



Clinical trial results:

A Clinical Outcomes Study of Darapladib versus Placebo in Subjects with Chronic Coronary Heart Disease to Compare the Incidence of Major Adverse Cardiovascular Events (MACE)

Summary

EudraCT number	2008-005575-96
Trial protocol	NL ES HU SE DE GB SK FR DK EE BE CZ PL BG IT GR
Global end of trial date	17 October 2013

Results information

Result version number	v1 (current)
This version publication date	27 April 2016
First version publication date	11 April 2015

Trial information

Trial identification

Sponsor protocol code	LPL100601
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00799903
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 866 435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 866 435-7343,

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	02 December 2013
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	17 October 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate clinical efficacy of long-term treatment with darapladib Enteric Coated tablets, 160 mg (oral once daily dose) as compared to placebo when added to standard of care in a chronic Coronary Heart Disease (CHD) patient population on the incidence of first occurrence of the composite of Major Adverse Cardiovascular Events (MACE) (cardiovascular death, non-fatal Myocardial Infarction (MI), non-fatal stroke).

Protection of trial subjects:

The secreted isoform of Lp-PLA2 was first identified on the basis of its in vitro ability to degrade platelet-activating factor (PAF), hence it is also known as PAF-acetylhydrolase (PAF-AH). Although the assertion that Lp-PLA2 degrades PAF in vivo remains unproven, PAF has been implicated in prothrombotic, allergic and inflammatory responses, suggesting that blocking its degradation in patients may be detrimental. Due to this theoretical concern, participants with severe asthma poorly controlled on pharmacotherapy and participants with a history of anaphylaxis, anaphylactoid (resembling anaphylaxis) reactions, or severe allergic responses were excluded from participating in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 December 2008
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	Estonia: 77
Country: Number of subjects enrolled	France: 250
Country: Number of subjects enrolled	Germany: 1089
Country: Number of subjects enrolled	Greece: 187
Country: Number of subjects enrolled	Hungary: 410
Country: Number of subjects enrolled	Italy: 256
Country: Number of subjects enrolled	Netherlands: 444
Country: Number of subjects enrolled	Norway: 113
Country: Number of subjects enrolled	Poland: 510
Country: Number of subjects enrolled	Romania: 411
Country: Number of subjects enrolled	Slovakia: 120
Country: Number of subjects enrolled	Spain: 474
Country: Number of subjects enrolled	Sweden: 299
Country: Number of subjects enrolled	United Kingdom: 184
Country: Number of subjects enrolled	Belgium: 202

Country: Number of subjects enrolled	Bulgaria: 222
Country: Number of subjects enrolled	Czech Republic: 774
Country: Number of subjects enrolled	Denmark: 102
Country: Number of subjects enrolled	Argentina: 542
Country: Number of subjects enrolled	Australia: 306
Country: Number of subjects enrolled	Brazil: 384
Country: Number of subjects enrolled	Canada: 780
Country: Number of subjects enrolled	Chile: 195
Country: Number of subjects enrolled	China: 369
Country: Number of subjects enrolled	Hong Kong: 117
Country: Number of subjects enrolled	India: 398
Country: Number of subjects enrolled	Japan: 318
Country: Number of subjects enrolled	Korea, Republic of: 503
Country: Number of subjects enrolled	Mexico: 141
Country: Number of subjects enrolled	New Zealand: 202
Country: Number of subjects enrolled	Pakistan: 250
Country: Number of subjects enrolled	Peru: 78
Country: Number of subjects enrolled	Philippines: 219
Country: Number of subjects enrolled	Russian Federation: 654
Country: Number of subjects enrolled	South Africa: 386
Country: Number of subjects enrolled	Taiwan: 200
Country: Number of subjects enrolled	Thailand: 207
Country: Number of subjects enrolled	Ukraine: 353
Country: Number of subjects enrolled	United States: 3102
Worldwide total number of subjects	15828
EEA total number of subjects	6124

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)	7701
From 65 to 84 years	8029
85 years and over	98

Subject disposition

Recruitment

Recruitment details:

The study consisted of a Screening Phase of up to 8 weeks duration, a Treatment Phase, an End-of-Treatment (EOT) visit, and a Follow-up visit scheduled for 35 +/- 7 days after last study drug intake. The median treatment duration was anticipated to be 2.75 years.

Pre-assignment

Screening details:

During the Screening Phase of the study, participants presenting with chronic Coronary Heart Disease (CHD) were randomized within 8 weeks. In addition to chronic CHD, participants were required to have at least one additional predictor of cardiovascular risk specified in the protocol.

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	Investigator, Monitor, Data analyst, Carer, Subject, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants were randomized to receive matching placebo once daily.

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

Dosage and administration details:

enteric-coated, micronized, free-base tablet dosed once daily with food and swallowed whole (not crushed or chewed)

Arm title	Darapladib
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Arm description:

Participants were randomized to receive darapladib 160 milligram (mg) enteric-coated tablets once daily.

Arm type	Experimental
Investigational medicinal product name	darapladib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

160 milligram (mg) enteric-coated, micronized, free-base tablet dosed once daily with food and swallowed whole (not crushed or chewed)

Number of subjects in period 1	Placebo	Darapladib
Started	7904	7924
Completed	7631	7646
Not completed	273	278
Consent withdrawn by subject	179	175
Investigator Site Closed	25	23
Lost to follow-up	69	80

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants were randomized to receive matching placebo once daily.	
Reporting group title	Darapladib
Reporting group description:	
Participants were randomized to receive darapladib 160 milligram (mg) enteric-coated tablets once daily.	

Reporting group values	Placebo	Darapladib	Total
Number of subjects	7904	7924	15828
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
arithmetic mean	64.3	64.5	
standard deviation	± 9.39	± 9.31	-
Gender categorical			
Units: Subjects			
Female	1506	1461	2967
Male	6398	6463	12861
Race, customized			
Units: Subjects			
White	6177	6233	12410
Japanese/East Asian (EA)/South EA Heritage (HER)	1017	1003	2020
Central/South Asian Heritage	347	347	694
Mixed Asian Heritage	2	1	3
African American (AA)/African Heritage (AH)	191	175	366
American Indian or Alaska Native	108	106	214
African American/African Heritage & White	36	37	73
American Indian or Alaska Native & White	12	11	23
Native Hawaiian or other Pacific Islander	11	4	15
AA/AH & American Indian or Alaska Native	2	1	3

Asian & White	0	3	3
Native Hawaiian or other Pacific Islander & White	0	2	2
African American/African Heritage & Asian	1	0	1
American Indian or Alaska Native & Asian	0	1	1

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants were randomized to receive matching placebo once daily.	
Reporting group title	Darapladib
Reporting group description:	
Participants were randomized to receive darapladib 160 milligram (mg) enteric-coated tablets once daily.	

Primary: Number of participants with first occurrence of any component of the composite of major adverse cardiovascular events (cardiovascular [CV] death, non-fatal myocardial infarction [MI] or non-fatal stroke) during the time period for follow-up of CV events

End point title	Number of participants with first occurrence of any component of the composite of major adverse cardiovascular events (cardiovascular [CV] death, non-fatal myocardial infarction [MI] or non-fatal stroke) during the time period for follow-up of CV events
End point description:	
CV death=death due to a CV cause, which included but was not limited to deaths resulting from stroke, arrhythmia, sudden death (witnessed/unwitnessed), MI, heart failure, pulmonary embolism, peripheral arterial disease, or complications of a CV procedure. Deaths not clearly attributable to non-CV causes are considered to be CV deaths. Acute MI=evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Prior MI diagnosed post-randomization (e.g., silent MI)=the development of new pathological Q waves with/without symptoms OR imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischemic cause (pre-event imaging data required for verification of new abnormality), OR pathological findings of a healed/healing MI. Stroke=presence of a new focal neurologic deficit thought to be of vascular origin, with signs/symptoms lasting >24 hours or results in death (in <24 hours).	
End point type	Primary
End point timeframe:	
From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)	

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 ^[1]	7924 ^[2]		
Units: participants	819	769		

Notes:

[1] - All Randomized (Intent-to-Treat [ITT]) Population: all randomized participants

[2] - All Randomized (Intent-to-Treat [ITT]) Population: all randomized participants

Statistical analyses

Statistical analysis title	Statistical Analysis for Primary Endpoint
Comparison groups	Placebo v Darapladib

Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.199 ^[3]
Method	Cox proportional hazard regression model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94
Confidence interval	
level	95.1 %
sides	2-sided
lower limit	0.85
upper limit	1.03

Notes:

[3] - Statistical significance of this P-value was based on the alpha-spending function of this study.

Secondary: Number of participants with first occurrence of any event in the composite of major coronary events (coronary heart disease [CHD] death, non-fatal MI, or urgent coronary revascularization [CR] for MI) during the time period for follow-up (FU) of CV events

End point title	Number of participants with first occurrence of any event in the composite of major coronary events (coronary heart disease [CHD] death, non-fatal MI, or urgent coronary revascularization [CR] for MI) during the time period for follow-up (FU) of CV events
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End point description:

CHD death=occurrence of a fatal MI, death caused by documented cardiac arrest, death resulting from heart failure in a participant with known CHD, death from other forms of acute/chronic CHD, unwitnessed death of unknown origin, or sudden death. Acute MI=evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Prior MI diagnosed post-randomization (e.g., silent MI)=the development of new pathological Q waves with/without symptoms OR imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischemic cause (pre-event imaging data required for verification of new abnormality), OR pathological findings of a healed/healing MI. Urgent CR for MI=ischemic discomfort at rest that prompted CR (percutaneous coronary intervention [PCI: any attempt at CR even if not successful] or coronary artery bypass graft) during the same hospitalization or resulted in hospital transfer for the purpose of CR.

End point type	Secondary
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End point timeframe:

From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 ^[4]	7924 ^[5]		
Units: participants	814	737		

Notes:

[4] - All Randomized (ITT) Population

[5] - All Randomized (ITT) Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #1
Comparison groups	Placebo v Darapladib

Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.045
Method	Cox proportional hazard regression model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1

Secondary: Number of participants with first occurrence of any event in the composite of total coronary events (CHD death, non-fatal MI, hospitalization for unstable angina, or any coronary revascularization procedure) during time period for FU of CV events

End point title	Number of participants with first occurrence of any event in the composite of total coronary events (CHD death, non-fatal MI, hospitalization for unstable angina, or any coronary revascularization procedure) during time period for FU of CV events
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End point description:

CHD death, acute MI, and prior MI are defined in the previous secondary endpoint (major coronary events). Hospitalization for unstable angina=one of the following, but not fulfilling the criteria for MI: ischemic discomfort at rest associated with electrocardiogram (ECG) changes leading to hospitalization; ischemic discomfort at rest regardless of ECG changes leading to hospitalization and revascularization during the same admission; ischemic discomfort at rest in hospital associated with ECG changes; ischemic discomfort at rest in hospital without ECG changes resulting in revascularization during the same admission. NOTE: The event was not considered to be unstable angina if, after invasive/non-invasive testing or other diagnostic testing, the discomfort is found not to be caused by myocardial ischemia.

End point type	Secondary
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End point timeframe:

From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 ^[6]	7924 ^[7]		
Units: participants	1269	1159		

Notes:

[6] - All Randomized (ITT) Population

[7] - All Randomized (ITT) Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #2
Comparison groups	Placebo v Darapladib

Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.019
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	0.98

Secondary: Number of participants with CV death during the time period for follow-up of CV events

End point title	Number of participants with CV death during the time period for follow-up of CV events
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End point description:

CV death is defined as a death due to a CV cause, which included but was not limited to deaths resulting from stroke, arrhythmia, sudden death (witnessed/unwitnessed), MI, heart failure, pulmonary embolism, peripheral arterial disease, or complications of a CV procedure. Deaths not clearly attributable to non-CV causes are considered to be CV deaths.

End point type	Secondary
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End point timeframe:

From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 ^[8]	7924 ^[9]		
Units: participants	373	359		

Notes:

[8] - All Randomized (ITT) Population

[9] - All Randomized (ITT) Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #3
Comparison groups	Placebo v Darapladib
Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.594
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.96

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.11

Secondary: Number of participants with first occurrence of MI (fatal/non-fatal) during the time period for follow-up of CV events

End point title	Number of participants with first occurrence of MI (fatal/non-fatal) during the time period for follow-up of CV events
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End point description:

Acute MI is defined as evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Prior MI diagnosed post-randomization (e.g., silent MI)=the development of new pathological Q waves with/without symptoms OR imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischemic cause (pre-event imaging data required for verification of new abnormality), OR pathological findings of a healed/healing MI.

End point type	Secondary
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End point timeframe:

From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 ^[10]	7924 ^[11]		
Units: participants	405	361		

Notes:

[10] - All Randomized (ITT) Population

[11] - All Randomized (ITT) Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #4
Comparison groups	Darapladib v Placebo
Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.108
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.03

Secondary: Number of participants with first occurrence of stroke (fatal/non-fatal) during the time period for follow-up of CV events

End point title	Number of participants with first occurrence of stroke (fatal/non-fatal) during the time period for follow-up of CV events
End point description: Stroke is defined as the presence of a new focal neurologic deficit thought to be of vascular origin, with signs/symptoms lasting >24 hours or results in death (in <24 hours).	
End point type	Secondary
End point timeframe: From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)	

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 ^[12]	7924 ^[13]		
Units: participants	152	154		

Notes:

[12] - All Randomized (ITT) Population

[13] - All Randomized (ITT) Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #5
Comparison groups	Placebo v Darapladib
Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.92
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.27

Secondary: Number of participants with first occurrence of any component of the composite of all-cause mortality, non-fatal MI, or non-fatal stroke during the time period for follow-up of CV events

End point title	Number of participants with first occurrence of any component of the composite of all-cause mortality, non-fatal MI, or non-fatal stroke during the time period for follow-up of CV events
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End point description:

Acute MI is defined as evidence of myocardial necrosis in a clinical setting consistent with myocardial ischemia. Prior MI diagnosed post-randomization (e.g., silent MI)=the development of new pathological Q waves with/without symptoms OR imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract, in the absence of a non-ischemic cause (pre-event imaging data required

for verification of new abnormality), OR pathological findings of a healed/healing MI. Stroke=presence of a new focal neurologic deficit thought to be of vascular origin, with signs/symptoms lasting >24 hours or results in death (in <24 hours).

End point type	Secondary
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End point timeframe:

From randomization until the End-of-Treatment visit or the last date on which endpoints were able to be assessed (up to 4.25 years/average of 3.51 years)

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 ^[14]	7924 ^[15]		
Units: participants	962	926		

Notes:

[14] - All Randomized (ITT) Population

[15] - All Randomized (ITT) Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #6
Comparison groups	Placebo v Darapladib
Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.397
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.05

Secondary: Number of participants with all-cause mortality during the time period for vital status

End point title	Number of participants with all-cause mortality during the time period for vital status
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End point description:

The number of participants with all-cause mortality was assessed.

End point type	Secondary
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End point timeframe:

From randomization until death or study completion (up to 4.49 years/average of 3.65 years)

End point values	Placebo	Darapladib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7904 ^[16]	7924 ^[17]		
Units: participants	577	582		

Notes:

[16] - All Randomized (ITT) Population

[17] - All Randomized (ITT) Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #7
Comparison groups	Placebo v Darapladib
Number of subjects included in analysis	15828
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.87
Method	Cox proportional hazards regression
Parameter estimate	Hazard ratio (HR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.13

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Start=Randomization; Stop=Longer of 35 days after last dose of IP or follow-up (FU) visit. "SAEs assessed as related to IP, study participation, or a GSK concomitant medication" and cancer/GI polyps/neoplasms were recorded up to/including any FU contact.

Adverse event reporting additional description:

SAEs and non-serious AEs were collected in members of the Safety Population, comprised of all randomized participants who received at least one dose of investigational product. Post-randomization AEs have an onset date that is on or after the randomization date.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants received matching placebo once daily.

Reporting group title	Darapladib
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Reporting group description:

Participants received darapladib 160 milligram (mg) enteric-coated tablets once daily.

Serious adverse events	Placebo	Darapladib	
Total subjects affected by serious adverse events			
subjects affected / exposed	3448 / 7890 (43.70%)	3369 / 7912 (42.58%)	
number of deaths (all causes)	577	582	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute lymphocytic leukaemia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Acute myeloid leukaemia			

subjects affected / exposed	0 / 7890 (0.00%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 5	
Adenocarcinoma			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Adenocarcinoma gastric			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	4 / 7890 (0.05%)	10 / 7912 (0.13%)	
occurrences causally related to treatment / all	1 / 4	4 / 11	
deaths causally related to treatment / all	0 / 1	1 / 1	
Adenocarcinoma pancreas			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Adenoid cystic carcinoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenocortical carcinoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ameloblastoma			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaplastic astrocytoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiosarcoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
B-cell lymphoma			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Basal cell carcinoma			
subjects affected / exposed	8 / 7890 (0.10%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 10	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign anorectal neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign breast neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign hepatic neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign lung neoplasm			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of thyroid gland			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (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	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign salivary gland neoplasm			
subjects affected / exposed	4 / 7890 (0.05%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct adenocarcinoma			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct cancer			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	1 / 2	
Bladder cancer			
subjects affected / exposed	19 / 7890 (0.24%)	21 / 7912 (0.27%)	
occurrences causally related to treatment / all	1 / 20	1 / 25	
deaths causally related to treatment / all	0 / 1	0 / 2	
Bladder cancer recurrent			

subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			
subjects affected / exposed	2 / 7890 (0.03%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 2	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder papilloma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone cancer			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bone cancer metastatic			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Bowen's disease			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			

subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Brain neoplasm benign			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Brain neoplasm malignant			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	7 / 7890 (0.09%)	9 / 7912 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage I			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial carcinoma			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
Cancer pain			

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid tumour of the duodenum			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid tumour of the gastrointestinal tract			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac myxoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix carcinoma			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	3 / 7890 (0.04%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 3	1 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Cholesteatoma			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrosarcoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic leukaemia			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia			
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chronic lymphocytic leukaemia stage 0			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear cell renal cell carcinoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	32 / 7890 (0.41%)	21 / 7912 (0.27%)	
occurrences causally related to treatment / all	0 / 33	1 / 22	
deaths causally related to treatment / all	0 / 5	0 / 6	
Colon cancer metastatic			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colon cancer stage 0			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer stage II			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Endometrial cancer			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer metastatic			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gallbladder cancer			

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Gastric adenoma			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			
subjects affected / exposed	10 / 7890 (0.13%)	10 / 7912 (0.13%)	
occurrences causally related to treatment / all	2 / 10	0 / 10	
deaths causally related to treatment / all	1 / 6	0 / 6	
Gastric cancer recurrent			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal carcinoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal stromal cancer			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal tract adenoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Glioma			

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Glottis carcinoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	6 / 7890 (0.08%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 4	0 / 3	
Hepatic cancer metastatic			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 1	
Hepatic neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Hypopharyngeal cancer			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypopharyngeal cancer recurrent			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal papillary-mucinous carcinoma of pancreas			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive lobular breast carcinoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine benign neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			
subjects affected / exposed	1 / 7890 (0.01%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 1	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Laryngeal cancer recurrent			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal squamous cell carcinoma			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leiomyosarcoma			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lentigo maligna			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lip and/or oral cavity cancer			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	3 / 7890 (0.04%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 3	2 / 7	
deaths causally related to treatment / all	0 / 0	1 / 3	
Lung adenocarcinoma metastatic			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung adenocarcinoma stage II			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma stage IV			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic			
subjects affected / exposed	7 / 7890 (0.09%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 5	0 / 4	
Lung carcinoma cell type unspecified recurrent			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung carcinoma cell type unspecified stage III			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung neoplasm			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung neoplasm malignant			
subjects affected / exposed	37 / 7890 (0.47%)	33 / 7912 (0.42%)	
occurrences causally related to treatment / all	0 / 38	0 / 33	
deaths causally related to treatment / all	0 / 19	0 / 19	
Lung squamous cell carcinoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphangiosis carcinomatosa			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lymphocytic lymphoma			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoma			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Malignant melanoma			
subjects affected / exposed	3 / 7890 (0.04%)	9 / 7912 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant melanoma in situ			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.00%)	1 / 7912 (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 unknown primary site			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Malignant palate neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant peritoneal neoplasm			

subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mantle cell lymphoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Mediastinum neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Meningioma			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma benign			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to abdominal cavity			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Metastases to adrenals			
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Metastases to biliary tract			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to bone			
subjects affected / exposed	6 / 7890 (0.08%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 4	0 / 4	
Metastases to central nervous system			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 0	
Metastases to liver			
subjects affected / exposed	9 / 7890 (0.11%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 5	0 / 3	
Metastases to lung			
subjects affected / exposed	7 / 7890 (0.09%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 5	0 / 1	
Metastases to lymph nodes			
subjects affected / exposed	7 / 7890 (0.09%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 4	0 / 3	
Metastases to peritoneum			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to pleura			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to spine			

subjects affected / exposed	4 / 7890 (0.05%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Metastases to the mediastinum			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Metastatic bronchial carcinoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic carcinoma of the bladder			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic lymphoma			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic malignant melanoma			
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 3	
Metastatic neoplasm			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 2	
Metastatic salivary gland cancer			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic squamous cell carcinoma			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Morton's neuroma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	2 / 3	0 / 4	
deaths causally related to treatment / all	1 / 1	0 / 0	
Neoplasm malignant			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Neoplasm prostate			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurilemmoma benign			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			

subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 4	
Non-small cell lung cancer metastatic			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal adenocarcinoma			
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
Oesophageal carcinoma			
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 3	0 / 3	
Optic nerve neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	8 / 7890 (0.10%)	17 / 7912 (0.21%)	
occurrences causally related to treatment / all	2 / 8	0 / 17	
deaths causally related to treatment / all	2 / 6	0 / 11	
Pancreatic carcinoma metastatic			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papilloma			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid tumour benign			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal carcinoma metastatic			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Phaeochromocytoma malignant			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pituitary tumour benign			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
Pleural mesothelioma			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Polycythaemia vera			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	64 / 7890 (0.81%)	67 / 7912 (0.85%)	
occurrences causally related to treatment / all	1 / 64	1 / 67	
deaths causally related to treatment / all	0 / 4	0 / 4	
Prostate cancer metastatic			
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 3	
Prostate cancer recurrent			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic adenoma			
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma			
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Rectal cancer			
subjects affected / exposed	10 / 7890 (0.13%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 14	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 0	
Rectosigmoid cancer			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal cancer			
subjects affected / exposed	6 / 7890 (0.08%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 1	
Renal cancer metastatic			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal cell carcinoma			
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 3	
Renal neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Salivary gland adenoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Signet-ring cell carcinoma			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin cancer			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer			
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 4	0 / 2	
Small cell lung cancer metastatic			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Small intestine adenocarcinoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Soft tissue cancer			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the oral cavity			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular malignant teratoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Throat cancer			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Thymoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell cancer of the renal pelvis and ureter			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			

subjects affected / exposed	4 / 7890 (0.05%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	1 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour haemorrhage			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour invasion			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteral neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ureteric cancer			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder adenoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract neoplasm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures with secondary generalisation			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm ruptured			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Angiopathy			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	24 / 7890 (0.30%)	35 / 7912 (0.44%)	
occurrences causally related to treatment / all	0 / 25	0 / 38	
deaths causally related to treatment / all	0 / 0	0 / 2	
Aortic aneurysm rupture			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 3	
Aortic arteriosclerosis			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic calcification			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dilatation			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Aortic stenosis			
subjects affected / exposed	15 / 7890 (0.19%)	16 / 7912 (0.20%)	
occurrences causally related to treatment / all	0 / 15	0 / 16	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic thrombosis			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial disorder			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial insufficiency			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial occlusive disease			

subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial rupture			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial stenosis			
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	6 / 7890 (0.08%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 3	
Arteriovenous fistula			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Artery dissection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bleeding varicose vein			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure fluctuation			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			

subjects affected / exposed	10 / 7890 (0.13%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 3	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	17 / 7890 (0.22%)	10 / 7912 (0.13%)	
occurrences causally related to treatment / all	1 / 17	2 / 10	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetic vascular disorder			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Embolism			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism venous			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extravasation blood			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Femoral artery aneurysm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery occlusion			

subjects affected / exposed	12 / 7890 (0.15%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 15	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematocoele			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	13 / 7890 (0.16%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 13	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemorrhage			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hypertension			
subjects affected / exposed	32 / 7890 (0.41%)	29 / 7912 (0.37%)	
occurrences causally related to treatment / all	3 / 34	0 / 33	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	16 / 7890 (0.20%)	15 / 7912 (0.19%)	
occurrences causally related to treatment / all	1 / 16	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoperfusion			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			

subjects affected / exposed	39 / 7890 (0.49%)	27 / 7912 (0.34%)	
occurrences causally related to treatment / all	0 / 41	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 2	
Hypovolaemic shock			
subjects affected / exposed	2 / 7890 (0.03%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 5	
Iliac artery occlusion			
subjects affected / exposed	7 / 7890 (0.09%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 9	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iliac artery rupture			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infarction			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intermittent claudication			
subjects affected / exposed	28 / 7890 (0.35%)	21 / 7912 (0.27%)	
occurrences causally related to treatment / all	0 / 35	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal haematoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemia			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic limb pain			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphocele			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypertension			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	8 / 7890 (0.10%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 9	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic venous thrombosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	55 / 7890 (0.70%)	46 / 7912 (0.58%)	
occurrences causally related to treatment / all	1 / 68	0 / 54	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery aneurysm			
subjects affected / exposed	2 / 7890 (0.03%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	21 / 7890 (0.27%)	23 / 7912 (0.29%)	
occurrences causally related to treatment / all	0 / 34	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			

subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peripheral embolism			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	20 / 7890 (0.25%)	19 / 7912 (0.24%)	
occurrences causally related to treatment / all	0 / 26	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peripheral vascular disorder			
subjects affected / exposed	27 / 7890 (0.34%)	24 / 7912 (0.30%)	
occurrences causally related to treatment / all	0 / 29	0 / 32	
deaths causally related to treatment / all	0 / 0	0 / 1	
Phlebitis			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis superficial			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Raynaud's phenomenon			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renovascular hypertension			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subclavian artery aneurysm			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian artery occlusion			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian artery stenosis			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian steal syndrome			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporal arteritis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thromboangiitis obliterans			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	3 / 7890 (0.04%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 3	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose ulceration			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	3 / 7890 (0.04%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein ruptured			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular insufficiency			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous insufficiency			

subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous stenosis			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Coronary revascularisation			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	15 / 7890 (0.19%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	0 / 17	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 2	
Axillary pain			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac complication associated with device			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	7 / 7890 (0.09%)	9 / 7912 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	18 / 7890 (0.23%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	0 / 18	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 2	
Chills			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	73 / 7890 (0.93%)	56 / 7912 (0.71%)	
occurrences causally related to treatment / all	1 / 73	0 / 56	
deaths causally related to treatment / all	1 / 73	0 / 56	
Device battery issue			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device lead damage			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device lead issue			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	11 / 7890 (0.14%)	12 / 7912 (0.15%)	
occurrences causally related to treatment / all	1 / 11	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device power source issue			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drowning			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Drug intolerance			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exercise tolerance decreased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Face oedema			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fat necrosis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	9 / 7890 (0.11%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	1 / 10	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised oedema			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ill-defined disorder			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site thrombosis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza like illness			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic ulcer			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipogranuloma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device complication			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device pain			

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site reaction			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ disorder			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Multi-organ failure			
subjects affected / exposed	6 / 7890 (0.08%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 6	0 / 6	
Nodule			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	196 / 7890 (2.48%)	191 / 7912 (2.41%)	
occurrences causally related to treatment / all	0 / 235	1 / 238	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	6 / 7890 (0.08%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyp			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Puncture site haemorrhage			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	12 / 7890 (0.15%)	12 / 7912 (0.15%)	
occurrences causally related to treatment / all	0 / 14	1 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
Spinal pain			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stent embolisation			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	22 / 7890 (0.28%)	24 / 7912 (0.30%)	
occurrences causally related to treatment / all	0 / 22	0 / 24	
deaths causally related to treatment / all	0 / 22	0 / 24	
Sudden death			
subjects affected / exposed	56 / 7890 (0.71%)	57 / 7912 (0.72%)	
occurrences causally related to treatment / all	0 / 56	1 / 57	
deaths causally related to treatment / all	0 / 56	1 / 57	
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis in device			

subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcer haemorrhage			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibulitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Allergic oedema			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Allergy to arthropod bite			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Allergy to arthropod sting			
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food allergy			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			

subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Disability			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired hydrocele			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acquired phimosis			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	28 / 7890 (0.35%)	31 / 7912 (0.39%)	
occurrences causally related to treatment / all	0 / 28	0 / 33	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast enlargement			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Epididymal cyst			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital pain			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gynaecomastia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian mass			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fluid collection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile swelling			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic disorder			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic obstruction			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatism			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	4 / 7890 (0.05%)	9 / 7912 (0.11%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	8 / 7890 (0.10%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal oedema			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal swelling			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			

subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterovaginal prolapse			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal polyp			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute lung injury			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	14 / 7890 (0.18%)	12 / 7912 (0.15%)	
occurrences causally related to treatment / all	0 / 15	0 / 13	
deaths causally related to treatment / all	0 / 4	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			

subjects affected / exposed	18 / 7890 (0.23%)	10 / 7912 (0.13%)	
occurrences causally related to treatment / all	0 / 18	0 / 12	
deaths causally related to treatment / all	0 / 4	0 / 2	
Apnoea			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asphyxia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Asthma			
subjects affected / exposed	8 / 7890 (0.10%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 0	
Atelectasis			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial hyperreactivity			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bronchitis chronic			

subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopleural fistula			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bronchopulmonary disease			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Chronic obstructive pulmonary disease			
subjects affected / exposed	52 / 7890 (0.66%)	50 / 7912 (0.63%)	
occurrences causally related to treatment / all	0 / 74	0 / 75	
deaths causally related to treatment / all	0 / 3	0 / 3	
Chronic respiratory failure			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cough			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic disorder			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic paralysis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphonia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	39 / 7890 (0.49%)	52 / 7912 (0.66%)	
occurrences causally related to treatment / all	0 / 42	0 / 55	
deaths causally related to treatment / all	0 / 0	0 / 2	
Dyspnoea exertional			
subjects affected / exposed	7 / 7890 (0.09%)	10 / 7912 (0.13%)	
occurrences causally related to treatment / all	1 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	6 / 7890 (0.08%)	10 / 7912 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	6 / 7890 (0.08%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemothorax			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydropneumothorax			

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	5 / 7890 (0.06%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Increased upper airway secretion			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Laryngeal cyst			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal oedema			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngospasm			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung consolidation			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung cyst			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 3	
Lung infiltration			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	1 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinal haematoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinal haemorrhage			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal cyst			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal mucosal hypertrophy			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal polyps			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal turbinate hypertrophy			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive airways disorder			
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organising pneumonia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal pain			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthopnoea			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Painful respiration			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal oedema			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	20 / 7890 (0.25%)	12 / 7912 (0.15%)	
occurrences causally related to treatment / all	0 / 22	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pleuritic pain			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 4	0 / 0	
Pneumonitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	6 / 7890 (0.08%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Productive cough			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial hypertension			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	26 / 7890 (0.33%)	35 / 7912 (0.44%)	
occurrences causally related to treatment / all	1 / 29	1 / 35	
deaths causally related to treatment / all	0 / 3	0 / 7	
Pulmonary fibrosis			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary haemorrhage			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary hypertension			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary mass			
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary oedema			
subjects affected / exposed	15 / 7890 (0.19%)	17 / 7912 (0.21%)	
occurrences causally related to treatment / all	0 / 15	1 / 17	
deaths causally related to treatment / all	0 / 1	0 / 4	
Respiratory arrest			

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory disorder			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Respiratory failure			
subjects affected / exposed	24 / 7890 (0.30%)	18 / 7912 (0.23%)	
occurrences causally related to treatment / all	0 / 25	0 / 18	
deaths causally related to treatment / all	0 / 10	0 / 3	
Restrictive pulmonary disease			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sleep apnoea syndrome			
subjects affected / exposed	6 / 7890 (0.08%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Snoring			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status asthmaticus			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord thickening			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wheezing			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Aggression			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agitation			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			

subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 2	
Confusional state			
subjects affected / exposed	12 / 7890 (0.15%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Conversion disorder			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	4 / 7890 (0.05%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	7 / 7890 (0.09%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 8	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression suicidal			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disorientation			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysthymic disorder			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination, auditory			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impulse-control disorder			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insomnia			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mania			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental disorder			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	6 / 7890 (0.08%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic attack			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychogenic seizure			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep disorder			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somatoform disorder cardiovascular			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal behaviour			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			

subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 7890 (0.01%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic liver disease			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bile duct obstruction			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	3 / 7890 (0.04%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary fistula			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis acute		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis		
subjects affected / exposed	24 / 7890 (0.30%)	21 / 7912 (0.27%)
occurrences causally related to treatment / all	0 / 25	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	24 / 7890 (0.30%)	19 / 7912 (0.24%)
occurrences causally related to treatment / all	0 / 24	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 1
Cholecystitis chronic		
subjects affected / exposed	7 / 7890 (0.09%)	5 / 7912 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	28 / 7890 (0.35%)	30 / 7912 (0.38%)
occurrences causally related to treatment / all	0 / 29	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis obstructive		
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholestasis		

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder disorder			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder pain			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder perforation			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatic cyst			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Hepatic function abnormal			

subjects affected / exposed	2 / 7890 (0.03%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	1 / 2	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic haemorrhage			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic mass			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic steatosis			
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatitis alcoholic			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis toxic			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular injury			

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatorenal failure			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatotoxicity			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocholecystis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic hepatitis			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Jaundice			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumobilia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal hypertension			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase abnormal			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
subjects affected / exposed	11 / 7890 (0.14%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	1 / 11	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase abnormal			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase			

increased			
subjects affected / exposed	6 / 7890 (0.08%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	1 / 6	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile output abnormal			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose decreased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose increased			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium decreased			

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure decreased			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure increased			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood urea increased			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood urine present			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-reactive protein increased			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac murmur			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac stress test abnormal			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid bruit			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ECG signs of myocardial ischaemia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			
subjects affected / exposed	4 / 7890 (0.05%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram ST segment depression			
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate decreased			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate increased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate irregular			

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme abnormal			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	5 / 7890 (0.06%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	1 / 5	2 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased5			
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	2 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular pressure increased			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	2 / 7890 (0.03%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	1 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Occult blood positive			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oxygen saturation decreased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Red blood cell sedimentation rate increased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scan myocardial perfusion abnormal			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcus test positive			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stroke volume decreased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin I increased			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			

subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
White blood cell count increased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bilirubin conjugated increased			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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			
Accident at home			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			

subjects affected / exposed	7 / 7890 (0.09%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial injury			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arterial restenosis			
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula thrombosis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod sting			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back injury			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone contusion			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain contusion			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns first degree			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns second degree			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac function disturbance postoperative			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac procedure complication			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Comminuted fracture			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			

subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	6 / 7890 (0.08%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery restenosis			
subjects affected / exposed	28 / 7890 (0.35%)	19 / 7912 (0.24%)	
occurrences causally related to treatment / all	0 / 31	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Eschar			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Excoriation			
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural haematoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye injury			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye penetration			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Face injury			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	17 / 7890 (0.22%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	0 / 17	0 / 11	
deaths causally related to treatment / all	0 / 2	0 / 1	
Femoral neck fracture			
subjects affected / exposed	12 / 7890 (0.15%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 12	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	11 / 7890 (0.14%)	12 / 7912 (0.15%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 2	0 / 1	
Fibula fracture			
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	4 / 7890 (0.05%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorder postoperative			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stoma complication			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft thrombosis			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gun shot wound			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			

subjects affected / exposed	11 / 7890 (0.14%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 11	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 0	
Heart injury			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	10 / 7890 (0.13%)	13 / 7912 (0.16%)	
occurrences causally related to treatment / all	0 / 10	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
Humerus fracture			
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site haematoma			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site haemorrhage			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia, obstructive			
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation of wound			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Internal injury			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc injury			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw fracture			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed	3 / 7890 (0.04%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney contusion			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laceration			

subjects affected / exposed	9 / 7890 (0.11%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament injury			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb crushing injury			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb traumatic amputation			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver contusion			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			

subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	8 / 7890 (0.10%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 8	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes postoperative			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle rupture			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle strain			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			

subjects affected / exposed	5 / 7890 (0.06%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Patella fracture			
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	5 / 7890 (0.06%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Periprosthetic fracture			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirenal haematoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poisoning			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post laminectomy syndrome			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Post procedural fistula			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	4 / 7890 (0.05%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural myocardial infarction			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural stroke			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural swelling			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative hernia			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative ileus			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Postoperative respiratory failure			

subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Postoperative thoracic procedure complication			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative thrombosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural headache			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural hypotension			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural nausea			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			

subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural vomiting			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pubis fracture			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary contusion			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	5 / 7890 (0.06%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal haematoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	9 / 7890 (0.11%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	6 / 7890 (0.08%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Shunt stenosis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fracture			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fractured base			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue injury			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic rupture			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splinter			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous haematoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	8 / 7890 (0.10%)	15 / 7912 (0.19%)	
occurrences causally related to treatment / all	0 / 10	1 / 16	
deaths causally related to treatment / all	0 / 2	0 / 5	
Subdural haemorrhage			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Suture related complication			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial rupture			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	8 / 7890 (0.10%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular injury			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	4 / 7890 (0.05%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	6 / 7890 (0.08%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 0	
Transfusion reaction			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transplant failure			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haemorrhage			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic renal injury			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ulna fracture			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder rupture			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular bypass dysfunction			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft complication			
subjects affected / exposed	6 / 7890 (0.08%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 7	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft occlusion			
subjects affected / exposed	8 / 7890 (0.10%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 11	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft thrombosis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular procedure complication			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venomous sting			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound evisceration			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haematoma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound necrosis			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Arteriovenous malformation			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial septal defect			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal vessel congenital anomaly			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syringomyelia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	17 / 7890 (0.22%)	17 / 7912 (0.21%)	
occurrences causally related to treatment / all	0 / 19	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 2	
Acute left ventricular failure			
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

Acute myocardial infarction			
subjects affected / exposed	359 / 7890 (4.55%)	303 / 7912 (3.83%)	
occurrences causally related to treatment / all	7 / 425	9 / 357	
deaths causally related to treatment / all	1 / 44	1 / 35	
Angina pectoris			
subjects affected / exposed	271 / 7890 (3.43%)	248 / 7912 (3.13%)	
occurrences causally related to treatment / all	0 / 309	0 / 282	
deaths causally related to treatment / all	0 / 3	0 / 0	
Angina unstable			
subjects affected / exposed	489 / 7890 (6.20%)	472 / 7912 (5.97%)	
occurrences causally related to treatment / all	8 / 618	2 / 569	
deaths causally related to treatment / all	0 / 6	0 / 4	
Aortic valve disease			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease mixed			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	10 / 7890 (0.13%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 11	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arrhythmia			
subjects affected / exposed	8 / 7890 (0.10%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 3	0 / 2	
Arrhythmia supraventricular			

subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	15 / 7890 (0.19%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 15	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 1	
Arteriospasm coronary			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	135 / 7890 (1.71%)	123 / 7912 (1.55%)	
occurrences causally related to treatment / all	2 / 164	0 / 153	
deaths causally related to treatment / all	0 / 2	0 / 0	
Atrial flutter			
subjects affected / exposed	27 / 7890 (0.34%)	27 / 7912 (0.34%)	
occurrences causally related to treatment / all	0 / 36	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	1 / 7890 (0.01%)	56 / 7912 (0.71%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial thrombosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	9 / 7890 (0.11%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			

subjects affected / exposed	12 / 7890 (0.15%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 12	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block first degree			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	7 / 7890 (0.09%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular dissociation			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bifascicular block			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	19 / 7890 (0.24%)	24 / 7912 (0.30%)	
occurrences causally related to treatment / all	0 / 19	1 / 25	
deaths causally related to treatment / all	0 / 1	0 / 1	
Bundle branch block left			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block right			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac aneurysm			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	26 / 7890 (0.33%)	28 / 7912 (0.35%)	
occurrences causally related to treatment / all	0 / 26	0 / 28	
deaths causally related to treatment / all	0 / 20	0 / 22	
Cardiac asthma			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac discomfort			
subjects affected / exposed	6 / 7890 (0.08%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	1 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorder			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	1 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure			
subjects affected / exposed	178 / 7890 (2.26%)	155 / 7912 (1.96%)	
occurrences causally related to treatment / all	2 / 244	3 / 225	
deaths causally related to treatment / all	1 / 36	0 / 26	
Cardiac failure acute			
subjects affected / exposed	16 / 7890 (0.20%)	10 / 7912 (0.13%)	
occurrences causally related to treatment / all	1 / 16	0 / 12	
deaths causally related to treatment / all	1 / 8	0 / 2	
Cardiac failure chronic			

subjects affected / exposed	19 / 7890 (0.24%)	17 / 7912 (0.21%)	
occurrences causally related to treatment / all	1 / 21	0 / 21	
deaths causally related to treatment / all	0 / 5	0 / 2	
Cardiac failure congestive			
subjects affected / exposed	135 / 7890 (1.71%)	125 / 7912 (1.58%)	
occurrences causally related to treatment / all	2 / 196	1 / 168	
deaths causally related to treatment / all	0 / 13	0 / 9	
Cardiac tamponade			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve disease			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	15 / 7890 (0.19%)	15 / 7912 (0.19%)	
occurrences causally related to treatment / all	1 / 15	1 / 15	
deaths causally related to treatment / all	1 / 14	1 / 15	
Cardiogenic shock			
subjects affected / exposed	11 / 7890 (0.14%)	16 / 7912 (0.20%)	
occurrences causally related to treatment / all	0 / 11	0 / 16	
deaths causally related to treatment / all	0 / 3	0 / 10	
Cardiomyopathy			
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiopulmonary failure			
subjects affected / exposed	2 / 7890 (0.03%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 5	
Cardiovascular deconditioning			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular disorder			
subjects affected / exposed	6 / 7890 (0.08%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 3	0 / 3	
Cardiovascular insufficiency			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
Chronic left ventricular failure			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronotropic incompetence			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conduction disorder			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive cardiomyopathy			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cor pulmonale chronic			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			

subjects affected / exposed	177 / 7890 (2.24%)	168 / 7912 (2.12%)	
occurrences causally related to treatment / all	0 / 190	0 / 185	
deaths causally related to treatment / all	0 / 6	0 / 2	
Coronary artery insufficiency			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Coronary artery occlusion			
subjects affected / exposed	17 / 7890 (0.22%)	19 / 7912 (0.24%)	
occurrences causally related to treatment / all	1 / 17	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	59 / 7890 (0.75%)	56 / 7912 (0.71%)	
occurrences causally related to treatment / all	3 / 64	0 / 59	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diastolic dysfunction			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrasystoles			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive cardiomyopathy			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive heart disease			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intracardiac thrombus			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	14 / 7890 (0.18%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	0 / 14	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 1	
Left ventricular dysfunction			
subjects affected / exposed	8 / 7890 (0.10%)	13 / 7912 (0.16%)	
occurrences causally related to treatment / all	0 / 8	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
Left ventricular failure			
subjects affected / exposed	6 / 7890 (0.08%)	12 / 7912 (0.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 14	
deaths causally related to treatment / all	0 / 2	0 / 2	
Left ventricular hypertrophy			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	9 / 7890 (0.11%)	10 / 7912 (0.13%)	
occurrences causally related to treatment / all	0 / 9	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve stenosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial fibrosis			

subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Myocardial infarction			
subjects affected / exposed	54 / 7890 (0.68%)	56 / 7912 (0.71%)	
occurrences causally related to treatment / all	1 / 55	1 / 56	
deaths causally related to treatment / all	0 / 21	1 / 34	
Myocardial ischaemia			
subjects affected / exposed	41 / 7890 (0.52%)	47 / 7912 (0.59%)	
occurrences causally related to treatment / all	0 / 45	0 / 49	
deaths causally related to treatment / all	0 / 2	0 / 2	
Myocarditis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	9 / 7890 (0.11%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	6 / 7890 (0.08%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial haemorrhage			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis constrictive			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postinfarction angina			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prinzmetal angina			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulseless electrical activity			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Right ventricular failure			
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sick sinus syndrome			
subjects affected / exposed	24 / 7890 (0.30%)	15 / 7912 (0.19%)	
occurrences causally related to treatment / all	0 / 24	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Silent myocardial infarction			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinoatrial block			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus arrhythmia			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus bradycardia			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular extrasystoles			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachyarrhythmia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			

subjects affected / exposed	8 / 7890 (0.10%)	14 / 7912 (0.18%)	
occurrences causally related to treatment / all	0 / 11	3 / 16	
deaths causally related to treatment / all	0 / 0	0 / 1	
Systolic dysfunction			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 5	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torsade de pointes			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve disease			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trifascicular block			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	1 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ventricular dyssynchrony			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			

subjects affected / exposed	9 / 7890 (0.11%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	19 / 7890 (0.24%)	22 / 7912 (0.28%)	
occurrences causally related to treatment / all	0 / 23	0 / 23	
deaths causally related to treatment / all	0 / 7	0 / 5	
Ventricular tachyarrhythmia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	42 / 7890 (0.53%)	37 / 7912 (0.47%)	
occurrences causally related to treatment / all	1 / 56	1 / 41	
deaths causally related to treatment / all	0 / 2	1 / 3	
Congenital coronary artery malformation			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	5 / 7890 (0.06%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Alcoholic seizure			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.00%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			

subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Aphasia			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance disorder			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia infarction			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Brain midline shift			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain oedema			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Brain stem haemorrhage			

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Brain stem infarction			
subjects affected / exposed	4 / 7890 (0.05%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Brain stem ischaemia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem stroke			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Carotid arteriosclerosis			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery disease			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	7 / 7890 (0.09%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	47 / 7890 (0.60%)	48 / 7912 (0.61%)	
occurrences causally related to treatment / all	0 / 51	0 / 54	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			

subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda equina syndrome			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central nervous system lesion			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar haemorrhage			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic mononeuropathy			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathy			
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disturbance in attention			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			

subjects affected / exposed	18 / 7890 (0.23%)	18 / 7912 (0.23%)	
occurrences causally related to treatment / all	1 / 18	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dizziness exertional			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness postural			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysaesthesia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyslalia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic cerebral infarction			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			

subjects affected / exposed	4 / 7890 (0.05%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalomalacia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	5 / 7890 (0.06%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	1 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paresis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Grand mal convulsion			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemorrhage intracranial			

subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Haemorrhagic cerebral infarction			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	19 / 7890 (0.24%)	15 / 7912 (0.19%)	
occurrences causally related to treatment / all	0 / 19	2 / 15	
deaths causally related to treatment / all	0 / 8	0 / 5	
Haemorrhagic transformation stroke			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Headache			
subjects affected / exposed	7 / 7890 (0.09%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	1 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hemianopia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiplegic migraine			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypertensive encephalopathy			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic coma			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic unconsciousness			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotonia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intercostal neuralgia			
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			

subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraventricular haemorrhage			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	20 / 7890 (0.25%)	13 / 7912 (0.16%)	
occurrences causally related to treatment / all	0 / 22	1 / 14	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ischaemic neuropathy			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	97 / 7890 (1.23%)	94 / 7912 (1.19%)	
occurrences causally related to treatment / all	1 / 107	1 / 99	
deaths causally related to treatment / all	0 / 4	0 / 15	
Lacunar infarction			
subjects affected / exposed	6 / 7890 (0.08%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	4 / 7890 (0.05%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Memory impairment			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningoradiculitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mononeuritis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoparesis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Movement disorder			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve compression			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve root compression			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Neuralgia			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuritis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuritis cranial			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurological symptom			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normal pressure hydrocephalus			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic intolerance			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraplegia			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paresis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve paresis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy chronic			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post herpetic neuralgia			

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	16 / 7890 (0.20%)	16 / 7912 (0.20%)	
occurrences causally related to treatment / all	0 / 16	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudoradicular syndrome			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radicular syndrome			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculitis lumbosacral			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Restless legs syndrome			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retrograde amnesia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reversible ischaemic neurological deficit			

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ruptured cerebral aneurysm			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	6 / 7890 (0.08%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Senile dementia			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sensory disturbance			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sensory loss			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Simple partial seizures			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Spinal claudication			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord disorder			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal haematoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitic myelopathy			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stupor			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	7 / 7890 (0.09%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Syncope			

subjects affected / exposed	79 / 7890 (1.00%)	72 / 7912 (0.91%)	
occurrences causally related to treatment / all	0 / 81	0 / 77	
deaths causally related to treatment / all	0 / 1	0 / 1	
Thalamic infarction			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic cerebral infarction			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic stroke			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	87 / 7890 (1.10%)	67 / 7912 (0.85%)	
occurrences causally related to treatment / all	4 / 98	0 / 75	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	0 / 7890 (0.00%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigeminal neuralgia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIIth nerve paralysis			

subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIth nerve paralysis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular parkinsonism			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery stenosis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo CNS origin			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord paralysis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
White matter lesion			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral arteriosclerosis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery embolism			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery occlusion			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery stenosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral circulatory failure			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			

subjects affected / exposed	2 / 7890 (0.03%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 2	
Cerebral infarction			
subjects affected / exposed	7 / 7890 (0.09%)	15 / 7912 (0.19%)	
occurrences causally related to treatment / all	0 / 7	1 / 16	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	28 / 7890 (0.35%)	33 / 7912 (0.42%)	
occurrences causally related to treatment / all	0 / 28	0 / 33	
deaths causally related to treatment / all	0 / 3	0 / 10	
Cerebrovascular disorder			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cervical myelopathy			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicobrachial syndrome			
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coma			

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Complex partial seizures			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complex regional pain syndrome			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
subjects affected / exposed	8 / 7890 (0.10%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Critical illness polyneuropathy			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dementia			
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dementia Alzheimer's type			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia with Lewy bodies			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressed level of consciousness			

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetic hyperosmolar coma			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	52 / 7890 (0.66%)	42 / 7912 (0.53%)	
occurrences causally related to treatment / all	2 / 54	0 / 43	
deaths causally related to treatment / all	1 / 3	0 / 1	
Anaemia macrocytic			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia megaloblastic			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia of chronic disease			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone marrow failure			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone marrow ischaemia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated intravascular coagulation			
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 3	
Febrile neutropenia			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemolytic anaemia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemorrhagic anaemia			
subjects affected / exposed	1 / 7890 (0.01%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hyperprothrombinaemia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypochromic anaemia			
subjects affected / exposed	3 / 7890 (0.04%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic thrombocytopenic purpura			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			

subjects affected / exposed	8 / 7890 (0.10%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Jaundice acholuric			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	2 / 7890 (0.03%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 2	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic anaemia			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spontaneous haematoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	7 / 7890 (0.09%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	1 / 7	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otosclerosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ototoxicity			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	6 / 7890 (0.08%)	14 / 7912 (0.18%)	
occurrences causally related to treatment / all	0 / 6	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo labyrinthine			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			

subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	16 / 7890 (0.20%)	16 / 7912 (0.20%)	
occurrences causally related to treatment / all	0 / 20	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryostenosis acquired			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic eye disease			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorder			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye haemorrhage			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye pain			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid ptosis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular fibrosis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular retrobulbar haemorrhage			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular vascular disorder			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmoplegia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pterygium			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery thrombosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal degeneration			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal ischaemia			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal tear			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vascular thrombosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative keratitis			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual acuity reduced			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	5 / 7890 (0.06%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia obstructive			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			

subjects affected / exposed	25 / 7890 (0.32%)	12 / 7912 (0.15%)	
occurrences causally related to treatment / all	1 / 25	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	7 / 7890 (0.09%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	1 / 7	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal strangulated hernia			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall mass			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute abdomen			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic pancreatitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fissure			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			

subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anorectal disorder			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendix disorder			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Buccal polyp			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	12 / 7890 (0.15%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 12	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	5 / 7890 (0.06%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colitis ulcerative			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic stenosis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	5 / 7890 (0.06%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental caries			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gastroparesis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic hernia			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	21 / 7890 (0.27%)	23 / 7912 (0.29%)	
occurrences causally related to treatment / all	3 / 21	3 / 25	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea haemorrhagic			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dieulafoy's vascular malformation			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	5 / 7890 (0.06%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal polyp			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	6 / 7890 (0.08%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 6	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			

subjects affected / exposed	7 / 7890 (0.09%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	2 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer perforation			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal vascular ectasia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Enteritis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical fistula			

subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epigastric discomfort			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive oesophagitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecal incontinence			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faeces discoloured			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral hernia, obstructive			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Frequent bowel movements			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallstone ileus			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric dysplasia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	3 / 7890 (0.04%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastric polyps			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	7 / 7890 (0.09%)	17 / 7912 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 17	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	6 / 7890 (0.08%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	1 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastritis			
subjects affected / exposed	18 / 7890 (0.23%)	12 / 7912 (0.15%)	
occurrences causally related to treatment / all	2 / 18	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis atrophic			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			

subjects affected / exposed	7 / 7890 (0.09%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroduodenal ulcer			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroduodenitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia haemorrhagic			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal erosion			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	26 / 7890 (0.33%)	30 / 7912 (0.38%)	
occurrences causally related to treatment / all	0 / 27	0 / 31	
deaths causally related to treatment / all	0 / 2	0 / 2	
Gastrointestinal ischaemia			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal motility disorder			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal necrosis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal pain			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal ulcer haemorrhage			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	18 / 7890 (0.23%)	14 / 7912 (0.18%)	
occurrences causally related to treatment / all	0 / 18	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophagitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			

subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic erosive gastritis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	8 / 7890 (0.10%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia oral			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileal ulcer			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			

subjects affected / exposed	7 / 7890 (0.09%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	1 / 7	1 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	
Ileus paralytic			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	48 / 7890 (0.61%)	31 / 7912 (0.39%)	
occurrences causally related to treatment / all	0 / 50	0 / 33	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia, obstructive			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Internal hernia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal infarction			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intestinal ischaemia			
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 1	
Intestinal obstruction			

subjects affected / exposed	7 / 7890 (0.09%)	9 / 7912 (0.11%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 3	0 / 0	
Intestinal perforation			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal ulcer			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	16 / 7890 (0.20%)	21 / 7912 (0.27%)	
occurrences causally related to treatment / all	0 / 16	0 / 23	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lip haematoma			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	10 / 7890 (0.13%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 11	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lumbar hernia			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	4 / 7890 (0.05%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	3 / 7890 (0.04%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery stenosis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric occlusion			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric panniculitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth cyst			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	12 / 7890 (0.15%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	0 / 13	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema mouth			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedematous pancreatitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal dysplasia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal perforation			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer haemorrhage			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	1 / 7890 (0.01%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral pain			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic calcification			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic disorder			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	15 / 7890 (0.19%)	15 / 7912 (0.19%)	
occurrences causally related to treatment / all	2 / 20	2 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	12 / 7890 (0.15%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	1 / 13	1 / 7	
deaths causally related to treatment / all	0 / 2	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis haemorrhagic			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Papilla of Vater stenosis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia oral			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer haemorrhage			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer perforation			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumatosis intestinalis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Poor dental condition			
subjects affected / exposed	0 / 7890 (0.00%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctalgia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctitis			

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctitis ulcerative			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	9 / 7890 (0.11%)	13 / 7912 (0.16%)	
occurrences causally related to treatment / all	0 / 9	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal prolapse			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reflux gastritis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Small intestinal obstruction			

subjects affected / exposed	9 / 7890 (0.11%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal perforation			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spigelian hernia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomach mass			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subileus			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tooth disorder			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toothache			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	7 / 7890 (0.09%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia, obstructive			

subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	16 / 7890 (0.20%)	18 / 7912 (0.23%)	
occurrences causally related to treatment / all	0 / 17	1 / 18	
deaths causally related to treatment / all	0 / 2	0 / 0	
Volvulus			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	12 / 7890 (0.15%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 14	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blister			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cold sweat			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			

subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Dermatitis allergic			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	14 / 7890 (0.18%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 20	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Drug eruption			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ecchymosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema asteatotic			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema multiforme			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema nodosum			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hyperhidrosis			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keloid scar			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytoclastic vasculitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic ulcer			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pemphigoid			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pruritus			
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyoderma gangrenosum			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash generalised			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin disorder			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin necrosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	8 / 7890 (0.10%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stasis dermatitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute prerenal failure			
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder dilatation			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder discomfort			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder dysfunction			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder hypertrophy			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus ureteric			
subjects affected / exposed	9 / 7890 (0.11%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			

subjects affected / exposed	5 / 7890 (0.06%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis glandularis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis haemorrhagic			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis noninfective			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis ulcerative			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic nephropathy			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis chronic			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	15 / 7890 (0.19%)	12 / 7912 (0.15%)	
occurrences causally related to treatment / all	0 / 18	0 / 22	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hydronephrosis			
subjects affected / exposed	7 / 7890 (0.09%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 7	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Incontinence			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower urinary tract symptoms			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Micturition disorder			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephritic syndrome			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	10 / 7890 (0.13%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			

subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurogenic bladder			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pollakiuria			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery arteriosclerosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery dissection			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stenosis			
subjects affected / exposed	4 / 7890 (0.05%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	8 / 7890 (0.10%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst haemorrhage			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	17 / 7890 (0.22%)	31 / 7912 (0.39%)	
occurrences causally related to treatment / all	0 / 17	1 / 34	
deaths causally related to treatment / all	0 / 8	0 / 5	
Renal failure acute			
subjects affected / exposed	61 / 7890 (0.77%)	83 / 7912 (1.05%)	
occurrences causally related to treatment / all	2 / 79	0 / 91	
deaths causally related to treatment / all	1 / 10	0 / 11	
Renal failure chronic			
subjects affected / exposed	13 / 7890 (0.16%)	10 / 7912 (0.13%)	
occurrences causally related to treatment / all	0 / 15	0 / 10	
deaths causally related to treatment / all	0 / 5	0 / 0	
Renal haemorrhage			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	8 / 7890 (0.10%)	9 / 7912 (0.11%)	
occurrences causally related to treatment / all	1 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal infarct			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal mass			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal pain			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular necrosis			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric obstruction			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral disorder			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder haemorrhage			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder polyp			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	19 / 7890 (0.24%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 20	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal disorder			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adrenal insufficiency			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism primary			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cyst			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid disorder			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic nodular goitre			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	19 / 7890 (0.24%)	13 / 7912 (0.16%)	
occurrences causally related to treatment / all	0 / 19	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arthritis			

subjects affected / exposed	7 / 7890 (0.09%)	13 / 7912 (0.16%)	
occurrences causally related to treatment / all	0 / 7	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis reactive			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Articular calcification			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back disorder			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	27 / 7890 (0.34%)	20 / 7912 (0.25%)	
occurrences causally related to treatment / all	0 / 31	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone erosion			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone fistula			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone lesion			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bone pain			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	9 / 7890 (0.11%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 9	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondromalacia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondropathy			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fistula			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inclusion body myositis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal mass			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			

subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc displacement			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	24 / 7890 (0.30%)	16 / 7912 (0.20%)	
occurrences causally related to treatment / all	0 / 25	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint effusion			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint swelling			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	9 / 7890 (0.11%)	13 / 7912 (0.16%)	
occurrences causally related to treatment / all	0 / 9	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metatarsalgia			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monarthritis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle haemorrhage			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	6 / 7890 (0.08%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	9 / 7890 (0.11%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	0 / 10	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal discomfort			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	6 / 7890 (0.08%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			

subjects affected / exposed	6 / 7890 (0.08%)	9 / 7912 (0.11%)	
occurrences causally related to treatment / all	0 / 6	2 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myofascial pain syndrome			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myositis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Osteoarthritis			
subjects affected / exposed	78 / 7890 (0.99%)	73 / 7912 (0.92%)	
occurrences causally related to treatment / all	0 / 86	0 / 81	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	5 / 7890 (0.06%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periarthritis			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	4 / 7890 (0.05%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	1 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 2	
Rheumatoid arthritis			

subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	9 / 7890 (0.11%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scoliosis			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			
subjects affected / exposed	16 / 7890 (0.20%)	13 / 7912 (0.16%)	
occurrences causally related to treatment / all	0 / 16	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal deformity			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	12 / 7890 (0.15%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 13	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitis			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	3 / 7890 (0.04%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolysis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon disorder			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis stenosaurs			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal sepsis			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall infection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	5 / 7890 (0.06%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess jaw			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatitis B			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary histoplasmosis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amoebiasis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendiceal abscess			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	19 / 7890 (0.24%)	15 / 7912 (0.19%)	
occurrences causally related to treatment / all	0 / 19	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerotic gangrene			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arthritis bacterial			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	2 / 7890 (0.03%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			

subjects affected / exposed	1 / 7890 (0.01%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial pyelonephritis			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary sepsis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone abscess			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Borrelia infection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	18 / 7890 (0.23%)	24 / 7912 (0.30%)	
occurrences causally related to treatment / all	0 / 18	0 / 27	
deaths causally related to treatment / all	0 / 2	0 / 0	
Bronchopneumonia			
subjects affected / exposed	7 / 7890 (0.09%)	12 / 7912 (0.15%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 2	0 / 4	
Bursitis infective			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbuncle			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site infection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	46 / 7890 (0.58%)	38 / 7912 (0.48%)	
occurrences causally related to treatment / all	0 / 53	0 / 44	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis gangrenous			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cellulitis staphylococcal			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis suppurative			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cholecystitis infective			

subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chronic sinusitis			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	8 / 7890 (0.10%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 1	0 / 0	
Device related sepsis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (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	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated tuberculosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diverticulitis			
subjects affected / exposed	11 / 7890 (0.14%)	15 / 7912 (0.19%)	
occurrences causally related to treatment / all	0 / 11	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dysentery			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear infection			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Echinococcosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis bacterial			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis enterococcal			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Endocarditis staphylococcal			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometritis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endophthalmitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis infectious			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter infection			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal bacteraemia			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal infection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Enterococcal sepsis			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Enterocolitis infectious			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	14 / 7890 (0.18%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 14	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	3 / 7890 (0.04%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia infection			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
External ear cellulitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural abscess			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile infection			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fungal oesophagitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder empyema			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			

subjects affected / exposed	4 / 7890 (0.05%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis viral			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	29 / 7890 (0.37%)	31 / 7912 (0.39%)	
occurrences causally related to treatment / all	0 / 32	0 / 34	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal viral infection			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital infection fungal			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft infection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
H1N1 influenza			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIV infection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haematoma infection			
subjects affected / exposed	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter gastritis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter infection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis A			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis B			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis C			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis E			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis viral			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster ophthalmic			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Histoplasmosis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site infection			

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected bites			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	4 / 7890 (0.05%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (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 chronic obstructive airways disease			
subjects affected / exposed	3 / 7890 (0.04%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective myositis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	7 / 7890 (0.09%)	7 / 7912 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 0	
Intertrigo candida			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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	2 / 7890 (0.03%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratitis herpetic			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney infection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Klebsiella bacteraemia			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leptospirosis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			

subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lobar pneumonia			
subjects affected / exposed	17 / 7890 (0.22%)	9 / 7912 (0.11%)	
occurrences causally related to treatment / all	0 / 17	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Localised infection			
subjects affected / exposed	9 / 7890 (0.11%)	9 / 7912 (0.11%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lower respiratory tract infection			
subjects affected / exposed	10 / 7890 (0.13%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 11	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			
subjects affected / exposed	8 / 7890 (0.10%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lyme disease			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphangitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastoiditis			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis bacterial			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Meningitis cryptococcal			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Mycoplasma infection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycotoxycosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising fasciitis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal candidiasis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	7 / 7890 (0.09%)	10 / 7912 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis chronic			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media chronic			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paronychia			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal abscess			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital cellulitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal abscess			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	7 / 7890 (0.09%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Peritonsillar abscess			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			

subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasmodium vivax infection			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal sepsis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	160 / 7890 (2.03%)	139 / 7912 (1.76%)	
occurrences causally related to treatment / all	0 / 176	0 / 157	
deaths causally related to treatment / all	0 / 20	0 / 18	
Pneumonia bacterial			
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Pneumonia chlamydial			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pneumonia klebsiella			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia necrotising			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia streptococcal			

subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	1 / 7890 (0.01%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative abscess			
subjects affected / exposed	0 / 7890 (0.00%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	3 / 7890 (0.04%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic abscess			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomembranous colitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonas infection			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoas abscess			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	3 / 7890 (0.04%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pyelonephritis			
subjects affected / exposed	6 / 7890 (0.08%)	12 / 7912 (0.15%)	
occurrences causally related to treatment / all	0 / 8	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	1 / 7890 (0.01%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis chronic			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyopneumothorax			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory tract infection			

subjects affected / exposed	7 / 7890 (0.09%)	8 / 7912 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory tract infection viral			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal abscess			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal infection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonella sepsis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonellosis			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal abscess			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrub typhus			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	23 / 7890 (0.29%)	35 / 7912 (0.44%)	
occurrences causally related to treatment / all	0 / 25	0 / 37	
deaths causally related to treatment / all	0 / 8	0 / 15	
Sepsis syndrome			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic embolus			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	25 / 7890 (0.32%)	9 / 7912 (0.11%)	
occurrences causally related to treatment / all	0 / 26	1 / 10	
deaths causally related to treatment / all	0 / 17	0 / 3	
Sialoadenitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinobronchitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Soft tissue infection			

subjects affected / exposed	0 / 7890 (0.00%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	6 / 7890 (0.08%)	6 / 7912 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal osteomyelitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal bacteraemia			
subjects affected / exposed	1 / 7890 (0.01%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal infection			
subjects affected / exposed	2 / 7890 (0.03%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Streptococcal sepsis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subacute endocarditis			

subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superinfection			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suspected transmission of an infectious agent via product			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinea pedis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue abscess			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheitis			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis viral			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	3 / 7890 (0.04%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Urethritis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	36 / 7890 (0.46%)	43 / 7912 (0.54%)	
occurrences causally related to treatment / all	0 / 49	0 / 44	
deaths causally related to treatment / all	0 / 1	0 / 2	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Urinary tract infection pseudomonal			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	15 / 7890 (0.19%)	14 / 7912 (0.18%)	
occurrences causally related to treatment / all	0 / 20	0 / 14	
deaths causally related to treatment / all	0 / 1	0 / 3	
Vaginal abscess			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	4 / 7890 (0.05%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis bacterial			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Viral tracheitis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	6 / 7890 (0.08%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection staphylococcal			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (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			
Acidosis			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cachexia			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Decreased appetite			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	24 / 7890 (0.30%)	33 / 7912 (0.42%)	
occurrences causally related to treatment / all	0 / 27	0 / 33	
deaths causally related to treatment / all	0 / 1	0 / 1	
Diabetes mellitus			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	8 / 7890 (0.10%)	26 / 7912 (0.33%)	
occurrences causally related to treatment / all	0 / 9	0 / 29	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic complication			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	5 / 7890 (0.06%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Failure to thrive			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Fluid overload			

subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid retention			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fructose intolerance			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	5 / 7890 (0.06%)	5 / 7912 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	5 / 7890 (0.06%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	9 / 7890 (0.11%)	11 / 7912 (0.14%)	
occurrences causally related to treatment / all	0 / 10	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hyperlipidaemia			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperosmolar state			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertriglyceridaemia			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoalbuminaemia			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	0 / 7890 (0.00%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	26 / 7890 (0.33%)	24 / 7912 (0.30%)	
occurrences causally related to treatment / all	0 / 28	0 / 26	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypokalaemia			
subjects affected / exposed	7 / 7890 (0.09%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	8 / 7890 (0.10%)	10 / 7912 (0.13%)	
occurrences causally related to treatment / all	0 / 9	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypophosphataemia			

subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (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	4 / 7890 (0.05%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insulin-requiring type 2 diabetes mellitus			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketoacidosis			
subjects affected / exposed	1 / 7890 (0.01%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	1 / 7890 (0.01%)	3 / 7912 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metabolic acidosis			
subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Metabolic syndrome			
subjects affected / exposed	0 / 7890 (0.00%)	1 / 7912 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	2 / 7890 (0.03%)	4 / 7912 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 1 diabetes mellitus			

subjects affected / exposed	2 / 7890 (0.03%)	2 / 7912 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	37 / 7890 (0.47%)	27 / 7912 (0.34%)	
occurrences causally related to treatment / all	0 / 38	0 / 28	
deaths causally related to treatment / all	0 / 1	0 / 1	
Vitamin B12 deficiency			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitamin D deficiency			
subjects affected / exposed	1 / 7890 (0.01%)	0 / 7912 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Placebo	Darapladib	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4885 / 7890 (61.91%)	5171 / 7912 (65.36%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	660 / 7890 (8.37%)	643 / 7912 (8.13%)	
occurrences (all)	751	749	
Hypotension			
subjects affected / exposed	181 / 7890 (2.29%)	184 / 7912 (2.33%)	
occurrences (all)	198	201	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	357 / 7890 (4.52%)	354 / 7912 (4.47%)	
occurrences (all)	384	377	
Non-cardiac chest pain			

subjects affected / exposed occurrences (all)	376 / 7890 (4.77%) 458	366 / 7912 (4.63%) 425	
Oedema peripheral subjects affected / exposed occurrences (all)	419 / 7890 (5.31%) 468	431 / 7912 (5.45%) 497	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	404 / 7890 (5.12%) 471	401 / 7912 (5.07%) 464	
Dyspnoea subjects affected / exposed occurrences (all)	346 / 7890 (4.39%) 395	324 / 7912 (4.10%) 354	
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	164 / 7890 (2.08%) 170	126 / 7912 (1.59%) 135	
Investigations Blood glucose increased subjects affected / exposed occurrences (all)	181 / 7890 (2.29%) 208	171 / 7912 (2.16%) 183	
Blood pressure increased subjects affected / exposed occurrences (all)	197 / 7890 (2.50%) 236	173 / 7912 (2.19%) 193	
Cardiac disorders Angina pectoris subjects affected / exposed occurrences (all)	528 / 7890 (6.69%) 645	457 / 7912 (5.78%) 563	
Atrial fibrillation subjects affected / exposed occurrences (all)	245 / 7890 (3.11%) 274	257 / 7912 (3.25%) 292	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	357 / 7890 (4.52%) 410	296 / 7912 (3.74%) 340	
Dizziness			

subjects affected / exposed	491 / 7890 (6.22%)	456 / 7912 (5.76%)	
occurrences (all)	556	533	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	208 / 7890 (2.64%)	191 / 7912 (2.41%)	
occurrences (all)	220	204	
Eye disorders			
Cataract			
subjects affected / exposed	198 / 7890 (2.51%)	203 / 7912 (2.57%)	
occurrences (all)	254	259	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	188 / 7890 (2.38%)	163 / 7912 (2.06%)	
occurrences (all)	213	183	
Abdominal pain upper			
subjects affected / exposed	152 / 7890 (1.93%)	180 / 7912 (2.28%)	
occurrences (all)	167	194	
Abnormal faeces			
subjects affected / exposed	63 / 7890 (0.80%)	728 / 7912 (9.20%)	
occurrences (all)	66	762	
Constipation			
subjects affected / exposed	255 / 7890 (3.23%)	247 / 7912 (3.12%)	
occurrences (all)	271	260	
Diarrhoea			
subjects affected / exposed	479 / 7890 (6.07%)	949 / 7912 (11.99%)	
occurrences (all)	566	1185	
Dyspepsia			
subjects affected / exposed	182 / 7890 (2.31%)	177 / 7912 (2.24%)	
occurrences (all)	197	197	
Flatulence			
subjects affected / exposed	92 / 7890 (1.17%)	189 / 7912 (2.39%)	
occurrences (all)	96	211	
Gastritis			
subjects affected / exposed	192 / 7890 (2.43%)	159 / 7912 (2.01%)	
occurrences (all)	204	166	
Gastrooesophageal reflux disease			

subjects affected / exposed	160 / 7890 (2.03%)	144 / 7912 (1.82%)	
occurrences (all)	169	160	
Large intestine polyp			
subjects affected / exposed	265 / 7890 (3.36%)	259 / 7912 (3.27%)	
occurrences (all)	328	285	
Nausea			
subjects affected / exposed	222 / 7890 (2.81%)	228 / 7912 (2.88%)	
occurrences (all)	250	253	
Skin and subcutaneous tissue disorders			
Skin odour abnormal			
subjects affected / exposed	34 / 7890 (0.43%)	383 / 7912 (4.84%)	
occurrences (all)	38	425	
Renal and urinary disorders			
Urine odour abnormal			
subjects affected / exposed	81 / 7890 (1.03%)	473 / 7912 (5.98%)	
occurrences (all)	83	491	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	401 / 7890 (5.08%)	385 / 7912 (4.87%)	
occurrences (all)	468	449	
Back pain			
subjects affected / exposed	466 / 7890 (5.91%)	421 / 7912 (5.32%)	
occurrences (all)	514	457	
Muscle spasms			
subjects affected / exposed	168 / 7890 (2.13%)	164 / 7912 (2.07%)	
occurrences (all)	184	185	
Musculoskeletal pain			
subjects affected / exposed	219 / 7890 (2.78%)	180 / 7912 (2.28%)	
occurrences (all)	239	190	
Myalgia			
subjects affected / exposed	244 / 7890 (3.09%)	207 / 7912 (2.62%)	
occurrences (all)	290	221	
Osteoarthritis			
subjects affected / exposed	176 / 7890 (2.23%)	167 / 7912 (2.11%)	
occurrences (all)	198	183	
Pain in extremity			

subjects affected / exposed	354 / 7890 (4.49%)	315 / 7912 (3.98%)	
occurrences (all)	399	357	
Infections and infestations			
Bronchitis			
subjects affected / exposed	416 / 7890 (5.27%)	389 / 7912 (4.92%)	
occurrences (all)	523	489	
Influenza			
subjects affected / exposed	253 / 7890 (3.21%)	223 / 7912 (2.82%)	
occurrences (all)	305	263	
Nasopharyngitis			
subjects affected / exposed	588 / 7890 (7.45%)	548 / 7912 (6.93%)	
occurrences (all)	754	825	
Sinusitis			
subjects affected / exposed	189 / 7890 (2.40%)	157 / 7912 (1.98%)	
occurrences (all)	231	195	
Upper respiratory tract infection			
subjects affected / exposed	425 / 7890 (5.39%)	367 / 7912 (4.64%)	
occurrences (all)	534	492	
Urinary tract infection			
subjects affected / exposed	296 / 7890 (3.75%)	260 / 7912 (3.29%)	
occurrences (all)	375	331	
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	608 / 7890 (7.71%)	566 / 7912 (7.15%)	
occurrences (all)	633	592	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 August 2009	Clarification and correction of different items in protocol. RATIONALE: Following initial investigator meetings and discussions of the original protocol, it became apparent that changes were needed to improve understanding of the protocol.
11 February 2010	The primary intent of this amendment was to add a single cognitive function assessment (Montreal Cognitive Assessment) for all participants (if an approved translation was available) prior to the end of the study. RATIONALE: This change added an exploratory assessment that was of scientific interest and may be relevant to planning future clinical trials among this patient population.
29 July 2010	The primary intent of this amendment was to revise the threshold for excluding participants of Japanese, Chinese, or Korean ancestry with plasma levels of Lp-PLA2 activity from ≤ 10 to ≤ 20.0 nanomoles (nmol)/minute (min)/milliliter (mL). RATIONALE: The original text excluded Japanese, Chinese, and Korean participants with plasma Lp-PLA2 activity ≤ 10 nmol/min/mL prior to randomization. This threshold was intended to be a surrogate measure for being homozygous for the 279F null variant allele, predominantly found in East Asians, and was listed as an exclusion criterion to avoid randomizing participants who would not be expected to produce circulating levels of the Lp-PLA2 enzyme. As participants who were homozygous for the 279F null allele would have no Lp-PLA2 enzyme to inhibit, it was important to identify these participants since there would be no clear rationale for exposing such participants to the investigational Lp-PLA2 inhibitor darapladib. Data from participants with chronic coronary heart disease in this study determined that Japanese, Chinese, and Korean participants who were homozygous for the 279F variant had reported baseline plasma Lp-PLA2 activity levels approaching 20.0 nmol/min/mL when measured by the assay used in this study. The text for the exclusion criterion pertaining to Japanese, Chinese, and Korean participants revised the threshold for the plasma Lp-PLA2 activity to ≤ 20.0 nmol/min/mL prior to randomization, which was expected to help ensure that Japanese, Chinese, and Korean participants who were homozygous for the 279F variant were not enrolled.
29 March 2012	The primary intent of this amendment was to allow the Follow-up visit to be conducted by telephone in participants who met pre-defined criteria. RATIONALE: This change allowed collection of study endpoints/safety data in participants unable to attend a Follow-up clinic visit.
10 October 2012	The primary intent was to allow increased collection of data on new cancer, recurrence of cancer, or progression of cancer; and adjudication of all GI neoplasms (malignant and benign) and all GI polyps (malignant, and benign, and non-neoplastic). RATIONALE: Darapladib was given by oral gavage to male and female rodents starting from before sexual maturation and continuing every day throughout their lifetime for up to 2 years. Data from these studies became available prior to the end of the study. Overall, the data suggested drug-related increases in the incidence of adenomas and/or adenocarcinomas of the jejunum in male mice and male rats given higher doses of darapladib. The Independent Data Monitoring Committee for both this study and the other Phase III study (Study SB480848/033) reviewed these data and re-reviewed the safety data, including reports of tumors in study participants. Following this review, the IDMC recommended that the trials continue without any changes. However, this protocol change was proposed and incorporated by the sponsor to allow a more thorough review of neoplasms reported in this study.

29 November 2012	This country-specific amendment for France was required by the French regulatory authority (ANSM). Participants diagnosed with inflammatory bowel disease (Crohn's disease or ulcerative colitis) must immediately discontinue investigational product (IP).
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Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported