

**Clinical trial results:****A Randomized, Double-blind, Placebo-controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at high risk for, Cardiovascular Disease who are Statin Intolerant.****Summary**

EudraCT number	2016-003485-11
Trial protocol	SK NL LV LT GB DK DE HU BG CZ PL ES HR BE AT RO
Global end of trial date	07 November 2022

Results information

Result version number	v1 (current)
This version publication date	10 November 2023
First version publication date	10 November 2023

Trial information**Trial identification**

Sponsor protocol code	1002-043
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02993406
WHO universal trial number (UTN)	-
Other trial identifiers	Nickname: CLEAR Outcomes

Notes:

Sponsors

Sponsor organisation name	Esperion Therapeutics
Sponsor organisation address	3891 Ranchero Drive, Suite 150, Ann Arbor, Michigan, United States, 48108
Public contact	Study Director, Esperion Therapeutics, medinfo@esperion.com
Scientific contact	Study Director, Esperion Therapeutics, medinfo@esperion.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	07 November 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	07 November 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate whether administration of bempedoic acid 180 milligrams per day (mg/day) versus placebo reduces the risk of MACE (Major Adverse Cardiovascular Event) in participants with, or at high risk for, cardiovascular disease (CVD) in participants who have, or are at high risk for cardiovascular disease and are statin intolerant.

Protection of trial subjects:

This study was designed, conducted, and monitored in accordance with Sponsor procedures, which comply with the ethical principles of Good Clinical Practice as required by the major regulatory authorities, and in accordance with the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 December 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 338
Country: Number of subjects enrolled	Austria: 22
Country: Number of subjects enrolled	Belgium: 89
Country: Number of subjects enrolled	Bulgaria: 854
Country: Number of subjects enrolled	Croatia: 103
Country: Number of subjects enrolled	Czechia: 399
Country: Number of subjects enrolled	Denmark: 88
Country: Number of subjects enrolled	Estonia: 11
Country: Number of subjects enrolled	Germany: 349
Country: Number of subjects enrolled	Hungary: 673
Country: Number of subjects enrolled	Latvia: 93
Country: Number of subjects enrolled	Lithuania: 237
Country: Number of subjects enrolled	Netherlands: 693
Country: Number of subjects enrolled	Poland: 617
Country: Number of subjects enrolled	Romania: 341
Country: Number of subjects enrolled	Slovakia: 615
Country: Number of subjects enrolled	Spain: 36
Country: Number of subjects enrolled	United States: 2866
Country: Number of subjects enrolled	Ukraine: 1408

Country: Number of subjects enrolled	Russian Federation: 1030
Country: Number of subjects enrolled	Argentina: 632
Country: Number of subjects enrolled	Mexico: 556
Country: Number of subjects enrolled	Brazil: 452
Country: Number of subjects enrolled	Serbia: 334
Country: Number of subjects enrolled	Australia: 306
Country: Number of subjects enrolled	South Africa: 222
Country: Number of subjects enrolled	India: 183
Country: Number of subjects enrolled	Canada: 152
Country: Number of subjects enrolled	New Zealand: 110
Country: Number of subjects enrolled	Colombia: 95
Country: Number of subjects enrolled	Chile: 43
Country: Number of subjects enrolled	Turkey: 23
Worldwide total number of subjects	13970
EEA total number of subjects	5220

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)	5766
From 65 to 84 years	8154
85 years and over	50

Subject disposition

Recruitment

Recruitment details:

This was a randomized, double-blind, placebo-controlled, parallel-group study that assessed the occurrence of major adverse cardiovascular event (MACE) in participants with, or at high risk for, cardiovascular disease (CVD) who were unable to tolerate statin therapy.

Pre-assignment

Screening details:

A total of 13970 participants were enrolled from over 1250 sites in 32 countries.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Bempedoic Acid 180 mg

Arm description:

Participants were administered with Bempedoic acid 180 mg tablet once daily orally.

Arm type	Experimental
Investigational medicinal product name	Bempedoic acid 180 mg tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants were administered with bempedoic acid 180 mg tablet orally once daily.

Arm title	Placebo Comparator
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Arm description:

Participants were administered with matching Placebo tablet once daily orally.

Arm type	Placebo
Investigational medicinal product name	Matching placebo tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Patients were administered with matching placebo tablet orally once daily.

Number of subjects in period 1	Bempedoic Acid 180 mg	Placebo Comparator
Started	6992	6978
Completed	6697	6620
Not completed	295	358
Consent withdrawn by subject	170	196
Physician decision	3	5
Administrative decision	1	-
Unclassifiable Response	105	139
Lost to follow-up	12	13
Sponsor decision	4	5

Baseline characteristics

Reporting groups

Reporting group title	Bempedoic Acid 180 mg
Reporting group description: Participants were administered with Bempedoic acid 180 mg tablet once daily orally.	
Reporting group title	Placebo Comparator
Reporting group description: Participants were administered with matching Placebo tablet once daily orally.	

Reporting group values	Bempedoic Acid 180 mg	Placebo Comparator	Total
Number of subjects	6992	6978	13970
Age categorical Units: Subjects			
Adults (18-64 years)	2859	2907	5766
From 65-84 years	4133	4071	8204
Age continuous Units: years			
arithmetic mean	65.5	65.5	-
standard deviation	± 9.0	± 8.9	-
Gender categorical Units: Subjects			
Female	3361	3379	6740
Male	3631	3599	7230
Ethnicity Units: Subjects			
Hispanic or Latino	1190	1143	2333
Not Hispanic or Latino	5802	5835	11637
Unknown or Not Reported	0	0	0
Race Units: Subjects			
American Indian or Alaska Native	240	247	487
Asian	130	136	266
Native Hawaiian or Other Pacific Islander	20	17	37
Black or African American	156	172	328
White	6397	6335	12732
More than one race	48	70	118
Unknown or Not Reported	1	1	2

End points

End points reporting groups

Reporting group title	Bempedoic Acid 180 mg
Reporting group description:	
Participants were administered with Bempedoic acid 180 mg tablet once daily orally.	
Reporting group title	Placebo Comparator
Reporting group description:	
Participants were administered with matching Placebo tablet once daily orally.	

Primary: Number of Participants With First Occurrence of Four Component Major Adverse Cardiovascular Events (MACE)

End point title	Number of Participants With First Occurrence of Four Component Major Adverse Cardiovascular Events (MACE)
End point description:	
The primary efficacy end point was a four-component composite of adjudicated MACE, defined as death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke, or coronary revascularization, as assessed in a time-to first-event analysis. Intention-to-Treat Population is defined as all randomized participants.	
End point type	Primary
End point timeframe:	
Up to 68 months	

End point values	Bempedoic Acid 180 mg	Placebo Comparator		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6992	6978		
Units: Participants	819	927		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Bempedoic Acid 180 mg v Placebo Comparator
Number of subjects included in analysis	13970
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	0.96

Secondary: Number of Participants With First Occurrence of Three Component MACE

End point title	Number of Participants With First Occurrence of Three Component MACE
End point description:	The first key secondary end point was a three-component MACE, defined as death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke.
End point type	Secondary
End point timeframe:	Up to 68 months

End point values	Bempedoic Acid 180 mg	Placebo Comparator		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6992	6978		
Units: Participants	575	663		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Bempedoic Acid 180 mg v Placebo Comparator
Number of subjects included in analysis	13970
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0058
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	0.96

Secondary: Number of Participants With First Occurrence of Myocardial Infarction

End point title	Number of Participants With First Occurrence of Myocardial Infarction
End point description:	Number of participants with time to first occurrence of fatal and non-fatal myocardial infarction are presented.
End point type	Secondary
End point timeframe:	Up to 68 months

End point values	Bempedoic Acid 180 mg	Placebo Comparator		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6992	6978		
Units: Participants	261	334		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Bempedoic Acid 180 mg v Placebo Comparator
Number of subjects included in analysis	13970
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0016
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	0.91

Secondary: Number of Participants With Time to First Occurrence of Coronary Revascularization

End point title	Number of Participants With Time to First Occurrence of Coronary Revascularization
End point description:	Number of participants with time to first occurrence of coronary revascularization are presented.
End point type	Secondary
End point timeframe:	Up to 68 months

End point values	Bempedoic Acid 180 mg	Placebo Comparator		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6992	6978		
Units: Participants	435	529		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Bempedoic Acid 180 mg v Placebo Comparator
Number of subjects included in analysis	13970
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0013
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.92

Secondary: Number of Participants With Time to First Occurrence of Stroke

End point title	Number of Participants With Time to First Occurrence of Stroke
End point description:	Number of participants with time to first occurrence of fatal and non-fatal stroke.
End point type	Secondary
End point timeframe:	Up to 68 months

End point values	Bempedoic Acid 180 mg	Placebo Comparator		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6992	6978		
Units: Participants	135	158		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Bempedoic Acid 180 mg v Placebo Comparator
Number of subjects included in analysis	13970
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1593
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.85

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.07

Secondary: Number of Participants With Time to Cardiovascular Death

End point title	Number of Participants With Time to Cardiovascular Death
End point description: Number of participants with time to cardiovascular death are presented.	
End point type	Secondary
End point timeframe: Up to 68 months	

End point values	Bempedoic Acid 180 mg	Placebo Comparator		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6992	6978		
Units: Participants	269	257		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Bempedoic Acid 180 mg v Placebo Comparator
Number of subjects included in analysis	13970
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6227
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.24

Secondary: Number of Participants With Time to All-cause Mortality

End point title	Number of Participants With Time to All-cause Mortality
End point description: Number of participants with time to all-cause mortality are presented. All-cause mortality is death due to any cause.	

End point type	Secondary
End point timeframe:	
Up to 68 months	

End point values	Bempedoic Acid 180 mg	Placebo Comparator		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6992	6978		
Units: Participants	434	420		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Bempedoic Acid 180 mg v Placebo Comparator
Number of subjects included in analysis	13970
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6608
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.18

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 68 months

Adverse event reporting additional description:

Serious adverse events (SAEs) and non-SAEs were collected from Safety Population. The Safety Population comprises of all randomized participants who received at least 1 dose of study medication (investigational product). Deaths were endpoints and not reported as SAEs. Negatively adjudicated non-fatal MACE events were reported as SAEs.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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Reporting groups

Reporting group title	Bempedoic Acid 180 mg
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Reporting group description:

Participants were administered with Bempedoic acid 180 mg tablet once daily orally.

Reporting group title	Placebo Comparator
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Reporting group description:

Participants were administered with matching Placebo tablet once daily orally.

Serious adverse events	Bempedoic Acid 180 mg	Placebo Comparator	
Total subjects affected by serious adverse events			
subjects affected / exposed	1767 / 7001 (25.24%)	1733 / 6964 (24.89%)	
number of deaths (all causes)	437	420	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	19 / 7001 (0.27%)	21 / 6964 (0.30%)	
occurrences causally related to treatment / all	0 / 19	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	14 / 7001 (0.20%)	23 / 6964 (0.33%)	
occurrences causally related to treatment / all	0 / 14	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			

subjects affected / exposed	13 / 7001 (0.19%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 13	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	9 / 7001 (0.13%)	7 / 6964 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	7 / 7001 (0.10%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	6 / 7001 (0.09%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	6 / 7001 (0.09%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		
subjects affected / exposed	5 / 7001 (0.07%)	7 / 6964 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	5 / 7001 (0.07%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		
subjects affected / exposed	4 / 7001 (0.06%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		

subjects affected / exposed	4 / 7001 (0.06%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	3 / 7001 (0.04%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic neoplasm		
subjects affected / exposed	3 / 7001 (0.04%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive lobular breast carcinoma		
subjects affected / exposed	3 / 7001 (0.04%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to liver		
subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		

subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma		
subjects affected / exposed	3 / 7001 (0.04%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal adenoma		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basal cell carcinoma		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm malignant		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer metastatic		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer recurrent		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma		

subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial adenocarcinoma		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lymph nodes		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelodysplastic syndrome		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		

subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland cancer		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine leiomyoma		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute myeloid leukaemia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma pancreas		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenoma benign		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Astrocytoma		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign lung neoplasm		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 bladder		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign ovarian tumour		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer female		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial carcinoma		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial neoplasm		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon neoplasm		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer		
subjects affected / exposed	1 / 7001 (0.01%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ductal adenocarcinoma of pancreas		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal carcinoma		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal cancer		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glioma		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer metastatic		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular carcinoma		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hodgkin's disease		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal papilloma of breast		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal proliferative breast lesion		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lip squamous cell carcinoma		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma recurrent		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma in situ		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of unknown primary site		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melanocytic naevus		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to bone		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to central nervous system		

subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic carcinoma of the bladder		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic renal cell carcinoma		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic uterine cancer		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm prostate		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine tumour of the lung		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-Hodgkin's lymphoma		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 stage I		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal cancer metastatic		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal squamous cell carcinoma		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian adenoma		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian endometrioid carcinoma		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian neoplasm		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma metastatic		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary thyroid cancer		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid tumour benign		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour benign		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	1 / 7001 (0.01%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer stage II		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal neoplasm		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer metastatic		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seborrhoeic keratosis		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer metastatic		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 skin		
subjects affected / exposed	1 / 7001 (0.01%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer stage III		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue cancer metastatic		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell cancer of the renal pelvis and ureter		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteral neoplasm		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acoustic neuroma		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal squamous cell carcinoma		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendix cancer		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell lymphoma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign breast neoplasm			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign renal neoplasm			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone cancer metastatic			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain cancer metastatic			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm benign			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage I			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer stage III		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast neoplasm		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Carcinoid tumour pulmonary		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma stage 0		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chest wall tumour		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholesteatoma		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
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	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenocarcinoma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Desmoplastic melanoma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enchondromatosis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epithelioid mesothelioma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epithelioid sarcoma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Follicular thyroid cancer			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder adenocarcinoma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma multiforme			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioblastoma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hormone receptor positive breast cancer			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial tumour haemorrhage			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Juvenile melanoma benign			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer recurrent			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer stage II			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer stage III		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
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	0 / 7001 (0.00%)	1 / 6964 (0.01%)
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 stage III		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung carcinoma cell type unspecified recurrent		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant mesenteric neoplasm		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of ampulla of Vater		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant peritoneal neoplasm		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Melanoma recurrent		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma benign		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lung		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic malignant melanoma		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic squamous cell carcinoma		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm malignant		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm skin		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma metastatic		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal neoplasm			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal neoplasm benign			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic neoplasm			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile cancer			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic adenoma			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schwannoma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin cancer			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestine carcinoma			

subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid adenoma			
subjects affected / exposed	0 / 7001 (0.00%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer metastatic			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Peripheral arterial occlusive disease			
subjects affected / exposed	30 / 7001 (0.43%)	25 / 6964 (0.36%)	
occurrences causally related to treatment / all	0 / 43	0 / 40	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			

subjects affected / exposed	29 / 7001 (0.41%)	26 / 6964 (0.37%)
occurrences causally related to treatment / all	0 / 29	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	16 / 7001 (0.23%)	9 / 6964 (0.13%)
occurrences causally related to treatment / all	0 / 16	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic aneurysm		
subjects affected / exposed	13 / 7001 (0.19%)	9 / 6964 (0.13%)
occurrences causally related to treatment / all	0 / 13	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic stenosis		
subjects affected / exposed	13 / 7001 (0.19%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 14	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Deep vein thrombosis		
subjects affected / exposed	5 / 7001 (0.07%)	19 / 6964 (0.27%)
occurrences causally related to treatment / all	0 / 5	2 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	5 / 7001 (0.07%)	11 / 6964 (0.16%)
occurrences causally related to treatment / all	0 / 6	1 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	5 / 7001 (0.07%)	7 / 6964 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	4 / 7001 (0.06%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery stenosis		

subjects affected / exposed	4 / 7001 (0.06%)	4 / 6964 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive urgency			
subjects affected / exposed	3 / 7001 (0.04%)	6 / 6964 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	3 / 7001 (0.04%)	5 / 6964 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	3 / 7001 (0.04%)	4 / 6964 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	3 / 7001 (0.04%)	9 / 6964 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accelerated hypertension			
subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			

subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose vein		
subjects affected / exposed	2 / 7001 (0.03%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic dissection		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic intramural haematoma		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brachiocephalic artery stenosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dry gangrene		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism arterial		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Essential hypertension		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.01%)	0 / 6964 (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	1 / 7001 (0.01%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.01%)	1 / 6964 (0.01%)	
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 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian vein thrombosis			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein ruptured			

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vasospasm		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic aneurysm rupture		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic occlusion		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic thrombosis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial thrombosis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic vascular disorder		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery occlusion		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Internal haemorrhage		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein thrombosis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Labile hypertension			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leriche syndrome			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penetrating atherosclerotic ulcer			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poor peripheral circulation			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renovascular hypertension			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian artery stenosis			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Stillbirth			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	50 / 7001 (0.71%)	57 / 6964 (0.82%)	
occurrences causally related to treatment / all	2 / 55	3 / 60	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	8 / 7001 (0.11%)	8 / 6964 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	8 / 7001 (0.11%)	10 / 6964 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	4 / 7001 (0.06%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing			
subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Facial pain			
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication of device insertion			
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated hernia			

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Swelling face		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Treatment failure		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ulcer haemorrhage		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vessel puncture site haematoma		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site joint inflammation		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral swelling		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Swelling		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	2 / 7001 (0.03%)	5 / 6964 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anti-neutrophil cytoplasmic antibody positive vasculitis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contrast media allergy			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart transplant rejection			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			

Cardiac assistance device user subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve prosthesis user subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amputee subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia subjects affected / exposed	19 / 7001 (0.27%)	15 / 6964 (0.22%)	
occurrences causally related to treatment / all	0 / 21	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp subjects affected / exposed	4 / 7001 (0.06%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse subjects affected / exposed	3 / 7001 (0.04%)	4 / 6964 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatism subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Prostatitis			
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acquired hydrocele			
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast enlargement			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymal cyst			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	1 / 7001 (0.01%)	5 / 6964 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			

subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine haemorrhage		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast discomfort		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast mass		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical dysplasia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic haemorrhage		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peyronie's disease		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectocele		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterovaginal prolapse		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal adhesion			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	24 / 7001 (0.34%)	27 / 6964 (0.39%)	
occurrences causally related to treatment / all	0 / 33	0 / 33	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	22 / 7001 (0.31%)	29 / 6964 (0.42%)	
occurrences causally related to treatment / all	0 / 24	3 / 30	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	18 / 7001 (0.26%)	29 / 6964 (0.42%)	
occurrences causally related to treatment / all	0 / 18	0 / 32	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	11 / 7001 (0.16%)	14 / 6964 (0.20%)	
occurrences causally related to treatment / all	0 / 11	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	9 / 7001 (0.13%)	11 / 6964 (0.16%)	
occurrences causally related to treatment / all	0 / 9	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	8 / 7001 (0.11%)	11 / 6964 (0.16%)	
occurrences causally related to treatment / all	0 / 8	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			

subjects affected / exposed	7 / 7001 (0.10%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	6 / 7001 (0.09%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	4 / 7001 (0.06%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Acute pulmonary oedema		
subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	3 / 7001 (0.04%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sleep apnoea syndrome		
subjects affected / exposed	3 / 7001 (0.04%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial hyperreactivity		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cough		

subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea exertional		
subjects affected / exposed	2 / 7001 (0.03%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary fibrosis		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Asthma late onset		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Asthma-chronic obstructive pulmonary disease overlap syndrome		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atelectasis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Combined pulmonary fibrosis and emphysema		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic pulmonary fibrosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum haematoma		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal turbinate abnormality		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal cyst		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal haemorrhage		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax spontaneous		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mas		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory distress		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchial dyskinesia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vocal cord leukoplakia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acquired diaphragmatic eventration		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphonia			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic paralysis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity pneumonitis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngospasm			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal septum deviation			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary microemboli			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory acidosis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Throat tightness			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	3 / 7001 (0.04%)	5 / 6964 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			

subjects affected / exposed	2 / 7001 (0.03%)	8 / 6964 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Alcohol withdrawal syndrome		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Confusional state		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	1 / 7001 (0.01%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Delusional disorder, unspecified type		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Emotional distress		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination, auditory		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Panic attack		

subjects affected / exposed	1 / 7001 (0.01%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sleep disorder		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stress		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Suicide attempt		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute psychosis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Alcohol use disorder		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholism		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depression suicidal		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug abuse		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insomnia			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mood disorder due to a general medical condition			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic stress disorder			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somatic symptom disorder			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device failure			
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device breakage			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device end of service			
subjects affected / exposed	0 / 7001 (0.00%)	4 / 6964 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device lead damage			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	38 / 7001 (0.54%)	15 / 6964 (0.22%)	
occurrences causally related to treatment / all	3 / 39	1 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	18 / 7001 (0.26%)	14 / 6964 (0.20%)	
occurrences causally related to treatment / all	0 / 21	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			

subjects affected / exposed	17 / 7001 (0.24%)	19 / 6964 (0.27%)
occurrences causally related to treatment / all	0 / 18	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct stone		
subjects affected / exposed	6 / 7001 (0.09%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	1 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis chronic		
subjects affected / exposed	4 / 7001 (0.06%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cholestasis		
subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary obstruction		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary colic		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary dyskinesia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis acute		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder disorder		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic steatosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice cholestatic		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nonalcoholic fatty liver disease		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ampulla of Vater stenosis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis obstructive		

subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder rupture			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic lesion			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post cholecystectomy syndrome			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Glomerular filtration rate decreased			
subjects affected / exposed	3 / 7001 (0.04%)	5 / 6964 (0.07%)	
occurrences causally related to treatment / all	2 / 4	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			
subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			

subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure increased		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction decreased		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
SARS-CoV-2 test positive		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Weight decreased		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Angiogram		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aspiration pleural cavity		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biopsy lung		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood bicarbonate decreased		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium increased		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood urea increased		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood uric acid increased		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac stress test abnormal		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza B virus test positive		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Investigation		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Troponin increased		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Alanine aminotransferase increased		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiogram			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial test			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose decreased			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood magnesium decreased			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram ST segment depression			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic specific antigen increased			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Red blood cell sedimentation rate increased			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Humerus fracture			
subjects affected / exposed	8 / 7001 (0.11%)	11 / 6964 (0.16%)	
occurrences causally related to treatment / all	0 / 8	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	7 / 7001 (0.10%)	8 / 6964 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	7 / 7001 (0.10%)	10 / 6964 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	7 / 7001 (0.10%)	9 / 6964 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	7 / 7001 (0.10%)	6 / 6964 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	6 / 7001 (0.09%)	6 / 6964 (0.09%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	5 / 7001 (0.07%)	6 / 6964 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			

subjects affected / exposed	5 / 7001 (0.07%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	5 / 7001 (0.07%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Ankle fracture		
subjects affected / exposed	4 / 7001 (0.06%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	4 / 7001 (0.06%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	4 / 7001 (0.06%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	4 / 7001 (0.06%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		
subjects affected / exposed	4 / 7001 (0.06%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	4 / 7001 (0.06%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		

subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	3 / 7001 (0.04%)	4 / 6964 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	3 / 7001 (0.04%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			

subjects affected / exposed	2 / 7001 (0.03%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hand fracture		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		
subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural complication		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematuria		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative ileus		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Skin laceration		

subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sternal fracture		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	2 / 7001 (0.03%)	8 / 6964 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemothorax		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Accidental overdose		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acetabulum fracture		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Animal bite		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous graft site stenosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Avulsion fracture		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brachial plexus injury		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery restenosis		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cartilage injury		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest injury		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary vascular graft occlusion		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	1 / 7001 (0.01%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated incisional hernia		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intentional overdose		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal anastomosis complication		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint capsule rupture		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		

subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck injury			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery restenosis			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural discomfort			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural pulmonary embolism			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative hypertension			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural complication			

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Scapula fracture		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column injury		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic liver injury		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna fracture		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Underdose		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft complication		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft occlusion		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular injury		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound secretion		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anaesthetic complication cardiac		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
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 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac function disturbance postoperative			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve replacement complication			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery restenosis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
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 / 7001 (0.00%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eschar			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fractured sacrum			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
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 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heat stroke			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb traumatic amputation			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lisfranc fracture			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle rupture			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital haematoma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve injury			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprocedural myocardial infarction			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprosthetic fracture			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharynx radiation injury			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poisoning deliberate			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post intensive care syndrome			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural fever			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic pain			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative thoracic procedure complication			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound complication			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	0 / 7001 (0.00%)	4 / 6964 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 7001 (0.00%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suture related complication			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon injury			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
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 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transplant failure			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm ruptured			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound complication			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 7001 (0.00%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital cystic kidney disease			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital ectopic pancreas			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trisomy 18			

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hereditary neuropathic amyloidosis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal malrotation			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cervix canal atresia			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	81 / 7001 (1.16%)	95 / 6964 (1.36%)	
occurrences causally related to treatment / all	2 / 107	3 / 111	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	56 / 7001 (0.80%)	82 / 6964 (1.18%)	
occurrences causally related to treatment / all	0 / 62	0 / 84	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	56 / 7001 (0.80%)	53 / 6964 (0.76%)	
occurrences causally related to treatment / all	3 / 58	0 / 54	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	39 / 7001 (0.56%)	37 / 6964 (0.53%)	
occurrences causally related to treatment / all	0 / 42	0 / 45	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			

subjects affected / exposed	35 / 7001 (0.50%)	38 / 6964 (0.55%)
occurrences causally related to treatment / all	0 / 43	0 / 46
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial infarction		
subjects affected / exposed	28 / 7001 (0.40%)	35 / 6964 (0.50%)
occurrences causally related to treatment / all	0 / 28	1 / 35
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	25 / 7001 (0.36%)	33 / 6964 (0.47%)
occurrences causally related to treatment / all	0 / 26	0 / 34
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure acute		
subjects affected / exposed	19 / 7001 (0.27%)	20 / 6964 (0.29%)
occurrences causally related to treatment / all	0 / 21	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure chronic		
subjects affected / exposed	16 / 7001 (0.23%)	13 / 6964 (0.19%)
occurrences causally related to treatment / all	1 / 16	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial flutter		
subjects affected / exposed	14 / 7001 (0.20%)	9 / 6964 (0.13%)
occurrences causally related to treatment / all	0 / 17	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		
subjects affected / exposed	14 / 7001 (0.20%)	10 / 6964 (0.14%)
occurrences causally related to treatment / all	0 / 14	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve stenosis		
subjects affected / exposed	12 / 7001 (0.17%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 12	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Acute myocardial infarction		

subjects affected / exposed	11 / 7001 (0.16%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	9 / 7001 (0.13%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular tachycardia		
subjects affected / exposed	9 / 7001 (0.13%)	14 / 6964 (0.20%)
occurrences causally related to treatment / all	0 / 15	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	7 / 7001 (0.10%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial ischaemia		
subjects affected / exposed	7 / 7001 (0.10%)	10 / 6964 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	6 / 7001 (0.09%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Acute coronary syndrome		
subjects affected / exposed	5 / 7001 (0.07%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute left ventricular failure		
subjects affected / exposed	4 / 7001 (0.06%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiogenic shock		

subjects affected / exposed	4 / 7001 (0.06%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	4 / 7001 (0.06%)	4 / 6964 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	4 / 7001 (0.06%)	7 / 6964 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	4 / 7001 (0.06%)	5 / 6964 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	3 / 7001 (0.04%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	3 / 7001 (0.04%)	4 / 6964 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	3 / 7001 (0.04%)	7 / 6964 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	3 / 7001 (0.04%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			

subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular extrasystoles		
subjects affected / exposed	3 / 7001 (0.04%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve incompetence		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bradyarrhythmia		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiomyopathy		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic left ventricular failure		
subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Congestive cardiomyopathy		
subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery occlusion		

subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	2 / 7001 (0.03%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Myocarditis		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular arrhythmia		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adams-Stokes syndrome		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia supraventricular		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis coronary artery		

subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve disease		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
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	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extrasystoles		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Microvascular coronary artery disease		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nodal arrhythmia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial haemorrhage		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrest		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular extrasystoles		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachyarrhythmia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tachyarrhythmia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Trifascicular block		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anginal equivalent		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriospasm coronary			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block left			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac asthma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiorenal syndrome			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diastolic dysfunction			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve disease			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial fibrosis			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal rhythm			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paroxysmal atrioventricular block			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial cyst			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulseless electrical activity			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
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	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	0 / 7001 (0.00%)	5 / 6964 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	41 / 7001 (0.59%)	36 / 6964 (0.52%)	
occurrences causally related to treatment / all	2 / 43	1 / 36	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			

subjects affected / exposed	23 / 7001 (0.33%)	16 / 6964 (0.23%)
occurrences causally related to treatment / all	0 / 24	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	23 / 7001 (0.33%)	27 / 6964 (0.39%)
occurrences causally related to treatment / all	0 / 25	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	21 / 7001 (0.30%)	25 / 6964 (0.36%)
occurrences causally related to treatment / all	0 / 21	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	10 / 7001 (0.14%)	14 / 6964 (0.20%)
occurrences causally related to treatment / all	0 / 10	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	7 / 7001 (0.10%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	7 / 7001 (0.10%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ischaemia		
subjects affected / exposed	5 / 7001 (0.07%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	5 / 7001 (0.07%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		

subjects affected / exposed	5 / 7001 (0.07%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	5 / 7001 (0.07%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		
subjects affected / exposed	5 / 7001 (0.07%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	4 / 7001 (0.06%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic stroke		
subjects affected / exposed	4 / 7001 (0.06%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar infarction		
subjects affected / exposed	4 / 7001 (0.06%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	4 / 7001 (0.06%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		

subjects affected / exposed	3 / 7001 (0.04%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 3	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	3 / 7001 (0.04%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	3 / 7001 (0.04%)	4 / 6964 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	3 / 7001 (0.04%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			

subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	2 / 7001 (0.03%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal claudication		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Balance disorder		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basal ganglia haemorrhage		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basilar artery occlusion		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain oedema		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery disease		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery occlusion		
subjects affected / exposed	1 / 7001 (0.01%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Carpal tunnel syndrome		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular insufficiency		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		

subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis toxic			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intercostal neuralgia			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraventricular haemorrhage			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cerebral infarction			

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leukoencephalopathy		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Monoplegia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myasthenia gravis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve compression		
subjects affected / exposed	1 / 7001 (0.01%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Optic neuritis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paralysis recurrent laryngeal nerve		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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	1 / 7001 (0.01%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord compression		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Status epilepticus		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tension headache		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic outlet syndrome		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient global amnesia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Unresponsive to stimuli		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vasogenic cerebral oedema		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar stroke		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Altered state of consciousness		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Amnesia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aphasia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Axonal neuropathy		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Basilar artery aneurysm		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain injury		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery aneurysm		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar haemorrhage		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar syndrome			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral atrophy			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delayed ischaemic neurological deficit			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dystonia			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Frontotemporal dementia			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic unconsciousness			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive encephalopathy			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intensive care unit acquired weakness			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbosacral radiculopathy			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myoclonus			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Normal pressure hydrocephalus		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraparesis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paresis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Partial seizures		
subjects affected / exposed	0 / 7001 (0.00%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral nerve lesion		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular pain		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord herniation			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery dissection			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo CNS origin			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord paralysis			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	18 / 7001 (0.26%)	14 / 6964 (0.20%)	
occurrences causally related to treatment / all	0 / 18	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	5 / 7001 (0.07%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			

subjects affected / exposed	3 / 7001 (0.04%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic disorder		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia folate deficiency		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile neutropenia		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercoagulation		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leukopenia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymph node pain		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normocytic anaemia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombocytopenia		

subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombotic thrombocytopenic purpura		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coagulopathy		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemolytic anaemia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Immune thrombocytopenia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
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	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Polycythaemia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic infarction		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	8 / 7001 (0.11%)	8 / 6964 (0.11%)	
occurrences causally related to treatment / all	1 / 9	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	4 / 7001 (0.06%)	4 / 6964 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness bilateral			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniere's disease			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	12 / 7001 (0.17%)	11 / 6964 (0.16%)	
occurrences causally related to treatment / all	0 / 13	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness transient			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctival haemorrhage			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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	1 / 7001 (0.01%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular fibrosis			

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Optic ischaemic neuropathy		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vein occlusion		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Amaurosis fugax		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Amblyopia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinal oedema		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinopathy		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular hole		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vascular occlusion			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
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 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	22 / 7001 (0.31%)	21 / 6964 (0.30%)	
occurrences causally related to treatment / all	0 / 25	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	13 / 7001 (0.19%)	4 / 6964 (0.06%)	
occurrences causally related to treatment / all	0 / 13	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	13 / 7001 (0.19%)	16 / 6964 (0.23%)	
occurrences causally related to treatment / all	0 / 18	1 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	11 / 7001 (0.16%)	6 / 6964 (0.09%)	
occurrences causally related to treatment / all	3 / 17	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			

subjects affected / exposed	10 / 7001 (0.14%)	11 / 6964 (0.16%)
occurrences causally related to treatment / all	0 / 11	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive pancreatitis		
subjects affected / exposed	9 / 7001 (0.13%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	8 / 7001 (0.11%)	8 / 6964 (0.11%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	5 / 7001 (0.07%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	5 / 7001 (0.07%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	5 / 7001 (0.07%)	7 / 6964 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	5 / 7001 (0.07%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	5 / 7001 (0.07%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Vomiting		

subjects affected / exposed	5 / 7001 (0.07%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal hernia		
subjects affected / exposed	4 / 7001 (0.06%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	4 / 7001 (0.06%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	4 / 7001 (0.06%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 4	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	4 / 7001 (0.06%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		
subjects affected / exposed	4 / 7001 (0.06%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain lower		
subjects affected / exposed	3 / 7001 (0.04%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	3 / 7001 (0.04%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		

subjects affected / exposed	3 / 7001 (0.04%)	5 / 6964 (0.07%)
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	3 / 7001 (0.04%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	3 / 7001 (0.04%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	3 / 7001 (0.04%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	3 / 7001 (0.04%)	7 / 6964 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Diaphragmatic hernia		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (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	2 / 7001 (0.03%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		

subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	2 / 7001 (0.03%)	7 / 6964 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	2 / 7001 (0.03%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated inguinal hernia		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis relapsing		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal adhesions		

subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute abdomen		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal incontinence		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal polyp		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's oesophagus		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic gastritis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis microscopic		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		

subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	1 / 7001 (0.01%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal stenosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterovesical fistula		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral hernia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer perforation		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal necrosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia, obstructive		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired gastric emptying		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia strangulated		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ischaemia		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal polyp		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal strangulation		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Irritable bowel syndrome		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal stenosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		

subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mechanical ileus		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery embolism		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery stenosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal motility disorder		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngo-oesophageal diverticulum		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spigelian hernia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stomach granuloma		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Varices oesophageal		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal incarcerated hernia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		

subjects affected / exposed	0 / 7001 (0.00%)	7 / 6964 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholic pancreatitis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis noninfective		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coeliac artery stenosis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dieulafoy's vascular malformation		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		

subjects affected / exposed	0 / 7001 (0.00%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Epiploic appendagitis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
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	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
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 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal ulcer haemorrhage		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated umbilical hernia		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
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 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal fluid collection		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jejunal perforation		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal food impaction		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal spasm		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal varices haemorrhage		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis haemorrhagic		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis ulcerative		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic pseudocyst			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis necrotising			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumatosis intestinalis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haematoma			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	6 / 7001 (0.09%)	5 / 6964 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			

subjects affected / exposed	5 / 7001 (0.07%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperhidrosis		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adiposis dolorosa		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nail bed inflammation		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peau d'orange		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rash pruritic		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer haemorrhage			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stasis dermatitis			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous emphysema			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin lesion			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	35 / 7001 (0.50%)	29 / 6964 (0.42%)
occurrences causally related to treatment / all	5 / 37	1 / 32
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	17 / 7001 (0.24%)	15 / 6964 (0.22%)
occurrences causally related to treatment / all	3 / 26	2 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	8 / 7001 (0.11%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		
subjects affected / exposed	7 / 7001 (0.10%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	1 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	7 / 7001 (0.10%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention		
subjects affected / exposed	7 / 7001 (0.10%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		
subjects affected / exposed	5 / 7001 (0.07%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	1 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		
subjects affected / exposed	4 / 7001 (0.06%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	2 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		

subjects affected / exposed	3 / 7001 (0.04%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		
subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stenosis		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder prolapse		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder tamponade		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertonic bladder		

subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrosclerosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvi-ureteric obstruction		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst ruptured		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal disorder		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal hypertension		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal mass		

subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular necrosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urate nephropathy		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral meatus stenosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urge incontinence		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder haemorrhage		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary incontinence		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract obstruction		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder diverticulum		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
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 / 7001 (0.00%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis haemorrhagic		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysuria		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery arteriosclerosis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal infarct		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal injury			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder polyp			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	1 / 7001 (0.01%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoparathyroidism			
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic nodular goitre			
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism primary			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	71 / 7001 (1.01%)	69 / 6964 (0.99%)	
occurrences causally related to treatment / all	0 / 81	0 / 75	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	16 / 7001 (0.23%)	11 / 6964 (0.16%)	
occurrences causally related to treatment / all	1 / 18	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	13 / 7001 (0.19%)	12 / 6964 (0.17%)	
occurrences causally related to treatment / all	0 / 14	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	12 / 7001 (0.17%)	15 / 6964 (0.22%)	
occurrences causally related to treatment / all	0 / 13	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	11 / 7001 (0.16%)	6 / 6964 (0.09%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			

subjects affected / exposed	10 / 7001 (0.14%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	2 / 12	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	10 / 7001 (0.14%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 12	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	8 / 7001 (0.11%)	9 / 6964 (0.13%)
occurrences causally related to treatment / all	0 / 9	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis		
subjects affected / exposed	4 / 7001 (0.06%)	7 / 6964 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity		
subjects affected / exposed	4 / 7001 (0.06%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc disorder		
subjects affected / exposed	4 / 7001 (0.06%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		
subjects affected / exposed	4 / 7001 (0.06%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	3 / 7001 (0.04%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		

subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	2 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	3 / 7001 (0.04%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	3 / 7001 (0.04%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	3 / 7001 (0.04%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fistula			
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	2 / 7001 (0.03%)	4 / 6964 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			

subjects affected / exposed	2 / 7001 (0.03%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Arthropathy		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Back disorder		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cartilage hypertrophy		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemarthrosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint stiffness		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Kyphosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metatarsalgia		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle haemorrhage		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neck mass		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporotic fracture		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pathological fracture		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
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 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudarthrosis		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriatic arthropathy		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		
subjects affected / exposed	1 / 7001 (0.01%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sympathetic posterior cervical syndrome		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial cyst		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Synovitis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendonitis		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tenosynovitis stenosans		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibromyalgia		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture pain		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma muscle		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc space narrowing		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb discomfort		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal stiffness		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
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	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis		
subjects affected / exposed	0 / 7001 (0.00%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthritis		

subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	0 / 7001 (0.00%)	3 / 6964 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic lupus erythematosus			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic spinal stenosis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	84 / 7001 (1.20%)	90 / 6964 (1.29%)	
occurrences causally related to treatment / all	0 / 86	0 / 90	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	84 / 7001 (1.20%)	81 / 6964 (1.16%)	
occurrences causally related to treatment / all	0 / 93	0 / 92	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	56 / 7001 (0.80%)	75 / 6964 (1.08%)	
occurrences causally related to treatment / all	0 / 56	0 / 76	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	24 / 7001 (0.34%)	22 / 6964 (0.32%)	
occurrences causally related to treatment / all	0 / 24	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			

subjects affected / exposed	23 / 7001 (0.33%)	33 / 6964 (0.47%)
occurrences causally related to treatment / all	0 / 24	1 / 34
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	19 / 7001 (0.27%)	8 / 6964 (0.11%)
occurrences causally related to treatment / all	0 / 19	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	19 / 7001 (0.27%)	27 / 6964 (0.39%)
occurrences causally related to treatment / all	2 / 24	0 / 35
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	11 / 7001 (0.16%)	21 / 6964 (0.30%)
occurrences causally related to treatment / all	0 / 11	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	10 / 7001 (0.14%)	7 / 6964 (0.10%)
occurrences causally related to treatment / all	1 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	8 / 7001 (0.11%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	7 / 7001 (0.10%)	8 / 6964 (0.11%)
occurrences causally related to treatment / all	0 / 8	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	7 / 7001 (0.10%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		

subjects affected / exposed	7 / 7001 (0.10%)	7 / 6964 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	5 / 7001 (0.07%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia bacterial		
subjects affected / exposed	5 / 7001 (0.07%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Septic shock		
subjects affected / exposed	5 / 7001 (0.07%)	8 / 6964 (0.11%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	4 / 7001 (0.06%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	4 / 7001 (0.06%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	4 / 7001 (0.06%)	5 / 6964 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		
subjects affected / exposed	4 / 7001 (0.06%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		

subjects affected / exposed	3 / 7001 (0.04%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic sinusitis		
subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	3 / 7001 (0.04%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	3 / 7001 (0.04%)	7 / 6964 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	3 / 7001 (0.04%)	6 / 6964 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection		
subjects affected / exposed	3 / 7001 (0.04%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection		
subjects affected / exposed	3 / 7001 (0.04%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		

subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	2 / 7001 (0.03%)	6 / 6964 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complicated appendicitis			
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer helicobacter			
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			

subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella sepsis		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	2 / 7001 (0.03%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis acute		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia legionella		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	2 / 7001 (0.03%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary sepsis		
subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal abscess		

subjects affected / exposed	2 / 7001 (0.03%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess intestinal		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess oral		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendiceal abscess		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Babesiosis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary sepsis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis viral		

subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve vegetation		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis staphylococcal		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis klebsiella		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related bacteraemia		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endophthalmitis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterobacter sepsis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal sepsis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epstein-Barr virus infection		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia bacteraemia		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis yersinia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Giardiasis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter infection		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster oticus		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious pleural effusion		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of bronchiectasis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney infection		

subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine infection		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung abscess		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningoencephalitis herpetic		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising fasciitis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis bacterial		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parotitis		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis infective		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perirectal abscess		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pilonidal cyst		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia influenzal		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pseudomonal		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural cellulitis		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		

subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus infection		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhinovirus infection		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue infection		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
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	1 / 7001 (0.01%)	0 / 6964 (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 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal bacteraemia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Suspected COVID-19		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic infection		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vestibular neuronitis		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Viral myocarditis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Viral pericarditis		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Viral upper respiratory tract infection		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal abscess		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess limb		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Acute HIV infection		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute sinusitis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atypical pneumonia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	0 / 7001 (0.00%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial sepsis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis infective		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter colitis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter gastroenteritis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis streptococcal		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium colitis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic abscess		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal perforated		
subjects affected / exposed	0 / 7001 (0.00%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis infectious		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterobacter bacteraemia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis bacterial		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis salmonella		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis B		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected bite		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective spondylitis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		

subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal sepsis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Listeriosis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lyme disease		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site infection		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelitis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising soft tissue infection		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmic herpes zoster		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis externa		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic abscess		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontitis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal abscess		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillar abscess		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia haemophilus		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
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	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural sepsis		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
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 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus bronchitis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
SARS-CoV-2 sepsis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Septic encephalopathy		
subjects affected / exposed	0 / 7001 (0.00%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sinusitis		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal skin infection		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Syphilis		

subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal infection			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection staphylococcal			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	11 / 7001 (0.16%)	16 / 6964 (0.23%)	
occurrences causally related to treatment / all	0 / 11	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	7 / 7001 (0.10%)	9 / 6964 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			

subjects affected / exposed	7 / 7001 (0.10%)	7 / 6964 (0.10%)
occurrences causally related to treatment / all	1 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	7 / 7001 (0.10%)	9 / 6964 (0.13%)
occurrences causally related to treatment / all	1 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	6 / 7001 (0.09%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	3 / 7001 (0.04%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	3 / 7001 (0.04%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic acidosis		
subjects affected / exposed	2 / 7001 (0.03%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		
subjects affected / exposed	2 / 7001 (0.03%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Decreased appetite		

subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	1 / 7001 (0.01%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	1 / 7001 (0.01%)	4 / 6964 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	1 / 7001 (0.01%)	0 / 6964 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity		

subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	1 / 7001 (0.01%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic complication		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Failure to thrive		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	0 / 7001 (0.00%)	3 / 6964 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypophagia		
subjects affected / exposed	0 / 7001 (0.00%)	1 / 6964 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ketoacidosis		
subjects affected / exposed	0 / 7001 (0.00%)	2 / 6964 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

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

Non-serious adverse events	Bempedoic Acid 180 mg	Placebo Comparator	
Total subjects affected by non-serious adverse events subjects affected / exposed	5805 / 7001 (82.92%)	5490 / 6964 (78.83%)	
Investigations Blood uric acid increased subjects affected / exposed occurrences (all)	393 / 7001 (5.61%) 439	186 / 6964 (2.67%) 201	
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	747 / 7001 (10.67%) 907	804 / 6964 (11.55%) 978	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	479 / 7001 (6.84%) 572	493 / 6964 (7.08%) 574	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Myalgia subjects affected / exposed occurrences (all)	548 / 7001 (7.83%) 675 404 / 7001 (5.77%) 458 392 / 7001 (5.60%) 511	554 / 6964 (7.96%) 722 450 / 6964 (6.46%) 511 470 / 6964 (6.75%) 599	
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	731 / 7001 (10.44%) 756	801 / 6964 (11.50%) 826	
Nasopharyngitis subjects affected / exposed occurrences (all) Urinary tract infection	351 / 7001 (5.01%) 424	389 / 6964 (5.59%) 462	

subjects affected / exposed occurrences (all)	539 / 7001 (7.70%) 802	515 / 6964 (7.40%) 784	
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	458 / 7001 (6.54%)	435 / 6964 (6.25%)	
occurrences (all)	509	475	
Hyperuricaemia			
subjects affected / exposed	763 / 7001 (10.90%)	393 / 6964 (5.64%)	
occurrences (all)	868	435	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 February 2017	Added a line for Amendment 1 version and date to reflect amendment version details. Changed Subject Inclusion Criteria #5 within Synopsis and Section 7.1 to require that women of childbearing potential must be willing to use 2 instead of 1 acceptable methods of birth control and to slightly revise the definition of true abstinence. These changes were completed to align requirements across multiple countries for birth control in women of childbearing potential. Changed Section 10.7.1, Participants Inadvertently Enrolled, and Section 10.7.3, Permanent Discontinuation of Investigational Medical Product, to require that women of childbearing potential must be willing to use 2 instead of 1 acceptable methods of birth control. These changes were completed to align requirements across multiple countries for birth control in women of childbearing potential. Changed names and titles of Sponsor representatives providing signage on the protocol amendment. Changed names and titles of Sponsor representatives providing signage on the protocol amendment.
15 November 2017	Clinical endpoint of hospitalization for unstable angina was removed from primary and all secondary composite endpoints. Sample size section was re-organized and redundant texts were removed for better clarity. Inclusion criterion for age was modified to add a cap of >85 years at Week -5 (Visit S1). Inclusion criterion for an acceptable method of birth control includes oral birth control medications (among other acceptable methods). Inclusion criterion of documented history of coronary artery disease for angiographic stenosis changed from >50% to ≥50%. Exclusion criterion for recent and unstable cardiovascular disease (CVD) was modified to explicitly list recent (within 90 days prior to or during screening) myocardial infarction (MI), coronary revascularization, peripheral arterial revascularization, ischemic stroke, carotid endarterectomy, and carotid stenting. Inclusion criteria already stated that recent and unstable CVD events did not qualify, but additional clarification was provided by explicitly excluding these CVD events. Exclusion criterion for HbA1C upper limit changed from ≥12% to ≥10% at Week 5 (Visit S1). Exclusion criterion for stable use of allowable medications was modified to specify that use of PCSK9 inhibitors must be stable for at least 12 weeks prior to screening. Instructions for taking investigational medicinal product (IMP) were modified to allow ingestion of IMP at a similar time of the day instead of just in the morning. Instruction that electrocardiogram (ECG) be obtained prior to blood collection removed to ease completion of these procedures. Urine pregnancy test (in female participants of childbearing potential) was added at Day 1 (Visit T1). Analysis of the secondary efficacy endpoint high-sensitivity C-reactive protein (hsCRP) was modified. Analysis for tertiary endpoints of lipid parameters at different time points was modified to use mixed model repeated measure instead of analysis of covariance (ANCOVA).
30 July 2018	Changed Subject Inclusion Criteria #2 within Synopsis and Section 7.1 to revise the definition of statin intolerance to include participants who have failed either 1) two or more statins at any dose, or 2) one statin at any dose and unwilling to attempt a second statin or advised by a physician to not attempt a second statin. This change will allow these participants with or at high risk for cardiovascular disease who cannot tolerate statin therapy but did not meet each detail of the previous statin intolerance definition (failure of 2 statins, one at the lowest dose) to enroll in the study. Changed Subject Inclusion Criteria #3 within Synopsis and Section 7.1 to revise written confirmation of statin intolerance provided by participants to include statement that many other participants who are unable to tolerate one statin/dose are able to tolerate a different statin or dose. This change will ensure that participants who have failed one statin at any dose or who have not tried low-dose statin and are unwilling to attempt another statin/dose are aware that many other participants who do try another statin/dose are able to tolerate it.

19 December 2019	<p>Revised the number of clinical sites to the actual number of sites included in the study. Study objectives were revised to include the assessment of efficacy outcomes. Efficacy and safety endpoints were revised to align with the revised study objectives. Revised the end of study definition by increasing the number of required clinical endpoints to 1620 and 810 respectively, resulting in increased number of planned participants. Revised the estimated study duration to accommodate the increase in number of clinical endpoints required to meet the defined end of study criteria. The addition of an adjudication committee, identified as the Diabetes Committee, has been included. Number of planned participants was revised to support the increased number of primary 4-component major adverse cardiovascular event (MACE) events. Adjusted the cap for participants who are a part of the group identified as 'high risk for a CVD event' based solely on Reynolds risk, SCORE risk, or coronary artery calcium score to 4200 randomized participants to accommodate for the increased number of planned participants. Clarified the elevated low-density lipoprotein cholesterol (LDL-C) monitoring and management plan. Revised statistics sections. Revised adverse events of special interest by removing hypoglycemia with associated metabolic acidosis and neurocognitive events. Neurocognitive events: Neurocognitive events was originally included as an adverse event of special interest (AESI) in this and other bempedoic acid protocols based on anecdotal reports of cognitive impairment linked to statin use. Revised the nonclinical experience, previous human experience, and risk benefit summary sections to include current information for the investigators. Prohibited and permitted concomitant medication were revised to align with revision to protocol defined elevated LDL-C monitoring and management plan.</p>
24 September 2020	<p>Secondary objectives revised to specifically refer to type 2 diabetes mellitus participants. Secondary efficacy time-to-event endpoints were revised to support the study Objectives. Secondary efficacy lipid and biomarker endpoint for glycosylated hemoglobin, Type A1C (HbA1C) revised to specifically refer to type 2 diabetes mellitus participants. Safety endpoints clarified by removing reference to muscle related adverse events (AEs) since they are already included with the AESI and including weight as a part of vital signs. Revised statistics sections, including plans for interim analysis, analysis populations, endpoint analysis plans, and analysis for AESI and post-randomization of adjunctive lipid-modifying therapy. Background information was revised. Permitted and prohibited concomitant medication sections were revised to include the prohibition of pravastatin at average daily dose greater than or equal to 80 mg and to Bempedoic Acid (ETC-1002) add clarification that any newly available proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitors that may become commercially available are also allowed. Study procedures and assessment section for in-clinic study visits starting at Month 6 in the study through end of study were revised to reflect allowable changes to the procedures to address the Coronavirus disease of 2019 (COVID-19) pandemic. Assessment of diabetes was revised to reflect the changes in scope for assessing the diagnosis of diabetes. Monitoring and management of potential hypoglycemia associated with metabolic acidosis was added to support further evaluation and characterization of this AESI. AESI sections were revised to reflect the current list of events being assessed in the study. Study monitoring was revised to include additional committees that would have access to source documentation. Administrative structure was revised to include additional monitoring vendor.</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported