjects at risk

[17] - N = the number of subjects at risk

Statistical analyses

Statistical analysis title	Primary Analysis
-----------------------------------	------------------

Statistical analysis description:

If the primary, key secondary, and endpoint of cardiovascular death reached a statistical significance level of 0.05, then the endpoint of all-cause death was tested at a significance level of 0.04 and remaining secondary endpoints were tested at an overall significance level of 0.01 by applying the Hochberg method.

The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

Comparison groups	Placebo v Evolocumab
Number of subjects included in analysis	27564
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0101 ^[18]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	0.95

Notes:

[18] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to First Coronary Revascularization

End point title	Time to First Coronary Revascularization
-----------------	--

End point description:

All deaths and potential endpoint events were adjudicated by an independent external CEC led by the TIMI Study Group, using standardized definitions based on the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials and the Third Universal Definition of Myocardial Infarction". Time to first coronary revascularization was defined as the time from randomization to the date of the coronary revascularization and was analyzed using Kaplan-Meier (KM) survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on last non-fatal potential endpoint collection date.

End point type	Secondary
----------------	-----------

End point timeframe:

Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.

End point values	Placebo	Evolocumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13780 ^[19]	13784 ^[20]		
Units: percentage of participants				
number (confidence interval 95%)				
KM estimate at 6 months (N = 13390, 13454)	1.87 (1.65 to 2.10)	1.60 (1.39 to 1.81)		
KM estimate at 12 months (N = 13029, 13130)	3.71 (3.39 to 4.02)	3.13 (2.84 to 3.42)		
KM estimate at 18 months (N = 12097, 12283)	5.20 (4.82 to 5.57)	4.16 (3.83 to 4.50)		
KM estimate at 24 months (N = 7812, 7952)	6.57 (6.14 to 7.00)	5.22 (4.84 to 5.61)		
KM estimate at 30 months (N = 3718, 3768)	7.91 (7.39 to 8.42)	6.13 (5.68 to 6.58)		
KM estimate at 36 months (N = 704, 710)	9.17 (8.46 to 9.87)	7.01 (6.36 to 7.65)		

Notes:

[19] - N = the number of subjects at risk

[20] - N = the number of subjects at risk

Statistical analyses

Statistical analysis title	Primary Analysis
-----------------------------------	------------------

Statistical analysis description:

If the primary, key secondary, and endpoint of cardiovascular death reached a statistical significance level of 0.05, then the endpoint of all-cause death was tested at a significance level of 0.04 and remaining secondary endpoints were tested at an overall significance level of 0.01 by applying the Hochberg method.

The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

Comparison groups	Placebo v Evolocumab
Number of subjects included in analysis	27564
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 ^[21]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	0.86

Notes:

[21] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to Cardiovascular Death or First Hospitalization for Worsening Heart Failure

End point title	Time to Cardiovascular Death or First Hospitalization for Worsening Heart Failure
-----------------	---

End point description:

All events were adjudicated by an independent external CEC led by the TIMI Study Group using standardized definitions. HF hospitalization was defined as an event that met all of the following criteria:

1. Admitted to hospital with a primary diagnosis of HF
2. In hospital for at least 24 hours

3. Documented new or worsening symptoms due to HF, including at least 1 of the following:
- Dyspnea
 - Decreased exercise tolerance
 - Fatigue
 - Other symptoms of worsened end-organ perfusion or volume overload
4. Evidence of new or worsening HF consisting of at least 2 physical exam findings or 1 physical exam finding and at least 1 laboratory criterion
5. Received new or increased treatment for HF.
- Time to CV death or first hospitalization for worsening HF was defined as the time from randomization to the first occurrence of any component of the endpoint analyzed using KM analysis. Participants with no event were censored based on last non-fatal potential endpoint collection date.

End point type	Secondary
----------------	-----------

End point timeframe:

Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.

End point values	Placebo	Evolocumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13780 ^[22]	13784 ^[23]		
Units: percentage of participants				
number (confidence interval 95%)				
KM estimate at 6 months (N = 13592, 13635)	0.79 (0.64 to 0.93)	0.64 (0.51 to 0.77)		
KM estimate at 12 months (N = 13455, 13481)	1.35 (1.16 to 1.54)	1.29 (1.10 to 1.48)		
KM estimate at 18 months (N = 12664, 12710)	1.99 (1.75 to 2.22)	1.99 (1.76 to 2.22)		
KM estimate at 24 months (N = 8265, 8304)	2.70 (2.41 to 2.98)	2.64 (2.36 to 2.92)		
KM estimate at 30 months (N = 3983, 3967)	3.45 (3.09 to 3.81)	3.31 (2.97 to 3.65)		
KM estimate at 36 months (N = 761, 737)	4.03 (3.50 to 4.55)	4.13 (3.57 to 4.68)		

Notes:

[22] - N = the number of subjects at risk

[23] - N = the number of subjects at risk

Statistical analyses

Statistical analysis title	Primary Analysis
----------------------------	------------------

Statistical analysis description:

If the primary, key secondary, and endpoint of cardiovascular death reached a statistical significance level of 0.05, then the endpoint of all-cause death was tested at a significance level of 0.04 and remaining secondary endpoints were tested at an overall significance level of 0.01 by applying the Hochberg method.

The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

Comparison groups	Placebo v Evolocumab
Number of subjects included in analysis	27564
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8179 ^[24]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.98

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.13

Notes:

[24] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to First Ischemic Fatal or non-Fatal Stroke or Transient Ischemic Attack

End point title	Time to First Ischemic Fatal or non-Fatal Stroke or Transient Ischemic Attack
-----------------	---

End point description:

All deaths and potential endpoint events were adjudicated by an independent external CEC led by the TIMI Study Group, using standardized definitions. Ischemic stroke was defined as an acute episode of focal cerebral, spinal, or retinal dysfunction caused by infarction of central nervous system tissue. Transient ischemic attack (TIA) was defined as a transient episode of focal neurological dysfunction caused by brain, spinal cord, or retinal ischemia, without acute infarction. Time to first ischemic fatal or non-fatal stroke or TIA was defined as the time from randomization to the first occurrence of any component of the endpoint and was analyzed using KM survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on last non-fatal potential endpoint collection date.

End point type	Secondary
----------------	-----------

End point timeframe:

Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.

End point values	Placebo	Evolocumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13780 ^[25]	13784 ^[26]		
Units: percentage of participants				
number (confidence interval 95%)				
KM estimate at 6 months (N = 13569, 13614)	0.61 (0.48 to 0.73)	0.42 (0.31 to 0.53)		
KM estimate at 12 months (N = 13394, 13445)	1.05 (0.88 to 1.22)	0.83 (0.67 to 0.98)		
KM estimate at 18 months (N = 12588, 12671)	1.52 (1.32 to 1.73)	1.18 (1.00 to 1.37)		
KM estimate at 24 months (N = 8209, 8279)	2.05 (1.81 to 2.30)	1.46 (1.25 to 1.66)		
KM estimate at 30 months (N = 3958, 3954)	2.40 (2.11 to 2.68)	1.92 (1.65 to 2.19)		
KM estimate at 36 months (N = 756, 738)	2.81 (2.41 to 3.21)	2.48 (2.01 to 2.95)		

Notes:

[25] - N = the number of subjects at risk

[26] - N = the number of subjects at risk

Statistical analyses

Statistical analysis title	Primary Analysis
----------------------------	------------------

Statistical analysis description:

If the primary, key secondary, and endpoint of cardiovascular death reached a statistical significance level of 0.05, then the endpoint of all-cause death was tested at a significance level of 0.04 and

remaining secondary endpoints were tested at an overall significance level of 0.01 by applying the Hochberg method.

The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

Comparison groups	Placebo v Evolocumab
Number of subjects included in analysis	27564
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0035 ^[27]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.92

Notes:

[27] - Two-sided log-rank test stratified by randomization stratification factors.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the first dose of study drug to the end of study. The median duration of follow-up was 26 months.

Adverse event reporting additional description:

Deaths by any cause were adjudicated efficacy endpoints in this study and were summarized as a secondary endpoint. Events that were negatively adjudicated (did not meet the definitions of an endpoint), were reclassified as an adverse event or serious adverse event.

Assessment type	Systematic
-----------------	------------

Dictionary used

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

Dictionary version	19.1
--------------------	------

Reporting groups

Reporting group title	Evolocumab
-----------------------	------------

Reporting group description:

Participants received evolocumab subcutaneous injections either 140 mg Q2W or 420 mg QM according to their own preference.

Reporting group title	Placebo
-----------------------	---------

Reporting group description:

Participants received placebo subcutaneous injections either once every 2 weeks (Q2W) or once a month (QM) according to their own preference.

Serious adverse events	Evolocumab	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	3410 / 13769 (24.77%)	3404 / 13756 (24.75%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma gastric			

subjects affected / exposed	4 / 13769 (0.03%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of appendix		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	17 / 13769 (0.12%)	12 / 13756 (0.09%)
occurrences causally related to treatment / all	0 / 17	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma pancreas		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal adenoma		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal gland cancer		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal neoplasm		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal cancer stage III		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal neoplasm		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anogenital warts		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma stage I		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell prolymphocytic leukaemia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	4 / 13769 (0.03%)	11 / 13756 (0.08%)
occurrences causally related to treatment / all	1 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Basosquamous carcinoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign gastric neoplasm		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign gastrointestinal neoplasm		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign lung neoplasm		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of adrenal gland		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of prostate		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of spinal cord		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign pancreatic neoplasm		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct cancer		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign renal neoplasm		

subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary adenoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder adenocarcinoma stage III		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	12 / 13769 (0.09%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 12	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder adenocarcinoma stage unspecified		
subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer recurrent		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage 0, with cancer in situ		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage I, with cancer in situ		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		

subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage III		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder papilloma		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	9 / 13769 (0.07%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma recurrent		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma stage I		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma stage II		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma stage III		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

Bladder transitional cell carcinoma stage IV		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bowen's disease		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain cancer metastatic		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm malignant		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer		
subjects affected / exposed	6 / 13769 (0.04%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 6	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer female		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer in situ		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer recurrent		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial carcinoma		

subjects affected / exposed	4 / 13769 (0.03%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial neoplasm		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burkitt's lymphoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carcinoid tumour pulmonary		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholesteatoma		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Choroid melanoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		

subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	4 / 13769 (0.03%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	11 / 13769 (0.08%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 12	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer metastatic		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer stage I		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer stage III		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon neoplasm		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal adenocarcinoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer metastatic		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatofibrosarcoma protuberans		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ductal adenocarcinoma of pancreas		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial adenocarcinoma		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial adenoma		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fallopian tube cancer		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibroma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Follicular thyroid cancer		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder neoplasm		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric adenoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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	5 / 13769 (0.04%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer stage 0		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer stage IV		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal carcinoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal neoplasm		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal tumour		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma		
subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma multiforme		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemangiopericytoma		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic neoplasm		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular carcinoma		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hodgkin's disease		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal papillary mucinous neoplasm		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal proliferative breast lesion		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal papillary-mucinous carcinoma of pancreas		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive breast carcinoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	2 / 13769 (0.01%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		

subjects affected / exposed	6 / 13769 (0.04%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Large cell lung cancer stage III		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer metastatic		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer stage 0		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer stage IV		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal squamous cell carcinoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lip and/or oral cavity cancer stage III		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lip squamous cell carcinoma		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liposarcoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	13 / 13769 (0.09%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 14	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma metastatic		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma stage I		
subjects affected / exposed	4 / 13769 (0.03%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma stage III		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma stage IV		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic		

subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage I		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage II		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage III		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage IV		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm		
subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	1 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm malignant		
subjects affected / exposed	19 / 13769 (0.14%)	15 / 13756 (0.11%)
occurrences causally related to treatment / all	0 / 21	1 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Lung squamous cell carcinoma metastatic		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

Lung squamous cell carcinoma stage I		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung squamous cell carcinoma stage III		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoproliferative disorder		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant anorectal neoplasm		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant ascites		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	5 / 13769 (0.04%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma in situ		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma of sites other		

than skin			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant mesenteric neoplasm			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of pleura			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of renal pelvis			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant peritoneal neoplasm			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant urinary tract neoplasm			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma benign			
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma			

subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mesothelioma malignant		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to adrenals		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	4 / 13769 (0.03%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to central nervous system		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to liver		
subjects affected / exposed	4 / 13769 (0.03%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lung		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lymph nodes		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to pleura		

subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to spine		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastasis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic bronchial carcinoma		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic malignant melanoma		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic squamous cell carcinoma		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
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 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelofibrosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm malignant		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm progression		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm prostate		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine tumour		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma metastatic		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-Hodgkin's lymphoma		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		

subjects affected / exposed	3 / 13769 (0.02%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer metastatic		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma metastatic		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal squamous cell carcinoma		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Oral cavity cancer metastatic		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oral neoplasm		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oral papilloma		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal cancer		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal squamous cell carcinoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian adenoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer stage II		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	5 / 13769 (0.04%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	1 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma metastatic		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary cystadenoma lymphomatosum		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary thyroid cancer		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid tumour benign		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Penile cancer		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pheochromocytoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal cancer		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal cancer stage IV		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal neoplasm benign		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	4 / 13769 (0.03%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Plasmacytoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural mesothelioma malignant		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polycythaemia vera		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer		
subjects affected / exposed	41 / 13769 (0.30%)	40 / 13756 (0.29%)
occurrences causally related to treatment / all	3 / 42	0 / 42
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	4 / 13769 (0.03%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 6	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage I		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage II		

subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage IV		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		
subjects affected / exposed	6 / 13769 (0.04%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	2 / 13769 (0.01%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 2	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer stage III		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer stage IV		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal adenoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		

subjects affected / exposed	9 / 13769 (0.07%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 11	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer metastatic		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer stage I		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma		
subjects affected / exposed	4 / 13769 (0.03%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma stage I		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma stage II		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma stage III		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal oncocytoma		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal neoplasm		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland adenoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sarcoma metastatic		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sarcoma		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Schwannoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	5 / 13769 (0.04%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer limited stage		

subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
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	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestine carcinoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue sarcoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spindle cell sarcoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		
subjects affected / exposed	0 / 13769 (0.00%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of head and neck		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of skin		

subjects affected / exposed	5 / 13769 (0.04%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity		
subjects affected / exposed	0 / 13769 (0.00%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the tongue		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the vulva		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue neoplasm malignant stage unspecified		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.01%)	0 / 13756 (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	3 / 13769 (0.02%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour haemorrhage			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Undifferentiated sarcoma			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteral neoplasm			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
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 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord neoplasm			
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer recurrent			

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm			
subjects affected / exposed	0 / 13769 (0.00%)	4 / 13756 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiopathy			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiosclerosis			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	27 / 13769 (0.20%)	27 / 13756 (0.20%)	
occurrences causally related to treatment / all	0 / 28	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic occlusion			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			

subjects affected / exposed	7 / 13769 (0.05%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 7	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic thrombosis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial occlusive disease		
subjects affected / exposed	1 / 13769 (0.01%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial thrombosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis		
subjects affected / exposed	2 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure fluctuation		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	5 / 13769 (0.04%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Cryoglobulinaemia		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Deep vein thrombosis		
subjects affected / exposed	7 / 13769 (0.05%)	14 / 13756 (0.10%)
occurrences causally related to treatment / all	0 / 7	1 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic vascular disorder		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dry gangrene		
subjects affected / exposed	4 / 13769 (0.03%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism arterial		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism venous		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		
subjects affected / exposed	2 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Granulomatosis with polyangiitis		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	2 / 13769 (0.01%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	56 / 13769 (0.41%)	41 / 13756 (0.30%)
occurrences causally related to treatment / all	2 / 59	1 / 41
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	15 / 13769 (0.11%)	12 / 13756 (0.09%)
occurrences causally related to treatment / all	0 / 15	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	9 / 13769 (0.07%)	13 / 13756 (0.09%)
occurrences causally related to treatment / all	1 / 12	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery occlusion		

subjects affected / exposed	5 / 13769 (0.04%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	31 / 13769 (0.23%)	22 / 13756 (0.16%)
occurrences causally related to treatment / all	0 / 41	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Internal haemorrhage		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leriche syndrome		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphocele		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neurogenic shock		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		

subjects affected / exposed	9 / 13769 (0.07%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic venous thrombosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	94 / 13769 (0.68%)	82 / 13756 (0.60%)
occurrences causally related to treatment / all	1 / 113	0 / 96
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	5 / 13769 (0.04%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery dissection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	20 / 13769 (0.15%)	16 / 13756 (0.12%)
occurrences causally related to treatment / all	0 / 21	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	27 / 13769 (0.20%)	33 / 13756 (0.24%)
occurrences causally related to treatment / all	0 / 30	0 / 37
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	5 / 13769 (0.04%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 5	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral circulatory failure		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	35 / 13769 (0.25%)	39 / 13756 (0.28%)
occurrences causally related to treatment / all	0 / 41	0 / 47
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	16 / 13769 (0.12%)	9 / 13756 (0.07%)
occurrences causally related to treatment / all	0 / 21	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral venous disease		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Poor peripheral circulation		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renovascular hypertension		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		

subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery embolism		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery occlusion		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery stenosis		
subjects affected / exposed	4 / 13769 (0.03%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian steal syndrome		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Superior vena cava syndrome		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Takayasu's arteritis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Temporal arteritis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thromboangiitis obliterans		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose ulceration		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose vein		
subjects affected / exposed	3 / 13769 (0.02%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular insufficiency		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular occlusion		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular stenosis		

subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasodilatation			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vena cava thrombosis			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Abscess drainage			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve replacement			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia prophylaxis			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial catheterisation			

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula operation		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Asthma prophylaxis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac ablation		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac pacemaker insertion		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac rehabilitation therapy		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac resynchronisation therapy		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary arterial stent insertion		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery bypass		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary revascularisation		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Elective procedure		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterostomy		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Finger amputation		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture treatment		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric banding reversal		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemostasis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.01%)	0 / 13756 (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	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia repair		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia repair		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Knee arthroplasty		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (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	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine anastomosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leg amputation		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Open reduction of fracture		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Percutaneous coronary intervention		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery bypass		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Plastic surgery to the face		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Preoperative care		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proctectomy		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rehabilitation therapy		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal anaesthesia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stent placement		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Therapy cessation			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toe amputation			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transcatheter aortic valve implantation			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral prostatectomy			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia repair			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral operation			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	8 / 13769 (0.06%)	6 / 13756 (0.04%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breakthrough pain			

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Catheter site extravasation		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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	4 / 13769 (0.03%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 4	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Chest pain		
subjects affected / exposed	42 / 13769 (0.31%)	49 / 13756 (0.36%)
occurrences causally related to treatment / all	0 / 43	1 / 53
deaths causally related to treatment / all	0 / 0	0 / 0
Complication associated with device		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cyst rupture		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug intolerance		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug withdrawal syndrome		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Exercise tolerance decreased		

subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fat necrosis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fatigue		
subjects affected / exposed	2 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gait disturbance		
subjects affected / exposed	5 / 13769 (0.04%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
General physical health deterioration		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised oedema		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hernia		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired healing		
subjects affected / exposed	4 / 13769 (0.03%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site inflammation		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated hernia		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inflammation		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mass		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device discomfort		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mucosal inflammation		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple organ dysfunction syndrome		
subjects affected / exposed	4 / 13769 (0.03%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-cardiac chest pain		

subjects affected / exposed	109 / 13769 (0.79%)	133 / 13756 (0.97%)
occurrences causally related to treatment / all	1 / 125	0 / 152
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	4 / 13769 (0.03%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pacemaker generated arrhythmia		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral swelling		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	5 / 13769 (0.04%)	9 / 13756 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Sensation of foreign body		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue inflammation		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Strangulated hernia		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical failure			
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent restenosis			
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Allergy to arthropod sting			

subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anaphylactic reaction		
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Anaphylactic shock		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug hypersensitivity		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Food allergy		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypersensitivity		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mite allergy		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sarcoidosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transplant rejection		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Abstains from alcohol			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disability			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance abuser			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social stay hospitalisation			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Adnexa uteri mass			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	30 / 13769 (0.22%)	26 / 13756 (0.19%)	
occurrences causally related to treatment / all	0 / 30	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast dysplasia			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Breast enlargement			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast pain			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical polyp			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix disorder			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial thickening			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital haemorrhage			

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Male genital tract fistula		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Metrorrhagia		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cyst		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic pain		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postmenopausal haemorrhage		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Priapism		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatitis		

subjects affected / exposed	1 / 13769 (0.01%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatomegaly		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Reproductive tract disorder		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal cyst		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal oedema		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spermatic cord inflammation		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine atony		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine enlargement		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine haemorrhage		

subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval disorder			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvar dysplasia			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal pruritus			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acquired diaphragmatic eventration			

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute pulmonary oedema		
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Acute respiratory distress syndrome		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute respiratory failure		
subjects affected / exposed	11 / 13769 (0.08%)	13 / 13756 (0.09%)
occurrences causally related to treatment / all	0 / 13	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Apnoea		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	8 / 13769 (0.06%)	11 / 13756 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Asthma-chronic obstructive pulmonary disease overlap syndrome		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atelectasis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
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 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	2 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	64 / 13769 (0.46%)	64 / 13756 (0.47%)
occurrences causally related to treatment / all	0 / 71	1 / 80
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic respiratory failure		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Combined pulmonary fibrosis and emphysema		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cough		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diaphragmatic paralysis		

subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphonia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		
subjects affected / exposed	28 / 13769 (0.20%)	18 / 13756 (0.13%)
occurrences causally related to treatment / all	0 / 28	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea at rest		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea exertional		
subjects affected / exposed	6 / 13769 (0.04%)	11 / 13756 (0.08%)
occurrences causally related to treatment / all	0 / 7	1 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epiglottic cyst		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	10 / 13769 (0.07%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 11	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		

subjects affected / exposed	7 / 13769 (0.05%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 7	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Haemothorax		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hiccups		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperventilation		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic pulmonary fibrosis		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal oedema		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal cyst		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal obstruction		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	4 / 13769 (0.03%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum deviation		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal turbinate hypertrophy		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nocturnal dyspnoea		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal pain		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthopnoea		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal cyst		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pickwickian syndrome		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural adhesion		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	5 / 13769 (0.04%)	11 / 13756 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural disorder		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		
subjects affected / exposed	3 / 13769 (0.02%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuritic pain		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		

subjects affected / exposed	8 / 13769 (0.06%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonitis		
subjects affected / exposed	5 / 13769 (0.04%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	5 / 13769 (0.04%)	10 / 13756 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Productive cough		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary alveolar haemorrhage		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary arterial hypertension		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	20 / 13769 (0.15%)	28 / 13756 (0.20%)
occurrences causally related to treatment / all	0 / 20	1 / 29
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary fibrosis		

subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mass		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary pain		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory disorder		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory distress		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory failure		
subjects affected / exposed	16 / 13769 (0.12%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 17	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Sleep apnoea syndrome		

subjects affected / exposed	6 / 13769 (0.04%)	13 / 13756 (0.09%)	
occurrences causally related to treatment / all	0 / 6	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stridor			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord leukoplakia			
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Affective disorder			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	2 / 13769 (0.01%)	4 / 13756 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety		
subjects affected / exposed	4 / 13769 (0.03%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety disorder		
subjects affected / exposed	0 / 13769 (0.00%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety disorder due to a general medical condition		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Burnout syndrome		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Confusional state		
subjects affected / exposed	4 / 13769 (0.03%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Conversion disorder		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium tremens		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Depressed mood		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	15 / 13769 (0.11%)	20 / 13756 (0.15%)
occurrences causally related to treatment / all	1 / 16	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Depression suicidal		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug abuse		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug dependence		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination, visual		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		

subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mania		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mental disorder		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes		
subjects affected / exposed	6 / 13769 (0.04%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mood disorder due to a general medical condition		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neurosis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Panic attack		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psychiatric decompensation		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Personality disorder		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychogenic seizure			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somatic symptom disorder			
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	6 / 13769 (0.04%)	6 / 13756 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device battery issue			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device breakage			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			

subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Device failure		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Device ineffective		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device leakage		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device loosening		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device malfunction		
subjects affected / exposed	5 / 13769 (0.04%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Device occlusion		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lead dislodgement		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis in device		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ampulla of Vater stenosis			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune hepatitis			
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct obstruction			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	6 / 13769 (0.04%)	5 / 13756 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	4 / 13769 (0.03%)	5 / 13756 (0.04%)	
occurrences causally related to treatment / all	1 / 5	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary cyst			

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	5 / 13769 (0.04%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis acute		
subjects affected / exposed	0 / 13769 (0.00%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis		
subjects affected / exposed	14 / 13769 (0.10%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 14	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	40 / 13769 (0.29%)	31 / 13756 (0.23%)
occurrences causally related to treatment / all	1 / 40	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis chronic		
subjects affected / exposed	5 / 13769 (0.04%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 5	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystochoolangitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	27 / 13769 (0.20%)	23 / 13756 (0.17%)
occurrences causally related to treatment / all	0 / 28	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis migration		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis obstructive		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholestasis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cirrhosis alcoholic		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug-induced liver injury		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder perforation		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder polyp		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic failure		

subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cyst		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic fibrosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic function abnormal		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic pain		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic steatosis		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis acute		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis alcoholic		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis toxic		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatorenal syndrome		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatotoxicity		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertransaminasaemia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liver disorder		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Porcelain gallbladder		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Portal vein thrombosis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subacute hepatic failure		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	11 / 13769 (0.08%)	15 / 13756 (0.11%)	
occurrences causally related to treatment / all	6 / 11	11 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriogram coronary			
subjects affected / exposed	5 / 13769 (0.04%)	3 / 13756 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriogram coronary abnormal			
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriogram coronary normal			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 13769 (0.04%)	11 / 13756 (0.08%)	
occurrences causally related to treatment / all	1 / 6	7 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatine phosphokinase increased			

subjects affected / exposed	7 / 13769 (0.05%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	5 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Blood creatinine increased		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood glucose decreased		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood glucose fluctuation		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood glucose increased		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium increased		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac stress test abnormal		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction decreased		

subjects affected / exposed	4 / 13769 (0.03%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram QT prolonged		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram ST segment depression		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram abnormal		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exercise electrocardiogram abnormal		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
False positive investigation result		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoglobin decreased		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Heart rate increased		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heart rate irregular		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme increased		
subjects affected / exposed	24 / 13769 (0.17%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	14 / 25	4 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis A antibody positive		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis A virus test positive		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis B antibody positive		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis C virus test positive		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza A virus test positive		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza B virus test positive		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
International normalised ratio abnormal		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
International normalised ratio increased		
subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Investigation		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lipase increased		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver function test abnormal		
subjects affected / exposed	7 / 13769 (0.05%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	3 / 7	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Liver function test increased		
subjects affected / exposed	0 / 13769 (0.00%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 0	3 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Medical observation		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial necrosis marker increased		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oxygen saturation decreased		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Precancerous cells present		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress echocardiogram		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid function test abnormal		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	6 / 13769 (0.04%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	2 / 7	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Troponin I increased		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Troponin T increased		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Weight decreased		

subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight increased			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic fistula			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic leak			

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anastomotic stenosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Animal bite		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Animal scratch		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ankle fracture		
subjects affected / exposed	8 / 13769 (0.06%)	12 / 13756 (0.09%)
occurrences causally related to treatment / all	0 / 10	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic injury		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial bypass occlusion		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial bypass thrombosis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial injury		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial restenosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula site complication		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthropod bite		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Avulsion fracture		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carbon monoxide poisoning		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery restenosis		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	4 / 13769 (0.03%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chemical burn of gastrointestinal tract		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chemical poisoning		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest injury		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle fracture		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Comminuted fracture		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	5 / 13769 (0.04%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		

subjects affected / exposed	6 / 13769 (0.04%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery restenosis		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cranial nerve injury		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	6 / 13769 (0.04%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse axonal injury		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dislocation of sternum		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dislocation of vertebra		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endotracheal intubation complication		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural haematoma		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye contusion		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye injury		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Eye operation complication		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Face injury		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	3 / 13769 (0.02%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	17 / 13769 (0.12%)	13 / 13756 (0.09%)
occurrences causally related to treatment / all	0 / 17	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	4 / 13769 (0.03%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		

subjects affected / exposed	20 / 13769 (0.15%)	9 / 13756 (0.07%)
occurrences causally related to treatment / all	1 / 20	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	5 / 13769 (0.04%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	4 / 13769 (0.03%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body aspiration		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture displacement		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fractured ischium		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Graft complication		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Graft thrombosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	6 / 13769 (0.04%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Heat exhaustion		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heat stroke		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	11 / 13769 (0.08%)	11 / 13756 (0.08%)
occurrences causally related to treatment / all	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		

subjects affected / exposed	6 / 13769 (0.04%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Ilium fracture		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	5 / 13769 (0.04%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Incomplete spinal fusion		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inflammation of wound		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Injury		
subjects affected / exposed	5 / 13769 (0.04%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intentional overdose		
subjects affected / exposed	1 / 13769 (0.01%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw fracture		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		

subjects affected / exposed	4 / 13769 (0.03%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation postoperative		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney contusion		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laceration		
subjects affected / exposed	4 / 13769 (0.03%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament rupture		
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Limb crushing injury		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb fracture		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		

subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Limb traumatic amputation		
subjects affected / exposed	4 / 13769 (0.03%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	7 / 13769 (0.05%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Medication error		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		
subjects affected / exposed	8 / 13769 (0.06%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 8	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Metal poisoning		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple injuries		

subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle contusion		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle rupture		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neck injury		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Open globe injury		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Overdose		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		
subjects affected / exposed	4 / 13769 (0.03%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial reocclusion		

subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery restenosis		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	3 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Perirenal haematoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peroneal nerve palsy postoperative		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumoconiosis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonitis chemical		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax traumatic		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Poisoning		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post concussion syndrome		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post laminectomy syndrome		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural complication		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural constipation		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematuria		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	6 / 13769 (0.04%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural myocardial infarction		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural swelling		

subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic neck syndrome		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic pain		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative respiratory failure		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative thoracic procedure complication		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural complication		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural haemorrhage		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural hypotension		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pneumothorax		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
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	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Radial head dislocation		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation mucositis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation oesophagitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		

subjects affected / exposed	7 / 13769 (0.05%)	11 / 13756 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	4 / 13769 (0.03%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Scapula fracture		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sacroiliac fracture		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seroma		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Skeletal injury		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin abrasion		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fracture		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fractured base		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Snake bite		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column injury		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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	5 / 13769 (0.04%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury lumbar		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic injury		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stab wound		

subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sternal fracture		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous haematoma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	6 / 13769 (0.04%)	11 / 13756 (0.08%)
occurrences causally related to treatment / all	0 / 6	1 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haemorrhage		
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon injury		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	6 / 13769 (0.04%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		

subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	7 / 13769 (0.05%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	0 / 13769 (0.00%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Transplant failure		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic arthritis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic fracture		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haematoma		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemothorax		

subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic shock		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic ulcer		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna fracture		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ulnar nerve injury		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	5 / 13769 (0.04%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stricture postoperative		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular bypass dysfunction		

subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft complication		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft occlusion		
subjects affected / exposed	2 / 13769 (0.01%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft thrombosis		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular procedure complication		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Wound		
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Wound dehiscence		
subjects affected / exposed	4 / 13769 (0.03%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound evisceration		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haemorrhage			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound necrosis			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound secretion			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Adenomatous polyposis coli			
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous malformation			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial septal defect			
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbohydrate metabolism disorder			

subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Exomphalos		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Corneal dystrophy		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal arteriovenous malformation		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hereditary motor and sensory neuropathy		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertrophic cardiomyopathy		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocele		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial lipoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subependymal nodular heterotopia		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	6 / 13769 (0.04%)	11 / 13756 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	11 / 13769 (0.08%)	23 / 13756 (0.17%)	
occurrences causally related to treatment / all	0 / 11	1 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	208 / 13769 (1.51%)	221 / 13756 (1.61%)	
occurrences causally related to treatment / all	4 / 240	6 / 250	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	233 / 13769 (1.69%)	278 / 13756 (2.02%)	
occurrences causally related to treatment / all	4 / 273	3 / 314	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			

subjects affected / exposed	10 / 13769 (0.07%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 11	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia		
subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia supraventricular		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteritis coronary		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		
subjects affected / exposed	119 / 13769 (0.86%)	132 / 13756 (0.96%)
occurrences causally related to treatment / all	0 / 157	2 / 155
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial flutter		
subjects affected / exposed	25 / 13769 (0.18%)	17 / 13756 (0.12%)
occurrences causally related to treatment / all	0 / 27	1 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial thrombosis		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	4 / 13769 (0.03%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	16 / 13769 (0.12%)	13 / 13756 (0.09%)
occurrences causally related to treatment / all	0 / 16	1 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block first degree		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	7 / 13769 (0.05%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Bifascicular block		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bradyarrhythmia		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	10 / 13769 (0.07%)	13 / 13756 (0.09%)
occurrences causally related to treatment / all	1 / 10	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block bilateral		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block right		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac aneurysm		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	3 / 13769 (0.02%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac asthma		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac disorder		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure acute		
subjects affected / exposed	13 / 13769 (0.09%)	10 / 13756 (0.07%)
occurrences causally related to treatment / all	0 / 13	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure		

subjects affected / exposed	66 / 13769 (0.48%)	66 / 13756 (0.48%)
occurrences causally related to treatment / all	0 / 71	1 / 73
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure chronic		
subjects affected / exposed	50 / 13769 (0.36%)	47 / 13756 (0.34%)
occurrences causally related to treatment / all	0 / 53	0 / 56
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure congestive		
subjects affected / exposed	46 / 13769 (0.33%)	37 / 13756 (0.27%)
occurrences causally related to treatment / all	0 / 48	0 / 40
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac flutter		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac tamponade		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac ventricular thrombosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiogenic shock		
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiomyopathy		

subjects affected / exposed	2 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiotoxicity		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiorenal syndrome		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular disorder		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Congestive cardiomyopathy		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	32 / 13769 (0.23%)	46 / 13756 (0.33%)
occurrences causally related to treatment / all	0 / 33	0 / 48
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery occlusion		
subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		

subjects affected / exposed	5 / 13769 (0.04%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery thrombosis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diastolic dysfunction		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dressler's syndrome		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extrasystoles		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Heart alternation		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heart valve incompetence		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive cardiomyopathy		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive heart disease		

subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracardiac thrombus		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	7 / 13769 (0.05%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	1 / 13769 (0.01%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Microvascular coronary artery disease		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		
subjects affected / exposed	11 / 13769 (0.08%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 12	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve stenosis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial infarction		

subjects affected / exposed	31 / 13769 (0.23%)	31 / 13756 (0.23%)
occurrences causally related to treatment / all	1 / 31	1 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial ischaemia		
subjects affected / exposed	26 / 13769 (0.19%)	21 / 13756 (0.15%)
occurrences causally related to treatment / all	0 / 26	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial necrosis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocarditis		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	7 / 13769 (0.05%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 7	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	4 / 13769 (0.03%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Prinzmetal angina		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pulseless electrical activity		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhythm idioventricular		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrest		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	4 / 13769 (0.03%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		
subjects affected / exposed	17 / 13769 (0.12%)	18 / 13756 (0.13%)
occurrences causally related to treatment / all	0 / 17	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus tachycardia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stress cardiomyopathy		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		

subjects affected / exposed	9 / 13769 (0.07%)	9 / 13756 (0.07%)
occurrences causally related to treatment / all	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	3 / 13769 (0.02%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Torsade de pointes		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular arrhythmia		
subjects affected / exposed	4 / 13769 (0.03%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular extrasystoles		
subjects affected / exposed	7 / 13769 (0.05%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular fibrillation		
subjects affected / exposed	12 / 13769 (0.09%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular hypertrophy		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular tachyarrhythmia		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular tachycardia		

subjects affected / exposed	23 / 13769 (0.17%)	27 / 13756 (0.20%)	
occurrences causally related to treatment / all	0 / 30	0 / 33	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	2 / 13769 (0.01%)	4 / 13756 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amnesia			
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amputation stump pain			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Apraxia			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arachnoid cyst			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			

subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Balance disorder		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Basal ganglia infarction		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basilar artery aneurysm		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basilar artery stenosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid arteriosclerosis		
subjects affected / exposed	5 / 13769 (0.04%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 5	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery disease		
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery occlusion		
subjects affected / exposed	3 / 13769 (0.02%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery stenosis		

subjects affected / exposed	37 / 13769 (0.27%)	39 / 13756 (0.28%)
occurrences causally related to treatment / all	2 / 39	0 / 43
deaths causally related to treatment / all	0 / 0	0 / 0
Carpal tunnel syndrome		
subjects affected / exposed	6 / 13769 (0.04%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cauda equina syndrome		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar ataxia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar infarction		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral arteriosclerosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery occlusion		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery stenosis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral atrophy		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haematoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral infarction		
subjects affected / exposed	5 / 13769 (0.04%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ischaemia		
subjects affected / exposed	1 / 13769 (0.01%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral thrombosis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral vasoconstriction		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	25 / 13769 (0.18%)	21 / 13756 (0.15%)
occurrences causally related to treatment / all	1 / 26	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular disorder		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular insufficiency		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical cord compression		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical myelopathy		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical radiculopathy		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicogenic headache		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Complex partial seizures		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Demyelinating polyneuropathy		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	4 / 13769 (0.03%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	15 / 13769 (0.11%)	19 / 13756 (0.14%)
occurrences causally related to treatment / all	1 / 15	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness postural		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dystonia		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalitis autoimmune		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		

subjects affected / exposed	5 / 13769 (0.04%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paralysis		
subjects affected / exposed	0 / 13769 (0.00%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		
subjects affected / exposed	9 / 13769 (0.07%)	17 / 13756 (0.12%)
occurrences causally related to treatment / all	0 / 9	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	4 / 13769 (0.03%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiplegic migraine		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocephalus		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive encephalopathy		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertonia		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic coma		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic encephalopathy		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
IIIrd nerve paralysis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial aneurysm		
subjects affected / exposed	3 / 13769 (0.02%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial mass		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cerebral infarction		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	6 / 13769 (0.04%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar infarction		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar stroke		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lethargy		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	2 / 13769 (0.01%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	1 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbosacral radiculopathy		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Meralgia paraesthetica		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine with aura		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Monoparesis		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Motor neurone disease		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve compression		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nervous system disorder		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgia		
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Neuritis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroglycopenia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuromuscular pain		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	5 / 13769 (0.04%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 5	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	3 / 13769 (0.02%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Paraparesis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paresis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinsonism		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Partial seizures		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral motor neuropathy		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral sensory neuropathy		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peroneal nerve palsy		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Petit mal epilepsy		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy idiopathic progressive		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postictal state		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	9 / 13769 (0.07%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Psychomotor hyperactivity		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudoradicular syndrome		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Quadriplegia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculopathy		
subjects affected / exposed	6 / 13769 (0.04%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retrograde amnesia		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		
subjects affected / exposed	14 / 13769 (0.10%)	10 / 13756 (0.07%)
occurrences causally related to treatment / all	0 / 14	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Sedation		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		

subjects affected / exposed	8 / 13769 (0.06%)	13 / 13756 (0.09%)
occurrences causally related to treatment / all	0 / 9	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Speech disorder		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal claudication		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord compression		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Status epilepticus		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stroke in evolution		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural effusion		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	63 / 13769 (0.46%)	56 / 13756 (0.41%)
occurrences causally related to treatment / all	2 / 64	0 / 59
deaths causally related to treatment / all	0 / 0	0 / 0
Tarsal tunnel syndrome		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tension headache		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic outlet syndrome		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.01%)	1 / 13756 (0.01%)
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	42 / 13769 (0.31%)	36 / 13756 (0.26%)
occurrences causally related to treatment / all	1 / 43	0 / 36
deaths causally related to treatment / all	0 / 0	0 / 0
Unresponsive to stimuli		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular encephalopathy		
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery occlusion		

subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	4 / 13769 (0.03%)	5 / 13756 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo CNS origin			
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual field defect			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord paralysis			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	27 / 13769 (0.20%)	27 / 13756 (0.20%)	
occurrences causally related to treatment / all	0 / 28	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia of chronic disease			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			

subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile neutropenia		
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic anaemia		
subjects affected / exposed	2 / 13769 (0.01%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic disorder		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochromic anaemia		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Immune thrombocytopenic purpura		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	9 / 13769 (0.07%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		
subjects affected / exposed	2 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenitis		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy mediastinal		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normochromic normocytic anaemia		
subjects affected / exposed	4 / 13769 (0.03%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancytopenia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pernicious anaemia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polycythaemia		

subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spleen disorder			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Acute vestibular syndrome			
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness neurosensory			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniere's disease			

subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inner ear inflammation		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Otorrhoea		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden hearing loss		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertigo		
subjects affected / exposed	9 / 13769 (0.07%)	13 / 13756 (0.09%)
occurrences causally related to treatment / all	0 / 9	1 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Tinnitus		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertigo positional		
subjects affected / exposed	7 / 13769 (0.05%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vestibular disorder		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vestibular ischaemia		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Angle closure glaucoma			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blepharochalasis			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	15 / 13769 (0.11%)	22 / 13756 (0.16%)	
occurrences causally related to treatment / all	0 / 16	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract nuclear			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryoadenitis acquired			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ectropion			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid ptosis			

subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iridocyclitis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular degeneration		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular fibrosis		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ocular myasthenia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmoplegia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pterygium		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery occlusion		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery thrombosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal detachment		
subjects affected / exposed	3 / 13769 (0.02%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal tear		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vascular disorder		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vein thrombosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Strabismus		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uveitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Visual acuity reduced		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous floaters			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	11 / 13769 (0.08%)	8 / 13756 (0.06%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			

subjects affected / exposed	12 / 13769 (0.09%)	19 / 13756 (0.14%)
occurrences causally related to treatment / all	1 / 13	3 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain lower		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	12 / 13769 (0.09%)	13 / 13756 (0.09%)
occurrences causally related to treatment / all	0 / 12	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholic pancreatitis		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Anal incontinence		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anastomotic ulcer perforation		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's oesophagus		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic gastritis		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coeliac artery stenosis		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	6 / 13769 (0.04%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	10 / 13769 (0.07%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 11	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		
subjects affected / exposed	2 / 13769 (0.01%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic fistula		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	9 / 13769 (0.07%)	9 / 13756 (0.07%)
occurrences causally related to treatment / all	1 / 9	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's disease		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	9 / 13769 (0.07%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	4 / 13769 (0.03%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	5 / 13769 (0.04%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		

subjects affected / exposed	5 / 13769 (0.04%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	1 / 13769 (0.01%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	7 / 13769 (0.05%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	1 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epiplonic appendagitis		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive oesophagitis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		

subjects affected / exposed	4 / 13769 (0.03%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	4 / 13769 (0.03%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cyst		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric disorder		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	9 / 13769 (0.07%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	7 / 13769 (0.05%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer perforation		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		

subjects affected / exposed	19 / 13769 (0.14%)	17 / 13756 (0.12%)
occurrences causally related to treatment / all	0 / 19	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis alcoholic		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal haemorrhage		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia haemorrhagic		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		

subjects affected / exposed	27 / 13769 (0.20%)	16 / 13756 (0.12%)
occurrences causally related to treatment / all	0 / 27	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal pain		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal polyp haemorrhage		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal ulcer		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal ulcer haemorrhage		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	14 / 13769 (0.10%)	15 / 13756 (0.11%)
occurrences causally related to treatment / all	0 / 14	1 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	4 / 13769 (0.03%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	4 / 13769 (0.03%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic erosive gastritis		

subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	3 / 13769 (0.02%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	6 / 13769 (0.04%)	10 / 13756 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids thrombosed		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hernial eventration		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	9 / 13769 (0.07%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	6 / 13769 (0.04%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired gastric emptying		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus paralytic		

subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated inguinal hernia		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated umbilical hernia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inflammatory bowel disease		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	32 / 13769 (0.23%)	22 / 13756 (0.16%)
occurrences causally related to treatment / all	0 / 34	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal dilatation		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal fistula		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ischaemia		

subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	3 / 13769 (0.02%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal polyp		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal prolapse		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal fluid collection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haematoma		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haemorrhage		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intussusception		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal obstruction		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal ulcer		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	10 / 13769 (0.07%)	16 / 13756 (0.12%)
occurrences causally related to treatment / all	0 / 10	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Leukoplakia oral		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-Weiss syndrome		

subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mechanical ileus		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric arterial occlusion		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery stenosis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery thrombosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric vein thrombosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	5 / 13769 (0.04%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	1 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Odynophagia		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal achalasia		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal food impaction		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal obstruction		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal spasm		
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal stenosis		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal varices haemorrhage		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		

subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis ulcerative		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Palatal swelling		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic cyst		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic disorder		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic necrosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic phlegmon		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic pseudocyst		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		

subjects affected / exposed	10 / 13769 (0.07%)	16 / 13756 (0.12%)
occurrences causally related to treatment / all	1 / 10	1 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	14 / 13769 (0.10%)	22 / 13756 (0.16%)
occurrences causally related to treatment / all	1 / 16	5 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis chronic		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis necrotising		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatolithiasis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontal disease		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal haematoma		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Proctitis		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	6 / 13769 (0.04%)	9 / 13756 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Reflux gastritis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retching		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal fibrosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haematoma		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haemorrhage		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland enlargement		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal haemorrhage		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	4 / 13769 (0.03%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestine ulcer		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Strangulated umbilical hernia		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress ulcer		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis mesenteric vessel		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue cyst		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue oedema		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth disorder		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth impacted		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	10 / 13769 (0.07%)	14 / 13756 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	13 / 13769 (0.09%)	9 / 13756 (0.07%)
occurrences causally related to treatment / all	0 / 13	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Varices oesophageal		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Volvulus		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vomiting		

subjects affected / exposed	4 / 13769 (0.03%)	10 / 13756 (0.07%)	
occurrences causally related to treatment / all	1 / 4	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal cyst			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis contact			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis exfoliative			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatomyositis			

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot		
subjects affected / exposed	6 / 13769 (0.04%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Drug eruption		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dry skin		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema		
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema nummular		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Excessive granulation tissue		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Excessive skin		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Henoch-Schonlein purpura		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperhidrosis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ingrowing nail		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lichen myxoedematosus		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lichen planus		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Papulopustular rosacea		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pemphigoid		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pruritus		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pruritus generalised		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriasis		
subjects affected / exposed	4 / 13769 (0.03%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Scar pain		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin exfoliation		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin ulcer		
subjects affected / exposed	5 / 13769 (0.04%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Stasis dermatitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous emphysema		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Swelling face		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	64 / 13769 (0.46%)	64 / 13756 (0.47%)	
occurrences causally related to treatment / all	3 / 69	0 / 66	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute prerenal failure			
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Azotaemia			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder dilatation			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder diverticulum			
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck obstruction			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder obstruction			

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder outlet obstruction		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder spasm		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder tamponade		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus bladder		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urethral		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		
subjects affected / exposed	3 / 13769 (0.02%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		
subjects affected / exposed	17 / 13769 (0.12%)	15 / 13756 (0.11%)
occurrences causally related to treatment / all	1 / 17	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis haemorrhagic		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysuria		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		
subjects affected / exposed	2 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis chronic		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis membranous		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	17 / 13769 (0.12%)	12 / 13756 (0.09%)
occurrences causally related to treatment / all	0 / 19	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage urinary tract		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		

subjects affected / exposed	3 / 13769 (0.02%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	16 / 13769 (0.12%)	29 / 13756 (0.21%)
occurrences causally related to treatment / all	0 / 16	1 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neurogenic bladder		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nocturia		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive uropathy		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prerenal failure		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelocaliectasis		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	1 / 13769 (0.01%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	3 / 13769 (0.02%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst haemorrhage		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	5 / 13769 (0.04%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		
subjects affected / exposed	4 / 13769 (0.03%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Renal infarct		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal mass		

subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal pain		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stress urinary incontinence		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric rupture		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		
subjects affected / exposed	9 / 13769 (0.07%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stenosis		
subjects affected / exposed	5 / 13769 (0.04%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary incontinence		

subjects affected / exposed	1 / 13769 (0.01%)	6 / 13756 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	14 / 13769 (0.10%)	4 / 13756 (0.03%)	
occurrences causally related to treatment / all	0 / 14	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinoma			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal mass			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basedow's disease			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism primary			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	4 / 13769 (0.03%)	3 / 13756 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoadosteronism			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			
subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	16 / 13769 (0.12%)	18 / 13756 (0.13%)	
occurrences causally related to treatment / all	0 / 16	1 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	11 / 13769 (0.08%)	13 / 13756 (0.09%)	
occurrences causally related to treatment / all	0 / 11	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			

subjects affected / exposed	4 / 13769 (0.03%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Back pain		
subjects affected / exposed	30 / 13769 (0.22%)	30 / 13756 (0.22%)
occurrences causally related to treatment / all	0 / 32	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Bone deformity		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone pain		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis		
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical spinal stenosis		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chondrocalcinosis pyrophosphate		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chondropathy		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		

subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic amyotrophy		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enthesopathy		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis of jaw		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facet joint syndrome		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Femoroacetabular impingement		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fibromyalgia		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Flank pain		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity		
subjects affected / exposed	7 / 13769 (0.05%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture nonunion		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Groin pain		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	8 / 13769 (0.06%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc disorder		
subjects affected / exposed	4 / 13769 (0.03%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc displacement		

subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	22 / 13769 (0.16%)	24 / 13756 (0.17%)
occurrences causally related to treatment / all	0 / 23	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw cyst		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint adhesion		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint effusion		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Joint instability		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint range of motion decreased		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint swelling		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Limb discomfort		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	21 / 13769 (0.15%)	17 / 13756 (0.12%)
occurrences causally related to treatment / all	0 / 21	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Mobility decreased		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Monarthrititis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle spasms		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	49 / 13769 (0.36%)	37 / 13756 (0.27%)
occurrences causally related to treatment / all	0 / 54	1 / 40
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		
subjects affected / exposed	5 / 13769 (0.04%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal stiffness		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	8 / 13769 (0.06%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	4 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia intercostal		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myofasciitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myopathy		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myositis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neck pain		
subjects affected / exposed	4 / 13769 (0.03%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathic arthropathy		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nodal osteoarthritis		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteitis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	91 / 13769 (0.66%)	100 / 13756 (0.73%)
occurrences causally related to treatment / all	1 / 93	0 / 109
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondritis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondrosis		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Osteolysis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		
subjects affected / exposed	4 / 13769 (0.03%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporotic fracture		

subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	8 / 13769 (0.06%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in jaw		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Patellofemoral pain syndrome		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.01%)	0 / 13756 (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	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthritis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyositis		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudarthrosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriatic arthropathy		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		
subjects affected / exposed	4 / 13769 (0.03%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	1 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	1 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	8 / 13769 (0.06%)	9 / 13756 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Seronegative arthritis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column stenosis		
subjects affected / exposed	6 / 13769 (0.04%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal instability		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	9 / 13769 (0.07%)	12 / 13756 (0.09%)
occurrences causally related to treatment / all	0 / 9	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		
subjects affected / exposed	8 / 13769 (0.06%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondyloarthropathy		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolysis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sympathetic posterior cervical syndrome		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Symphysiolysis		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.01%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Synovitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon necrosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Trigger finger		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral foraminal stenosis		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral osteophyte		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal sepsis			
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess bacterial			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	10 / 13769 (0.07%)	4 / 13756 (0.03%)	
occurrences causally related to treatment / all	0 / 10	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess of eyelid			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess of salivary gland			

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess soft tissue		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute sinusitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Amoebic dysentery		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.01%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula infection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendiceal abscess		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	20 / 13769 (0.15%)	14 / 13756 (0.10%)
occurrences causally related to treatment / all	0 / 20	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		

subjects affected / exposed	2 / 13769 (0.01%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Arteritis infective		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atypical pneumonia		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial pericarditis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial prostatitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial pyelonephritis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial sepsis		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteroides bacteraemia		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Beta haemolytic streptococcal infection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone abscess		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast abscess		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	17 / 13769 (0.12%)	30 / 13756 (0.22%)
occurrences causally related to treatment / all	1 / 17	1 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis bacterial		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Burkholderia cepacia complex infection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burkholderia pseudomallei infection		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis infective		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter gastroenteritis		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carbuncle		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Catheter site infection		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis gangrenous		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	39 / 13769 (0.28%)	28 / 13756 (0.20%)
occurrences causally related to treatment / all	1 / 43	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicitis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatitis B		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic sinusitis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	6 / 13769 (0.04%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	3 / 13769 (0.02%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic abscess		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Creutzfeldt-Jakob disease		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	3 / 13769 (0.02%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis escherichia		

subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		
subjects affected / exposed	1 / 13769 (0.01%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	2 / 13769 (0.01%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	16 / 13769 (0.12%)	26 / 13756 (0.19%)
occurrences causally related to treatment / all	0 / 18	0 / 29
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema infected		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic pneumonia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Empyema		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalitis viral		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis bacterial		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis haemophilus		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endophthalmitis		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis infectious		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterobacter bacteraemia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal bacteraemia		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal sepsis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Epiglottitis		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	16 / 13769 (0.12%)	19 / 13756 (0.14%)
occurrences causally related to treatment / all	0 / 17	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipeloid		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia bacteraemia		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		
subjects affected / exposed	4 / 13769 (0.03%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile infection		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fungal peritonitis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Furuncle		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder empyema		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		

subjects affected / exposed	6 / 13769 (0.04%)	12 / 13756 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis viral		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	19 / 13769 (0.14%)	14 / 13756 (0.10%)
occurrences causally related to treatment / all	0 / 20	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis adenovirus		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis bacterial		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis clostridial		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis rotavirus		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis salmonella		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		

subjects affected / exposed	3 / 13769 (0.02%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gingival abscess		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Graft infection		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma infection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter infection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis A		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis B		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis C		
subjects affected / exposed	3 / 13769 (0.02%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis E		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	5 / 13769 (0.04%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site infection		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected bite		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site infection		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected cyst		

subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infection in an immunocompromised host		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious colitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious pleural effusion		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	3 / 13769 (0.02%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Infective tenosynovitis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		

subjects affected / exposed	9 / 13769 (0.07%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney infection		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngitis		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	6 / 13769 (0.04%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	14 / 13769 (0.10%)	15 / 13756 (0.11%)
occurrences causally related to treatment / all	1 / 15	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection viral		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung abscess		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		
subjects affected / exposed	5 / 13769 (0.04%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mastoiditis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinitis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site infection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis bacterial		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis pneumococcal		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle abscess		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasopharyngitis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neurosyphilis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenic infection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nosocomial infection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmic herpes zoster		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oral fungal infection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		

subjects affected / exposed	2 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	16 / 13769 (0.12%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	1 / 18	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis acute		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis chronic		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis externa		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis externa bacterial		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreas infection		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paronychia		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parotitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic abscess		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Perineal abscess		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontitis		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Perirectal abscess		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	4 / 13769 (0.03%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis bacterial		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal abscess		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis streptococcal		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumococcal sepsis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	147 / 13769 (1.07%)	152 / 13756 (1.10%)
occurrences causally related to treatment / all	1 / 154	1 / 162
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia adenoviral		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia bacterial		
subjects affected / exposed	18 / 13769 (0.13%)	11 / 13756 (0.08%)
occurrences causally related to treatment / all	0 / 18	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia legionella		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia influenzal		

subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pneumococcal		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
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	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	4 / 13769 (0.03%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural pneumonia		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural sepsis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	0 / 13769 (0.00%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		

subjects affected / exposed	3 / 13769 (0.02%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate infection		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic abscess		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoas abscess		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary sepsis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	10 / 13769 (0.07%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 12	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		

subjects affected / exposed	6 / 13769 (0.04%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 6	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyonephrosis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal abscess		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
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	8 / 13769 (0.06%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection bacterial		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhinitis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhinovirus infection		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salmonellosis		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salpingitis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal abscess		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal infection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	21 / 13769 (0.15%)	31 / 13756 (0.23%)
occurrences causally related to treatment / all	0 / 22	0 / 32
deaths causally related to treatment / all	0 / 0	0 / 0
Septic shock		
subjects affected / exposed	6 / 13769 (0.04%)	9 / 13756 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Sinusitis		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin bacterial infection		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin infection		

subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue infection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spermatic cord funiculitis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic abscess		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal abscess		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	1 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	1 / 13769 (0.01%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal sepsis		

subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous abscess		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Testicular abscess		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tick-borne viral encephalitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth abscess		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheitis		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	6 / 13769 (0.04%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection bacterial		
subjects affected / exposed	0 / 13769 (0.00%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteritis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	41 / 13769 (0.30%)	37 / 13756 (0.27%)
occurrences causally related to treatment / all	0 / 48	0 / 42
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	7 / 13769 (0.05%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	12 / 13769 (0.09%)	15 / 13756 (0.11%)
occurrences causally related to treatment / all	0 / 13	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Vestibular neuronitis		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection		

subjects affected / exposed	4 / 13769 (0.03%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Viral myocarditis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral pericarditis		
subjects affected / exposed	2 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Viral upper respiratory tract infection		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vulval abscess		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound abscess		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection		
subjects affected / exposed	6 / 13769 (0.04%)	11 / 13756 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection bacterial		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection staphylococcal		

subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Abnormal loss of weight			
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	16 / 13769 (0.12%)	18 / 13756 (0.13%)	
occurrences causally related to treatment / all	0 / 17	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	61 / 13769 (0.44%)	56 / 13756 (0.41%)	
occurrences causally related to treatment / all	2 / 71	3 / 60	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	6 / 13769 (0.04%)	11 / 13756 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			

subjects affected / exposed	10 / 13769 (0.07%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	0 / 10	1 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	2 / 13769 (0.01%)	3 / 13756 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	3 / 13769 (0.02%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid retention		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glucose tolerance impaired		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	6 / 13769 (0.04%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperammonaemia		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		

subjects affected / exposed	8 / 13769 (0.06%)	8 / 13756 (0.06%)
occurrences causally related to treatment / all	1 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperinsulinaemic hypoglycaemia		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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	10 / 13769 (0.07%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypernatraemia		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperosmolar hyperglycaemic state		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	1 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	17 / 13769 (0.12%)	11 / 13756 (0.08%)
occurrences causally related to treatment / all	0 / 17	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia unawareness		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		

subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	6 / 13769 (0.04%)	7 / 13756 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	5 / 13769 (0.04%)	5 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovitaminosis		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (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 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ketoacidosis		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malnutrition		
subjects affected / exposed	0 / 13769 (0.00%)	2 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		
subjects affected / exposed	2 / 13769 (0.01%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity		

subjects affected / exposed	3 / 13769 (0.02%)	6 / 13756 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Type 1 diabetes mellitus		
subjects affected / exposed	0 / 13769 (0.00%)	1 / 13756 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	12 / 13769 (0.09%)	4 / 13756 (0.03%)
occurrences causally related to treatment / all	0 / 12	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Vitamin B12 deficiency		
subjects affected / exposed	1 / 13769 (0.01%)	0 / 13756 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

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

Non-serious adverse events	Evolocumab	Placebo
Total subjects affected by non-serious adverse events		
subjects affected / exposed	3500 / 13769 (25.42%)	3438 / 13756 (24.99%)
Vascular disorders		
Hypertension		
subjects affected / exposed	1069 / 13769 (7.76%)	1157 / 13756 (8.41%)
occurrences (all)	1193	1315
Infections and infestations		
Nasopharyngitis		
subjects affected / exposed	1067 / 13769 (7.75%)	1021 / 13756 (7.42%)
occurrences (all)	1364	1260
Upper respiratory tract infection		
subjects affected / exposed	692 / 13769 (5.03%)	649 / 13756 (4.72%)
occurrences (all)	807	788
Metabolism and nutrition disorders		

Diabetes mellitus subjects affected / exposed	1156 / 13769 (8.40%)	1096 / 13756 (7.97%)	
occurrences (all)	1255	1200	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 September 2012	<ul style="list-style-type: none">• add testing for prior or existing Hepatitis C virus (HCV) infection in high risk individuals and monitoring of viral load in those who show evidence thereof• add the exclusion of family history of hereditary muscular disorders• add instruction that investigators will ask study subjects to promptly report muscle pain, cramps, or weakness especially if accompanied by malaise or fever and provide further detail regarding stopping rules for atorvastatin and investigational product in case of elevated creatine kinase levels• provide guidance regarding actions to take if the subject requires treatment with a strong CYP3A4 inhibitor while on study• add baseline electrocardiogram (ECG) in triplicate for all subjects, not just at sites provided with centralized ECG services equipment• add a description of composition and role of the Clinical Events Committee (CEC)• add serum pregnancy testing at the randomization visit (day 1) for women of childbearing potential• add ezetimibe use at baseline to covariates
24 September 2012	<ul style="list-style-type: none">• add study name FOURIER• add phase 3 formulation information for IP and introduce the prefilled autoinjector/pen for administration of the IP• modify Schedule of Assessments for reduced visit frequency and IP administration by autoinjector/pen at locations external to study center• prolong the time investigators are not to perform non-protocol testing of blinded analytes to 12 weeks after last IP administration or end of study, whichever is later• provide more specificity about adjudicated clinical events• add information about the study Executive Committee and Lipid Monitoring Committee• add reporting requirements for product/device complaints• replace routine visits with administration of IP external to the study center• extend maximal duration of screening from 12 to 15 weeks• add HCV testing at enrollment and evaluation of viral load during the study, if positive, for subjects with a history of HCV infection• increase planned sites to 1000• clarify definition of metabolic syndrome in inclusion criteria• add homozygous familial hypercholesterolemia and LDL or plasma apheresis within 12 months to exclusions• add Israel and Australasia• clarify that all cause death, MI, stroke, revascularization, hospitalization for unstable angina, hospitalization for HF, and TIA are not considered SAEs in this study, but will be handled as efficacy endpoints• clarify that Amgen will review all fatal endpoints to evaluate whether the cause of death is due to a SAE that is a specific concern for a protein therapeutic or which may be individually informative. If detected, Amgen will notify the investigator to submit a SAE eCRF within 24 hours of Amgen's notification.• change time to first hospitalization for worsening HF secondary endpoint to composite endpoint of time to CV death or hospitalization for HF• add secondary endpoint of time to ischemic fatal or non-fatal stroke or TIA• modify lab assessment schedule, including collection biomarker samples

12 December 2012	<ul style="list-style-type: none"> • clarify that the reporting process for potential endpoints and the information collected corresponds to the requirements and the information collected for serious adverse events • clarify that the physical exam should include a neurological exam • increase the upper age limit to 85 years from 80 years • add notification of the investigator if triglycerides are > 1000 mg/dL • add collection of the reason why subjects switch investigational product administration regimen • add alert threshold for elevated triglycerides • add measurement of urine microalbumin at week 48 and end of study
16 July 2013	<ul style="list-style-type: none"> • allow statins other than atorvastatin for background lipid lowering therapy • redefine the acceptable lipid therapy, including changes in allowed lipid therapy other than statins • include symptomatic peripheral arterial disease as evidence of cardiovascular disease • minor modifications of the risk factors for eligibility • add the automated mini doser (also referred to as the 3.5 mL personal injector) to the investigational product administration devices • increase the number of study centers • allow QM dosing from initiation of IP administration • add option of an informed consent for screening and lipid therapy titration only • update the section on withdrawal from treatment • update sections on adverse event and serious adverse event reporting
28 August 2014	<ul style="list-style-type: none"> • increase enrollment from approximately 22,500 to up to approximately 27,500 randomized subjects • update key sponsor contact information • add the product name evolocumab
29 September 2015	<ul style="list-style-type: none"> • add the major components of the primary objective and endpoint as separate secondary objectives and endpoints • revise statistical testing to account for the additional secondary endpoints • add adjudication of new onset diabetes. • revise section on prohibited treatments during the study to account for recent results of another trial (IMPROVE-IT) and enable addition of ezetimibe in subjects experiencing an acute coronary syndrome during the study. Ezetimibe was not prohibited prior to this amendment, as long as subjects were on stable doses at the time of randomization. • add HbA1c to blood draws at week 24 and Q24W visit to assist detection of new onset diabetes. • revise end-of-study procedures to enable more flexibility for sites to schedule end-of-study visits and add a safety contact at 30 days after last administration of IP if the end-of-study visit is less than 30 days after last IP. • add text for the collection of vital status information.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported