

**Clinical trial results:****A Multicenter, Open-label, Single-arm, Extension Study to Assess Long-term Safety of Evolocumab Therapy in Patients With Clinically Evident Cardiovascular Disease****Summary**

EudraCT number	2015-004780-36
Trial protocol	SK PL HU CZ
Global end of trial date	21 March 2022

Results information

Result version number	v2 (current)
This version publication date	21 April 2023
First version publication date	24 February 2023
Version creation reason	<ul style="list-style-type: none">• Correction of full data set enhancement of terminology for timeframe

Trial information**Trial identification**

Sponsor protocol code	20130295
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02867813
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Amgen Inc.
Sponsor organisation address	One Amgen Center Drive, Thousand Oaks, CA, United States,
Public contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, medinfo@amgen.com
Scientific contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, medinfo@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	26 July 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	21 March 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to describe the safety and tolerability of long-term administration of evolocumab.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 September 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 1348
Country: Number of subjects enrolled	United States: 2201
Country: Number of subjects enrolled	Czechia: 763
Country: Number of subjects enrolled	Hungary: 225
Country: Number of subjects enrolled	Russian Federation: 364
Country: Number of subjects enrolled	Slovakia: 79
Country: Number of subjects enrolled	Ukraine: 55
Worldwide total number of subjects	5035
EEA total number of subjects	2415

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)	2947
From 65 to 84 years	2083
85 years and over	5

Subject disposition

Recruitment

Recruitment details:

This was an open-label extension of study 20110118 (NCT01764633). Eligible participants were enrolled after the completion of the 20110118 study. 5035 participants were enrolled at 195 centers in Czech Republic, Hungary, Poland, Russia, Slovakia, Ukraine, and the United States from 02 September 2016 to 17 March 2022.

Pre-assignment

Screening details:

5035 participants were enrolled and 5031 of those participants received study drug.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
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Arm title	Placebo Q2W or QM in Parent Study
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Arm description:

Participants in the parent study who received placebo subcutaneous injections either every 2 weeks (Q2W) or monthly (QM), and received evolocumab 140 mg Q2W or 420 mg QM in the open label extension according to the participant's preference.

Arm type	Experimental
Investigational medicinal product name	Evolocumab
Investigational medicinal product code	
Other name	Repatha
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

140 mg every Q2W or 420 mg QM, according to the subject's preference.

Arm title	Evolocumab Q2W or QM in Parent Study
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Arm description:

Participants in the parent study who received evolocumab subcutaneous injections either Q2W or QM, and received evolocumab 140 mg Q2W or 420 mg QM in the open label extension according to the participant's preference.

Arm type	Experimental
Investigational medicinal product name	Evolocumab
Investigational medicinal product code	
Other name	Repatha
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

140 mg every Q2W or 420 mg QM, according to the subject's preference.

Number of subjects in period 1	Placebo Q2W or QM in Parent Study	Evolocumab Q2W or QM in Parent Study
Started	2535	2500
Completed	2084	2090
Not completed	451	410
Consent withdrawn by subject	57	56
Decision by Sponsor	7	7
Death	294	268
Lost to follow-up	91	78
Missing	2	1

Baseline characteristics

Reporting groups

Reporting group title	Placebo Q2W or QM in Parent Study
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Reporting group description:

Participants in the parent study who received placebo subcutaneous injections either every 2 weeks (Q2W) or monthly (QM), and received evolocumab 140 mg Q2W or 420 mg QM in the open label extension according to the participant's preference.

Reporting group title	Evolocumab Q2W or QM in Parent Study
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Reporting group description:

Participants in the parent study who received evolocumab subcutaneous injections either Q2W or QM, and received evolocumab 140 mg Q2W or 420 mg QM in the open label extension according to the participant's preference.

Reporting group values	Placebo Q2W or QM in Parent Study	Evolocumab Q2W or QM in Parent Study	Total
Number of subjects	2535	2500	5035
Age Categorical			
Units: Subjects			
Adults (18-64 years)	1512	1435	2947
From 65-84 years	1019	1064	2083
85 years and over	4	1	5
Gender Categorical			
Units: Subjects			
Female	638	622	1260
Male	1897	1878	3775
Ethnicity			
Units: Subjects			
Hispanic/Latino	55	63	118
Not Hispanic/Latino	2480	2437	4917
Race			
Units: Subjects			
American Indian or Alaska Native	5	2	7
Asian	9	21	30
Black or African American	112	117	229
Native Hawaiian or Other Pacific Islander	5	4	9
White	2394	2346	4740
Multiple	4	4	8
Other	6	6	12

End points

End points reporting groups

Reporting group title	Placebo Q2W or QM in Parent Study
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Reporting group description:

Participants in the parent study who received placebo subcutaneous injections either every 2 weeks (Q2W) or monthly (QM), and received evolocumab 140 mg Q2W or 420 mg QM in the open label extension according to the participant's preference.

Reporting group title	Evolocumab Q2W or QM in Parent Study
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Reporting group description:

Participants in the parent study who received evolocumab subcutaneous injections either Q2W or QM, and received evolocumab 140 mg Q2W or 420 mg QM in the open label extension according to the participant's preference.

Primary: Number of Participants Who Experienced an Adverse Event

End point title	Number of Participants Who Experienced an Adverse Event ^[1]
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End point description:

All adverse event summaries for the primary analysis of the primary endpoint (OLE study period only) included all treatment-emergent events reported on the Event electronic case report form (eCRF), including CEC positively reviewed events and disease-related events.

End point type	Primary
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End point timeframe:

Up to 5 years

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this end point.

End point values	Placebo Q2W or QM in Parent Study	Evolocumab Q2W or QM in Parent Study		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2532	2499		
Units: Participants	2144	2084		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change of Low-density Lipoprotein Cholesterol (LDL-C) From Baseline at Each Scheduled Visit

End point title	Percent Change of Low-density Lipoprotein Cholesterol (LDL-C) From Baseline at Each Scheduled Visit
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End point description:

End point type	Secondary
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End point timeframe:

Week 12, Week 24, Week 48, Week 72, Week 96, Week 120, Week 144, Week 168, Week 192, Week 216, Week 260

End point values	Placebo Q2W or QM in Parent Study	Evolocumab Q2W or QM in Parent Study		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2532	2499		
Units: Percent Change				
arithmetic mean (standard deviation)				
Week 12	-55.93 (± 33.73)	-58.43 (± 30.64)		
Week 24	-56.69 (± 33.58)	-58.38 (± 31.52)		
Week 48	-58.52 (± 33.66)	-59.05 (± 33.06)		
Week 72	-56.35 (± 33.73)	-56.90 (± 33.14)		
Week 96	-55.70 (± 33.72)	-56.62 (± 33.36)		
Week 120	-53.37 (± 36.77)	-54.89 (± 35.99)		
Week 144	-56.96 (± 32.82)	-57.38 (± 32.34)		
Week 168	-56.49 (± 37.04)	-58.22 (± 34.60)		
Week 192	-57.42 (± 35.43)	-58.81 (± 33.27)		
Week 216	-54.68 (± 35.53)	-57.11 (± 32.89)		
Week 260	-53.69 (± 37.51)	-56.63 (± 36.14)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved an LDL-C level < 40 mg/dL

End point title	Percentage of Participants who Achieved an LDL-C level < 40 mg/dL
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End point description:

End point type	Secondary
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End point timeframe:

Baseline, Week 12, Week 24, Week 48, Week 72, Week 96, Week 120, Week 144, Week 168, Week 192, Week 216, Week 260

End point values	Placebo Q2W or QM in Parent Study	Evolocumab Q2W or QM in Parent Study		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2532	2499		
Units: Percentage of Participants				
number (confidence interval 95%)				
Week 12	58.7 (56.7 to 60.6)	61.4 (59.4 to 63.3)		
Week 24	60.2 (58.2 to 62.1)	61.6 (59.7 to 63.5)		
Week 48	61.7 (59.8 to 63.7)	61.9 (60.0 to 63.9)		
Week 72	59.7 (57.7 to 61.7)	58.5 (56.5 to 60.5)		
Week 96	57.3 (55.3 to 59.3)	59.9 (57.8 to 61.9)		
Week 120	54.6 (52.5 to 56.6)	56.4 (54.4 to 58.5)		
Week 144	59.6 (57.6 to 61.7)	60.4 (58.3 to 62.4)		
Week 168	60.9 (58.8 to 63.0)	61.5 (59.4 to 63.5)		
Week 192	61.8 (59.4 to 64.1)	62.3 (59.9 to 64.7)		
Week 216	56.0 (53.6 to 58.3)	59.2 (56.9 to 61.5)		
Week 260	56.9 (54.6 to 59.1)	59.2 (56.9 to 61.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 up to approximately 5 years during the OLE study.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.1
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Reporting groups

Reporting group title	Placebo in Parent Study
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Reporting group description: -

Reporting group title	Evolocumab in Parent Study
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Reporting group description: -

Serious adverse events	Placebo in Parent Study	Evolocumab in Parent Study	
Total subjects affected by serious adverse events			
subjects affected / exposed	1077 / 2532 (42.54%)	1045 / 2499 (41.82%)	
number of deaths (all causes)	308	287	
number of deaths resulting from adverse events	189	184	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-cell lymphoma			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign male reproductive tract neoplasm			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of ampulla of Vater			

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign spleen tumour		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute myeloid leukaemia		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma gastric		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	5 / 2532 (0.20%)	10 / 2499 (0.40%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 3
Adenocarcinoma pancreas		
subjects affected / exposed	3 / 2532 (0.12%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Anal cancer metastatic		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Anal squamous cell carcinoma		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage I, without cancer in situ		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage I, with cancer in situ		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer recurrent		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	6 / 2532 (0.24%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 2
Bladder adenocarcinoma stage unspecified		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer stage I		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		

subjects affected / exposed	2 / 2532 (0.08%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma metastatic		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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 / 2532 (0.00%)	1 / 2499 (0.04%)
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	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer female		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer metastatic		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder papilloma		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Carcinoid tumour pulmonary		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial carcinoma		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	3 / 2532 (0.12%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial adenocarcinoma		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ductal adenocarcinoma of pancreas		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Diffuse large B-cell lymphoma stage IV		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	0 / 2532 (0.00%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Colorectal cancer		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Follicular lymphoma		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder cancer metastatic		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastric cancer		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal cancer metastatic		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal tract adenoma		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive lobular breast carcinoma		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive breast carcinoma		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal proliferative breast lesion		
subjects affected / exposed	2 / 2532 (0.08%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular carcinoma		
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Hepatic cancer		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Glottis carcinoma		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma multiforme		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Invasive ductal breast carcinoma		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Keratoacanthoma		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer stage III		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal papilloma		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal squamous cell carcinoma		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leiomyoma		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lip and/or oral cavity cancer		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	10 / 2532 (0.39%)	6 / 2499 (0.24%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 5	0 / 4
Lung adenocarcinoma stage I		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma stage IV		
subjects affected / exposed	3 / 2532 (0.12%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0
Lung cancer metastatic		
subjects affected / exposed	3 / 2532 (0.12%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 1
Lung carcinoma cell type unspecified stage I		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung neoplasm		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Lung neoplasm malignant		

subjects affected / exposed	5 / 2532 (0.20%)	6 / 2499 (0.24%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 4	0 / 4
Metastatic neoplasm		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic squamous cell carcinoma		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Myelodysplastic syndrome		
subjects affected / exposed	3 / 2532 (0.12%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoma		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant melanoma		
subjects affected / exposed	3 / 2532 (0.12%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant pleural effusion		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mantle cell lymphoma stage III		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to bone		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to central nervous system		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastases to liver		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lung		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to spinal cord		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastases to spine		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasopharyngeal cancer		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma metastatic		

subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma of the skin		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nodular melanoma		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Non-small cell lung cancer metastatic		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Non-small cell lung cancer stage IV		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma stage III		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal cancer metastatic		

subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ovarian cancer		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Ovarian cancer stage II		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paget's disease of nipple		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	2 / 2532 (0.08%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 4
Neoplasm malignant		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Pancreatic carcinoma stage IV		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Prostatic adenoma		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary cystadenoma lymphomatosum		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic neoplasm		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Phosphaturic mesenchymal tumour		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pituitary tumour benign		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	3 / 2532 (0.12%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Pleomorphic adenoma		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Porocarcinoma		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer		
subjects affected / exposed	18 / 2532 (0.71%)	16 / 2499 (0.64%)
occurrences causally related to treatment / all	0 / 18	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 2
Prostate cancer metastatic		
subjects affected / exposed	3 / 2532 (0.12%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1
Prostate cancer stage I		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage IV		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pancreatic neoplasm		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	3 / 2532 (0.12%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Soft tissue sarcoma		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer metastatic		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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 / 2532 (0.04%)	0 / 2499 (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	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer stage II		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer stage IV		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Renal cell carcinoma		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Renal cell carcinoma stage I		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Skin cancer		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell carcinoma		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	3 / 2532 (0.12%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 2
Small cell lung cancer extensive stage		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Small cell lung cancer metastatic		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Rectal cancer		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of skin		
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the hypopharynx		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the tongue		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Testis cancer		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid neoplasm		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsil cancer		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma		
subjects affected / exposed	4 / 2532 (0.16%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma urethra		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Uterine cancer		

subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Uterine leiomyoma			
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer stage III			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	3 / 2532 (0.12%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	7 / 2532 (0.28%)	10 / 2499 (0.40%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arterial perforation			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial stenosis			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			

subjects affected / exposed	3 / 2532 (0.12%)	7 / 2499 (0.28%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 1
Arteriovenous fistula		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Accelerated hypertension		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Aneurysm		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic aneurysm		
subjects affected / exposed	13 / 2532 (0.51%)	10 / 2499 (0.40%)
occurrences causally related to treatment / all	0 / 13	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 1
Aortic aneurysm rupture		
subjects affected / exposed	3 / 2532 (0.12%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 0
Aortic arteriosclerosis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic thrombosis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bleeding varicose vein		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	1 / 2532 (0.04%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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 / 2532 (0.28%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic macroangiopathy		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic vascular disorder		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	0 / 2532 (0.00%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism arterial		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery aneurysm		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Giant cell arteritis		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	20 / 2532 (0.79%)	10 / 2499 (0.40%)
occurrences causally related to treatment / all	0 / 22	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	3 / 2532 (0.12%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive urgency		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		

subjects affected / exposed	7 / 2532 (0.28%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Blue toe syndrome		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery embolism		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Internal haemorrhage		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Leriche syndrome		
subjects affected / exposed	3 / 2532 (0.12%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		

subjects affected / exposed	5 / 2532 (0.20%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	24 / 2532 (0.95%)	26 / 2499 (1.04%)
occurrences causally related to treatment / all	0 / 26	0 / 32
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	4 / 2532 (0.16%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	1 / 2532 (0.04%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	1 / 2532 (0.04%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral circulatory failure		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		

subjects affected / exposed	6 / 2532 (0.24%)	10 / 2499 (0.40%)
occurrences causally related to treatment / all	0 / 6	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 1
Peripheral vascular disorder		
subjects affected / exposed	4 / 2532 (0.16%)	10 / 2499 (0.40%)
occurrences causally related to treatment / all	0 / 5	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1
Peripheral venous disease		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Raynaud's phenomenon		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery stenosis		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery embolism		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian vein occlusion		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior vena cava stenosis			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	2 / 2532 (0.08%)	4 / 2499 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Varicose vein			
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vena cava thrombosis			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous haemorrhage			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Hip arthroplasty			

subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin neoplasm excision			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tissue expansion procedure			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
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			
Adverse drug reaction			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	5 / 2532 (0.20%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	1 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chest discomfort			
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	15 / 2532 (0.59%)	7 / 2499 (0.28%)	
occurrences causally related to treatment / all	0 / 15	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site pain			

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exercise tolerance decreased		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hernia		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired healing		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site haematoma		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	9 / 2532 (0.36%)	10 / 2499 (0.40%)
occurrences causally related to treatment / all	0 / 9	0 / 10
deaths causally related to treatment / all	0 / 9	0 / 10
Inflammation		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple organ dysfunction syndrome		
subjects affected / exposed	0 / 2532 (0.00%)	6 / 2499 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 3
Non-cardiac chest pain		

subjects affected / exposed	26 / 2532 (1.03%)	37 / 2499 (1.48%)
occurrences causally related to treatment / all	0 / 28	0 / 41
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumatosis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prosthetic cardiac valve stenosis		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular stent occlusion		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stent-graft endoleak		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden cardiac death		
subjects affected / exposed	7 / 2532 (0.28%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 7	0 / 3
Sudden death		
subjects affected / exposed	10 / 2532 (0.39%)	6 / 2499 (0.24%)
occurrences causally related to treatment / all	1 / 10	0 / 6
deaths causally related to treatment / all	1 / 10	0 / 6
Systemic inflammatory response syndrome		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contrast media allergy			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Prostatic dysplasia			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adnexa uteri mass			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balanoposthitis			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	9 / 2532 (0.36%)	7 / 2499 (0.28%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cyst			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erectile dysfunction			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital haemorrhage			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
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 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic haematoma			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic organ prolapse			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			

subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine inflammation			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	6 / 2532 (0.24%)	9 / 2499 (0.36%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			

subjects affected / exposed	8 / 2532 (0.32%)	23 / 2499 (0.92%)
occurrences causally related to treatment / all	0 / 9	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 3
Aspiration		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	7 / 2532 (0.28%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Asthma late onset		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchopulmonary disease		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	25 / 2532 (0.99%)	30 / 2499 (1.20%)
occurrences causally related to treatment / all	0 / 42	0 / 39
deaths causally related to treatment / all	0 / 2	0 / 2
Chronic respiratory failure		

subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cough		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea exertional		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Epistaxis		
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrothorax		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	3 / 2532 (0.12%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic pulmonary fibrosis		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	2 / 2532 (0.08%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infiltration		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonitis aspiration		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	1 / 2532 (0.04%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax spontaneous		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	12 / 2532 (0.47%)	12 / 2499 (0.48%)
occurrences causally related to treatment / all	0 / 12	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary fibrosis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary haemorrhage		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epiglottic mass		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory arrest		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Respiratory failure		
subjects affected / exposed	13 / 2532 (0.51%)	16 / 2499 (0.64%)
occurrences causally related to treatment / all	0 / 15	0 / 17
deaths causally related to treatment / all	0 / 3	0 / 2
Sleep apnoea syndrome		
subjects affected / exposed	5 / 2532 (0.20%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheal stenosis		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder due to a general medical condition			
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Confusional state			
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			

subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mania		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Alcohol abuse		
subjects affected / exposed	1 / 2532 (0.04%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Mental status changes		
subjects affected / exposed	9 / 2532 (0.36%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 10	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic stress disorder		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Suicidal ideation		

subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paranoia			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Product issues			
Device dislocation			
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lead dislodgement			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device mechanical issue			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device power source issue			
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device stimulation issue			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Alcoholic liver disease			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dilatation			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract disorder			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cirrhosis alcoholic			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			

subjects affected / exposed	1 / 2532 (0.04%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	7 / 2532 (0.28%)	10 / 2499 (0.40%)
occurrences causally related to treatment / all	0 / 7	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis chronic		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	13 / 2532 (0.51%)	11 / 2499 (0.44%)
occurrences causally related to treatment / all	0 / 14	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatic failure		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cholangitis acute		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis		

subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperplastic cholecystopathy			
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Squamous cell carcinoma antigen			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level below therapeutic			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio decreased			

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus test positive			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin I increased			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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			
Ankle fracture			
subjects affected / exposed	5 / 2532 (0.20%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Aortic pseudoaneurysm			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial injury			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod bite			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain contusion			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns second degree			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbon monoxide poisoning			
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac procedure complication			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
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 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical vertebral fracture		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Compression fracture		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Accidental overdose		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Burns third degree		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Contusion		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery reocclusion		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery restenosis		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Crush injury		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dural tear		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Face injury		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	9 / 2532 (0.36%)	10 / 2499 (0.40%)
occurrences causally related to treatment / all	0 / 12	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 1
Femoral neck fracture		
subjects affected / exposed	1 / 2532 (0.04%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral nerve injury		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	6 / 2532 (0.24%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dislocation of sternum		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body in gastrointestinal tract		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fractured sacrum		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Frostbite		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Graft haemorrhage		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gun shot wound			
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Head injury			
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	5 / 2532 (0.20%)	9 / 2499 (0.36%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	2 / 2532 (0.08%)	5 / 2499 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ilium fracture			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated incisional hernia			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional overdose			

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc injury		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw fracture		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament rupture		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament sprain		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb crushing injury		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic organ injury		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
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	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Overdose		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	3 / 2532 (0.12%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pneumothorax		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation proctitis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	3 / 2532 (0.12%)	6 / 2499 (0.24%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	0 / 2532 (0.00%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 3
Periprocedural myocardial infarction		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		

subjects affected / exposed	0 / 2532 (0.00%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural hypotension		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural pulmonary embolism		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative respiratory failure		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax traumatic		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Skin laceration		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		

subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic rupture		
subjects affected / exposed	3 / 2532 (0.12%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	4 / 2532 (0.16%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon injury		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		

subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular access complication		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft complication		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	4 / 2532 (0.16%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	0 / 2532 (0.00%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm ruptured		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound complication		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound dehiscence		

subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound necrosis			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Gastrointestinal arteriovenous malformation			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Talipes			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute cardiac event			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute coronary syndrome			
subjects affected / exposed	10 / 2532 (0.39%)	6 / 2499 (0.24%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 1	
Acute left ventricular failure			
subjects affected / exposed	5 / 2532 (0.20%)	3 / 2499 (0.12%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	

Acute myocardial infarction		
subjects affected / exposed	74 / 2532 (2.92%)	52 / 2499 (2.08%)
occurrences causally related to treatment / all	0 / 85	0 / 58
deaths causally related to treatment / all	0 / 5	0 / 6
Aortic valve stenosis		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Angina unstable		
subjects affected / exposed	49 / 2532 (1.94%)	37 / 2499 (1.48%)
occurrences causally related to treatment / all	0 / 53	0 / 41
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve disease mixed		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve disease		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Angina pectoris		
subjects affected / exposed	56 / 2532 (2.21%)	52 / 2499 (2.08%)
occurrences causally related to treatment / all	0 / 64	0 / 67
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		
subjects affected / exposed	57 / 2532 (2.25%)	47 / 2499 (1.88%)
occurrences causally related to treatment / all	0 / 68	0 / 64
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Arrhythmic storm		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Arrhythmia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial flutter		
subjects affected / exposed	11 / 2532 (0.43%)	13 / 2499 (0.52%)
occurrences causally related to treatment / all	0 / 12	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	8 / 2532 (0.32%)	9 / 2499 (0.36%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	4 / 2532 (0.16%)	5 / 2499 (0.20%)
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	9 / 2532 (0.36%)	9 / 2499 (0.36%)
occurrences causally related to treatment / all	0 / 9	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	16 / 2532 (0.63%)	13 / 2499 (0.52%)
occurrences causally related to treatment / all	3 / 16	0 / 13
deaths causally related to treatment / all	1 / 13	0 / 6
Cardiac asthma		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1
Cardiomyopathy		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiogenic shock		
subjects affected / exposed	5 / 2532 (0.20%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Cardiac failure congestive		
subjects affected / exposed	37 / 2532 (1.46%)	40 / 2499 (1.60%)
occurrences causally related to treatment / all	0 / 48	0 / 50
deaths causally related to treatment / all	0 / 3	0 / 4
Cardiac failure chronic		

subjects affected / exposed	13 / 2532 (0.51%)	23 / 2499 (0.92%)
occurrences causally related to treatment / all	0 / 17	0 / 25
deaths causally related to treatment / all	0 / 3	0 / 1
Cardiac failure acute		
subjects affected / exposed	21 / 2532 (0.83%)	17 / 2499 (0.68%)
occurrences causally related to treatment / all	1 / 22	0 / 21
deaths causally related to treatment / all	1 / 5	0 / 3
Cardiac failure		
subjects affected / exposed	46 / 2532 (1.82%)	44 / 2499 (1.76%)
occurrences causally related to treatment / all	0 / 68	0 / 58
deaths causally related to treatment / all	0 / 8	0 / 13
Cardiac disorder		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiovascular disorder		
subjects affected / exposed	4 / 2532 (0.16%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 4	0 / 0
Coronary artery disease		
subjects affected / exposed	41 / 2532 (1.62%)	30 / 2499 (1.20%)
occurrences causally related to treatment / all	0 / 42	2 / 31
deaths causally related to treatment / all	0 / 3	0 / 0
Coronary artery insufficiency		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Coronary artery occlusion		
subjects affected / exposed	4 / 2532 (0.16%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		

subjects affected / exposed	8 / 2532 (0.32%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	1 / 2532 (0.04%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Intracardiac thrombus		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic left ventricular failure		
subjects affected / exposed	0 / 2532 (0.00%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular insufficiency		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paroxysmal atrioventricular block		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	8 / 2532 (0.32%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Mitral valve incompetence		
subjects affected / exposed	1 / 2532 (0.04%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve prolapse		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve stenosis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial infarction		
subjects affected / exposed	25 / 2532 (0.99%)	20 / 2499 (0.80%)
occurrences causally related to treatment / all	0 / 26	0 / 22
deaths causally related to treatment / all	0 / 8	0 / 3
Myocardial ischaemia		
subjects affected / exposed	15 / 2532 (0.59%)	11 / 2499 (0.44%)
occurrences causally related to treatment / all	0 / 16	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 1
Nodal arrhythmia		

subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Right ventricular failure		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Sinus arrhythmia		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		
subjects affected / exposed	7 / 2532 (0.28%)	8 / 2499 (0.32%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular extrasystoles		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular arrhythmia		
subjects affected / exposed	4 / 2532 (0.16%)	6 / 2499 (0.24%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
Supraventricular tachycardia		

subjects affected / exposed	2 / 2532 (0.08%)	8 / 2499 (0.32%)
occurrences causally related to treatment / all	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Tachyarrhythmia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	3 / 2532 (0.12%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid valve incompetence		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachyarrhythmia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular extrasystoles		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular fibrillation		
subjects affected / exposed	4 / 2532 (0.16%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Ventricular tachycardia		
subjects affected / exposed	17 / 2532 (0.67%)	14 / 2499 (0.56%)
occurrences causally related to treatment / all	1 / 19	0 / 19
deaths causally related to treatment / all	0 / 1	0 / 0
Wolff-Parkinson-White syndrome		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachyarrhythmia			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Axonal neuropathy			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance disorder			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid arteriosclerosis			
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery disease			

subjects affected / exposed	2 / 2532 (0.08%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery occlusion		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery stenosis		
subjects affected / exposed	11 / 2532 (0.43%)	10 / 2499 (0.40%)
occurrences causally related to treatment / all	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Carpal tunnel syndrome		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cauda equina syndrome		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral amyloid angiopathy		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral arteriosclerosis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ataxia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		

subjects affected / exposed	5 / 2532 (0.20%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1
Cerebral infarction		
subjects affected / exposed	4 / 2532 (0.16%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ischaemia		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	25 / 2532 (0.99%)	20 / 2499 (0.80%)
occurrences causally related to treatment / all	0 / 25	1 / 20
deaths causally related to treatment / all	0 / 4	1 / 3
Cervical radiculopathy		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Headache		
subjects affected / exposed	2 / 2532 (0.08%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		

subjects affected / exposed	8 / 2532 (0.32%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness postural		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic stroke		
subjects affected / exposed	4 / 2532 (0.16%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paralysis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paresis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Focal dyscognitive seizures		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	3 / 2532 (0.12%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Haemorrhagic cerebral infarction		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic stroke		
subjects affected / exposed	3 / 2532 (0.12%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1
Dementia Alzheimer's type		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hemianopia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		

subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive encephalopathy		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	3 / 2532 (0.12%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Intracranial aneurysm		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cerebral infarction		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	18 / 2532 (0.71%)	27 / 2499 (1.08%)
occurrences causally related to treatment / all	0 / 19	2 / 29
deaths causally related to treatment / all	0 / 1	0 / 1
Lacunar infarction		

subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lacunar stroke		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Memory impairment		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	3 / 2532 (0.12%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparaesthesia		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		

subjects affected / exposed	4 / 2532 (0.16%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve compression		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paresis cranial nerve		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Partial seizures		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral nerve lesion		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral sensorimotor neuropathy		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral sensory neuropathy		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Phantom limb syndrome		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post stroke epilepsy		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Psychogenic seizure		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Moyamoya disease		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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 / 2532 (0.04%)	0 / 2499 (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	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord compression		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitic myelopathy		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	2 / 2532 (0.08%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	19 / 2532 (0.75%)	14 / 2499 (0.56%)
occurrences causally related to treatment / all	0 / 20	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Thalamic infarction		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	11 / 2532 (0.43%)	14 / 2499 (0.56%)	
occurrences causally related to treatment / all	0 / 12	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	4 / 2532 (0.16%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar stroke			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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			
Agranulocytosis			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			

subjects affected / exposed	13 / 2532 (0.51%)	18 / 2499 (0.72%)
occurrences causally related to treatment / all	0 / 13	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia macrocytic		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia of malignant disease		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia vitamin B12 deficiency		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Blood loss anaemia		
subjects affected / exposed	5 / 2532 (0.20%)	8 / 2499 (0.32%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile neutropenia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heparin-induced thrombocytopenia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	4 / 2532 (0.16%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic haemorrhage			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute vestibular syndrome			
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
External ear disorder			

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular ataxia			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	4 / 2532 (0.16%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	5 / 2532 (0.20%)	4 / 2499 (0.16%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo labyrinthine			
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	3 / 2532 (0.12%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurosensory hypoacusis			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			

subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract		
subjects affected / exposed	11 / 2532 (0.43%)	8 / 2499 (0.32%)
occurrences causally related to treatment / all	0 / 16	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Choroidal detachment		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Conjunctival haemorrhage		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinopathy		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epiretinal membrane		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid bleeding		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid ptosis		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular rupture			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	3 / 2532 (0.12%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal symptom			

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal mass		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain		
subjects affected / exposed	4 / 2532 (0.16%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal incarcerated hernia		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abnormal faeces		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal stenosis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's disease		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	2 / 2532 (0.08%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon dysplasia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's oesophagus		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		

subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	0 / 2532 (0.00%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	4 / 2532 (0.16%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive duodenitis		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral hernia		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral hernia strangulated		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric perforation		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	3 / 2532 (0.12%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		

subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer perforation		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric volvulus		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis alcoholic		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
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	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal disorder		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal vascular malformation haemorrhagic		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	6 / 2532 (0.24%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic erosive gastritis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	11 / 2532 (0.43%)	16 / 2499 (0.64%)
occurrences causally related to treatment / all	0 / 13	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 2
Hiatus hernia		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated inguinal hernia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	8 / 2532 (0.32%)	11 / 2499 (0.44%)
occurrences causally related to treatment / all	0 / 8	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia strangulated		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal obstruction		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ischaemia		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Intestinal perforation		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal pseudo-obstruction		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Irritable bowel syndrome		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal haemorrhage		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal angina		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	3 / 2532 (0.12%)	6 / 2499 (0.24%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	7 / 2532 (0.28%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Melaena		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery thrombosis		

subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Nausea		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive pancreatitis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Odynophagia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oedematous pancreatitis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal food impaction		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal haemorrhage		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal stenosis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer haemorrhage		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal varices haemorrhage		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic failure		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	5 / 2532 (0.20%)	10 / 2499 (0.40%)
occurrences causally related to treatment / all	1 / 6	1 / 12
deaths causally related to treatment / all	0 / 1	0 / 0
Pancreatitis chronic		
subjects affected / exposed	1 / 2532 (0.04%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis necrotising		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	5 / 2532 (0.20%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proctitis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	1 / 2532 (0.04%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal prolapse		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haemorrhage		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland cyst		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vomiting		

subjects affected / exposed	3 / 2532 (0.12%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	6 / 2532 (0.24%)	4 / 2499 (0.16%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	6 / 2532 (0.24%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	5 / 2532 (0.20%)	8 / 2499 (0.32%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Neuropathic ulcer			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Actinic keratosis			

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Angioedema		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blister		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cutaneous lupus erythematosus		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermal cyst		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis bullous		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis herpetiformis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot		

subjects affected / exposed	3 / 2532 (0.12%)	4 / 2499 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema multiforme			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkeratosis			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic skin ulcer			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin lesion			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Haemorrhage urinary tract			
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			

subjects affected / exposed	25 / 2532 (0.99%)	30 / 2499 (1.20%)
occurrences causally related to treatment / all	0 / 27	0 / 32
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder stenosis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus bladder		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		
subjects affected / exposed	1 / 2532 (0.04%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		
subjects affected / exposed	3 / 2532 (0.12%)	6 / 2499 (0.24%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis haemorrhagic		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	1 / 2532 (0.04%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Focal segmental glomerulosclerosis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	5 / 2532 (0.20%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric stenosis		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	4 / 2532 (0.16%)	9 / 2499 (0.36%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive nephropathy		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal embolism		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Renal failure		
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal haematoma		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal haemorrhage		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Renal mass		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric obstruction		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incontinence		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		
subjects affected / exposed	1 / 2532 (0.04%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral perforation		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stenosis		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract disorder		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract obstruction		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
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	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
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 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 2532 (0.08%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back disorder			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	6 / 2532 (0.24%)	3 / 2499 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Intervertebral disc disorder			
subjects affected / exposed	4 / 2532 (0.16%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	3 / 2532 (0.12%)	8 / 2499 (0.32%)	
occurrences causally related to treatment / all	0 / 3	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	8 / 2532 (0.32%)	6 / 2499 (0.24%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint swelling			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc displacement			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
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 / 2532 (0.12%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	4 / 2532 (0.16%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondromalacia			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Compartment syndrome		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma muscle		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	0 / 2532 (0.00%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Osteolysis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Knee impingement syndrome		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in jaw		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pathological fracture		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Kyphosis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	4 / 2532 (0.16%)	9 / 2499 (0.36%)
occurrences causally related to treatment / all	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	6 / 2532 (0.24%)	6 / 2499 (0.24%)
occurrences causally related to treatment / all	1 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal discomfort		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myopathy		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	37 / 2532 (1.46%)	36 / 2499 (1.44%)
occurrences causally related to treatment / all	0 / 42	0 / 37
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal stenosis		
subjects affected / exposed	1 / 2532 (0.04%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondyloarthropathy		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		

subjects affected / exposed	3 / 2532 (0.12%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	1 / 2532 (0.04%)	8 / 2499 (0.32%)
occurrences causally related to treatment / all	0 / 1	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthritis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scoliosis		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	3 / 2532 (0.12%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriatic arthropathy		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal disorder			
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	3 / 2532 (0.12%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abscess bacterial			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal abscess			
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute endocarditis			

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	7 / 2532 (0.28%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	4 / 2532 (0.16%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast abscess		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis infective		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Asymptomatic COVID-19		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atypical pneumonia		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial infection		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Coccidioidomycosis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic abscess		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronavirus infection		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	3 / 2532 (0.12%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	8 / 2532 (0.32%)	10 / 2499 (0.40%)
occurrences causally related to treatment / all	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
COVID-19 pneumonia		
subjects affected / exposed	32 / 2532 (1.26%)	23 / 2499 (0.92%)
occurrences causally related to treatment / all	0 / 32	0 / 23
deaths causally related to treatment / all	0 / 7	0 / 7
Cellulitis		
subjects affected / exposed	17 / 2532 (0.67%)	20 / 2499 (0.80%)
occurrences causally related to treatment / all	0 / 21	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis infective		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholera		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
COVID-19		
subjects affected / exposed	15 / 2532 (0.59%)	15 / 2499 (0.60%)
occurrences causally related to treatment / all	0 / 16	0 / 16
deaths causally related to treatment / all	0 / 3	0 / 4
Cystitis klebsiella		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		

subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	11 / 2532 (0.43%)	7 / 2499 (0.28%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema infected		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis bacterial		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis bacterial		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia bacteraemia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural abscess		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fungal skin infection		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder empyema		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	3 / 2532 (0.12%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	4 / 2532 (0.16%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis bacterial		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder abscess		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	3 / 2532 (0.12%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
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	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	11 / 2532 (0.43%)	6 / 2499 (0.24%)
occurrences causally related to treatment / all	0 / 11	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Lung abscess		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint abscess		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney infection		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella infection		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella sepsis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		

subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lyme disease		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningoencephalitis viral		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metapneumovirus infection		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenic sepsis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Otitis media chronic		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	6 / 2532 (0.24%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis acute		

subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
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	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Paronychia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parotid abscess		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perihepatic abscess		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perineal abscess		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia legionella		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	50 / 2532 (1.97%)	74 / 2499 (2.96%)
occurrences causally related to treatment / all	0 / 55	0 / 83
deaths causally related to treatment / all	0 / 6	0 / 10
Pneumonia aspiration		
subjects affected / exposed	4 / 2532 (0.16%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumonia bacterial		
subjects affected / exposed	9 / 2532 (0.36%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Pneumonia escherichia		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal abscess		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pseudomonal		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia streptococcal		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	2 / 2532 (0.08%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural sepsis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rocky mountain spotted fever		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal abscess		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	5 / 2532 (0.20%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	14 / 2532 (0.55%)	23 / 2499 (0.92%)
occurrences causally related to treatment / all	0 / 14	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 3
Septic arthritis staphylococcal		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Septic shock		
subjects affected / exposed	3 / 2532 (0.12%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Serratia infection		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal abscess		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous abscess		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal osteomyelitis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal bacteraemia		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal sepsis		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		

subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	14 / 2532 (0.55%)	13 / 2499 (0.52%)
occurrences causally related to treatment / all	0 / 15	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	3 / 2532 (0.12%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Wound sepsis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	7 / 2532 (0.28%)	4 / 2499 (0.16%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Vestibular neuronitis		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Viral upper respiratory tract infection		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection bacterial		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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 pseudomonal			
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypertriglyceridaemia			
subjects affected / exposed	0 / 2532 (0.00%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	6 / 2532 (0.24%)	10 / 2499 (0.40%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	8 / 2532 (0.32%)	12 / 2499 (0.48%)	
occurrences causally related to treatment / all	0 / 9	1 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	2 / 2532 (0.08%)	4 / 2499 (0.16%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	5 / 2532 (0.20%)	2 / 2499 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Failure to thrive			

subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (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	2 / 2532 (0.08%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity		
subjects affected / exposed	2 / 2532 (0.08%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mineral deficiency		

subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malnutrition		
subjects affected / exposed	1 / 2532 (0.04%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic acidosis		
subjects affected / exposed	0 / 2532 (0.00%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	1 / 2532 (0.04%)	1 / 2499 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	2 / 2532 (0.08%)	5 / 2499 (0.20%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	5 / 2532 (0.20%)	0 / 2499 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	1 / 2532 (0.04%)	3 / 2499 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypervolaemia		
subjects affected / exposed	1 / 2532 (0.04%)	2 / 2499 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1

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

Non-serious adverse events	Placebo in Parent Study	Evolocumab in Parent Study	
Total subjects affected by non-serious adverse events subjects affected / exposed	956 / 2532 (37.76%)	959 / 2499 (38.38%)	
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	327 / 2532 (12.91%) 386	355 / 2499 (14.21%) 416	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all)	144 / 2532 (5.69%) 169 133 / 2532 (5.25%) 153	138 / 2499 (5.52%) 172 137 / 2499 (5.48%) 156	
Infections and infestations Bronchitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all)	162 / 2532 (6.40%) 205 208 / 2532 (8.21%) 284 157 / 2532 (6.20%) 199	173 / 2499 (6.92%) 212 162 / 2499 (6.48%) 225 156 / 2499 (6.24%) 176	
Metabolism and nutrition disorders Diabetes mellitus subjects affected / exposed occurrences (all)	139 / 2532 (5.49%) 150	135 / 2499 (5.40%) 144	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 November 2017	The protocol was amended for the following reasons: <ul style="list-style-type: none">• Updated method of evolocumab distribution to subjects• Updated primary completion and end of study definitions• Replaced end of study visit with safety follow-up phone call• Clarified collection of demographic and baseline data• Clarified that subjects who discontinue evolocumab should remain on-study when possible• Defined lost to follow-up
08 April 2019	The protocol was amended for the following reasons: <ul style="list-style-type: none">• Added exploratory endpoint• Added that subjects would be followed through study termination irrespective of receiving treatment, unless subject withdrew consent• Added concomitant therapy instructions• Added instructions for investigators for handling subjects who become pregnant• Updated list of analysis sets to include long-term safety analysis set, OLE Safety Analysis Set, and OLE CANTAB analysis set• Clarified which endpoints would use which analysis sets• Added list of adverse events to be reviewed by CEC
26 February 2020	The protocol was amended for the following reasons: <ul style="list-style-type: none">• Clarified that all serious drug-related events must be recorded and reported to sponsor or designee within 24 hours• Added coronary revascularization procedure and death information to schedule of assessments• Clarified that all adverse event summaries for the primary analysis of the primary endpoint would include all treatment-emergent events reported on the event eCRF, including CEC reviewed events and disease-related events• Replaced "automated mini-doser (AMD)" with "personal injector (PI)" to align with program-level naming convention

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported