



Clinical trial results:

A Clinical Outcomes Study of Darapladib versus Placebo in Subjects Following Acute Coronary Syndrome to Compare the Incidence of Major Adverse Cardiovascular Events (MACE).

(Short title: The Stabilization Of pLaques using Darapladib-Thrombolysis In Myocardial Infarction 52 [SOLID-TIMI 52] Trial)

Summary

EudraCT number	2009-012581-32
Trial protocol	GB DE BE ES NL SE DK HU CZ SK PL BG IT
Global end of trial date	24 April 2014

Results information

Result version number	v1 (current)
This version publication date	27 April 2016
First version publication date	10 April 2015

Trial information

Trial identification

Sponsor protocol code	SB-480848/033
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01000727
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	10 June 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	24 April 2014
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 with placebo when added to standard of care in an ACS patient population on the incidence of first occurrence of the composite of major coronary events (i.e., CHD death, non-fatal MI, or urgent coronary revascularization for myocardial ischemia).

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	07 December 2009
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	Denmark: 442
Country: Number of subjects enrolled	France: 270
Country: Number of subjects enrolled	Germany: 510
Country: Number of subjects enrolled	Hungary: 350
Country: Number of subjects enrolled	Italy: 229
Country: Number of subjects enrolled	Netherlands: 622
Country: Number of subjects enrolled	Poland: 1056
Country: Number of subjects enrolled	Romania: 246
Country: Number of subjects enrolled	Slovakia: 203
Country: Number of subjects enrolled	Spain: 166
Country: Number of subjects enrolled	Sweden: 157
Country: Number of subjects enrolled	United Kingdom: 168
Country: Number of subjects enrolled	Belgium: 138
Country: Number of subjects enrolled	Bulgaria: 284

Country: Number of subjects enrolled	Czech Republic: 443
Country: Number of subjects enrolled	Argentina: 159
Country: Number of subjects enrolled	Australia: 209
Country: Number of subjects enrolled	Brazil: 414
Country: Number of subjects enrolled	Canada: 327
Country: Number of subjects enrolled	Chile: 155
Country: Number of subjects enrolled	China: 445
Country: Number of subjects enrolled	Colombia: 172
Country: Number of subjects enrolled	India: 345
Country: Number of subjects enrolled	Israel: 690
Country: Number of subjects enrolled	Japan: 211
Country: Number of subjects enrolled	Korea, Republic of: 119
Country: Number of subjects enrolled	New Zealand: 121
Country: Number of subjects enrolled	Peru: 55
Country: Number of subjects enrolled	Philippines: 110
Country: Number of subjects enrolled	Russian Federation: 876
Country: Number of subjects enrolled	South Africa: 296
Country: Number of subjects enrolled	Taiwan: 130
Country: Number of subjects enrolled	Thailand: 114
Country: Number of subjects enrolled	Turkey: 9
Country: Number of subjects enrolled	Ukraine: 306
Country: Number of subjects enrolled	United States: 2479
Worldwide total number of subjects	13026
EEA total number of subjects	5284

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)	6794
From 65 to 84 years	6101
85 years and over	131

Subject disposition

Recruitment

Recruitment details:

This study consisted of a Screening Phase of ≤ 30 days, a Treatment Phase, an End-of-Treatment (EOT) visit, and a Follow-up visit scheduled for 35 \pm 7 days after the last study drug intake. The median treatment duration was anticipated to be 3 years.

Pre-assignment

Screening details:

During the screening phase of the study, participants presenting with acute coronary syndrome (ACS) were randomized within 30 days. Approximately 77% of participants underwent percutaneous coronary intervention (PCI) for the qualifying event.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, 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	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

dosed once daily with food and swallowed whole (not crushed or chewed)

Arm title	Darapladib 160 mg
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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 160 mg
Started	6522	6504
Completed	6347	6328
Not completed	175	176
Consent withdrawn by subject	111	109
Lost to follow-up	41	43
Study Closed/Terminated	23	24

Baseline characteristics

Reporting groups

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

Reporting group values	Placebo	Darapladib 160 mg	Total
Number of subjects	6522	6504	13026
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	64.1	-
standard deviation	± 9.5	± 9.52	-
Gender categorical			
Units: Subjects			
Female	1669	1657	3326
Male	4853	4847	9700
Race, customized			
Units: Subjects			
White	5469	5452	10921
Japanese/East Asian Heritage (EAH) /South EAH(SEAH)	583	574	1157
Central/South Asian Heritage	200	211	411
Mixed Asian Heritage	2	3	5
African American/African Heritage (AH)	160	155	315
American Indian or Alaska Native (AN)	56	52	108
American Indian or AN & White	23	31	54
Native Hawaiian or Other Pacific Islander (OPI)	9	5	14
African American/AH & American Indian or AN & White	8	5	13
African American/AH & White	4	5	9

African American/AH & American Indian or AN	4	4	8
Asian & White	1	3	4
Japanese/EAH/SEAH & Native Hawaiian or OPI	1	1	2
African American/AH & Asian	1	0	1
African American/AH & Asian & White	1	0	1
African American/AH & Native Hawaiian or OPI	0	1	1
American Indian or AN & Native Hawaiian or OPI	0	1	1
Native Hawaiian or OPI & White	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 160 mg
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 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 event

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 event
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	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 3.80 years/average of 2.39 years)	

End point values	Placebo	Darapladib 160 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6522 ^[1]	6504 ^[2]		
Units: participants	910	903		

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 160 mg

Number of subjects included in analysis	13026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.929 [3]
Method	Cox Proportional Hazard Regression Model
Parameter estimate	Hazard ratio (HR)
Point estimate	1
Confidence interval	
level	95.02 %
sides	2-sided
lower limit	0.91
upper limit	1.09

Notes:

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

Secondary: 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
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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	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 3.80 years/average of 2.39 years)

End point values	Placebo	Darapladib 160 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6522 ^[4]	6504 ^[5]		
Units: participants	838	824		

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 160 mg

Number of subjects included in analysis	13026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.777 ^[6]
Method	Cox Proportional Hazard Regression Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.99
Confidence interval	
level	95.02 %
sides	2-sided
lower limit	0.9
upper limit	1.09

Notes:

[6] - Statistical significance of this p-value is based on the alpha-spending function of this study.

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

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

CV death is defined as a death due to a CV cause, which includes but is 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 3.80 years/average of 2.39 years)

End point values	Placebo	Darapladib 160 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6522 ^[7]	6504 ^[8]		
Units: participants	268	243		

Notes:

[7] - All Randomized ITT Population

[8] - All Randomized ITT Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #2
Comparison groups	Placebo v Darapladib 160 mg
Number of subjects included in analysis	13026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.274
Method	Cox Proportional Hazard Regression Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.08

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

End point title	Number of participants with first occurrence of MI (fatal/non-fatal) during the time period for follow-up of cardiovascular 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 3.80 years/average of 2.39 years)

End point values	Placebo	Darapladib 160 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6522 ^[9]	6504 ^[10]		
Units: participants	564	547		

Notes:

[9] - All Randomized ITT Population

[10] - All Randomized ITT Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #3
Comparison groups	Darapladib 160 mg v Placebo
Number of subjects included in analysis	13026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.631
Method	Cox Proportional Hazard Regression Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.09

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

End point title	Number of participants with first occurrence of stroke (fatal/non-fatal) during the time period for follow-up of cardiovascular 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 3.80 years/average of 2.39 years)

End point values	Placebo	Darapladib 160 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6522 ^[11]	6504 ^[12]		
Units: participants	130	145		

Notes:

[11] - All Randomized ITT Population

[12] - All Randomized ITT Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #4
Comparison groups	Placebo v Darapladib 160 mg
Number of subjects included in analysis	13026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.354
Method	Cox Proportional Hazard Regression Model
Parameter estimate	Hazard ratio (HR)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.42

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

End point title	Number of participants with CHD death during the time period for follow-up of cardiovascular events
End point description:	CHD death is defined as the 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.

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 3.80 years/average of 2.39 years)

End point values	Placebo	Darapladib 160 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6522 ^[13]	6504 ^[14]		
Units: participants	241	211		

Notes:

[13] - All-Randomized ITT Population

[14] - All-Randomized ITT Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #5
Comparison groups	Placebo v Darapladib 160 mg
Number of subjects included in analysis	13026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.161
Method	Cox Proportional Hazard Regression Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.05

Secondary: Number of participants with urgent coronary revascularization for myocardial ischemia during the time period for follow-up of cardiovascular events

End point title	Number of participants with urgent coronary revascularization for myocardial ischemia during the time period for follow-up of cardiovascular events
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End point description:

Urgent coronary revascularization for myocardial ischemia is defined as ischemic discomfort at rest that prompts coronary revascularization (PCI or coronary artery bypass graft [CABG]) during the same hospitalization or resulting in hospital transfer for the purpose of coronary revascularization. PCI is defined as any attempt at revascularization even if not successful (e.g., angioplasty, atherectomy or stenting).

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 3.80 years/average of 2.39 years)

End point values	Placebo	Darapladib 160 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6522 ^[15]	6504 ^[16]		
Units: participants	218	237		

Notes:

[15] - All-Randomized ITT Population

[16] - All-Randomized ITT Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #6
Comparison groups	Placebo v Darapladib 160 mg
Number of subjects included in analysis	13026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.36
Method	Cox Proportional Hazard Regression Model
Parameter estimate	Hazard ratio (HR)
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.31

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 the 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 the time period for FU of CV events
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End point description:

CHD death, acute MI, and prior MI diagnosed post-randomization are defined in the primary 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 was found not to be caused by myocardial ischemia. Coronary revascularization procedures exclude PCI planned prior to randomization but performed after randomization.

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 3.80 years/average of 2.39 years)

End point values	Placebo	Darapladib 160 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6522 ^[17]	6504 ^[18]		
Units: participants	1352	1290		

Notes:

[17] - All-Randomized ITT Population

[18] - All-Randomized ITT Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #7
Comparison groups	Placebo v Darapladib 160 mg
Number of subjects included in analysis	13026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.202
Method	Cox Proportional Hazard Regression Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.03

Secondary: Number of participants with first occurrence of any coronary revascularization procedures (excluding coronary revascularization planned prior to randomization, but performed after randomization) during the time period for follow-up of cardiovascular event

End point title	Number of participants with first occurrence of any coronary revascularization procedures (excluding coronary revascularization planned prior to randomization, but performed after randomization) during the time period for follow-up of cardiovascular event
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End point description:

All coronary revascularization procedures (except for PCI planned prior to randomization but performed after randomization) are included. Examples include coronary artery bypass graft, balloon angioplasty and stenting.

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 3.80 years/average of 2.39 years)

End point values	Placebo	Darapladib 160 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6522 ^[19]	6504 ^[20]		
Units: participants	967	926		

Notes:

[19] - All-Randomized ITT Population

[20] - All-Randomized ITT Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #8
Comparison groups	Placebo v Darapladib 160 mg
Number of subjects included in analysis	13026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.329
Method	Cox Proportional Hazard Regression Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.05

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 cardiovascular 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 cardiovascular 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 3.80 years/average of 2.39 years)

End point values	Placebo	Darapladib 160 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6522 ^[21]	6504 ^[22]		
Units: participants	928	914		

Notes:

[21] - All Randomized ITT Population

[22] - All Randomized ITT Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #9
Comparison groups	Placebo v Darapladib 160 mg
Number of subjects included in analysis	13026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.797
Method	Cox Proportional Hazard Regression Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.08

Secondary: Number of participants with first occurrence of any event in the composite of CHD death and non-fatal MI during the time period for follow-up of cardiovascular events

End point title	Number of participants with first occurrence of any event in the composite of CHD death and non-fatal MI during the time period for follow-up of cardiovascular 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. CHD death is defined as the 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.

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 3.80 years/average of 2.39 years)

End point values	Placebo	Darapladib 160 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6522 ^[23]	6504 ^[24]		
Units: participants	725	701		

Notes:

[23] - All Randomized ITT Population

[24] - All Randomized ITT Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #10
Comparison groups	Placebo v Darapladib 160 mg
Number of subjects included in analysis	13026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.546
Method	Cox Proportional Hazard Regression Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.07

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
End point description:	The number of participants with all-cause mortality was assessed.
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 3.80 years/average of 2.39 years)

End point values	Placebo	Darapladib 160 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6522 ^[25]	6504 ^[26]		
Units: participants	403	376		

Notes:

[25] - All Randomized ITT Population

[26] - All Randomized ITT Population

Statistical analyses

Statistical analysis title	Statistical Analysis for Secondary Endpoint #11
Comparison groups	Placebo v Darapladib 160 mg
Number of subjects included in analysis	13026
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.362
Method	Cox Proportional Hazard Regression Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.08

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Start=Randomization; Stop=The longer of 42 days after last dose of IP/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 randomised 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	16.1
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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	3011 / 6465 (46.57%)	2933 / 6452 (45.46%)	
number of deaths (all causes)	403	376	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute myeloid leukaemia			
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute promyelocytic leukaemia			

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Adenocarcinoma gastric		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	7 / 6465 (0.11%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma pancreas		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenoma benign		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenosquamous cell lung cancer		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Anal cancer		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Angiocentric lymphoma		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Angiosarcoma metastatic		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
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	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma recurrent		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Basal cell carcinoma		
subjects affected / exposed	4 / 6465 (0.06%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Benign anorectal neoplasm		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign breast neoplasm		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign gastric neoplasm		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign gastrointestinal neoplasm		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign laryngeal neoplasm		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of adrenal gland		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of prostate		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct cancer		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Bladder cancer		

subjects affected / exposed	15 / 6465 (0.23%)	10 / 6452 (0.15%)
occurrences causally related to treatment / all	1 / 15	0 / 10
deaths causally related to treatment / all	0 / 3	0 / 1
Bladder cancer recurrent		
subjects affected / exposed	5 / 6465 (0.08%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage 0, with cancer in situ		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		
subjects affected / exposed	4 / 6465 (0.06%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder papilloma		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone giant cell tumour benign		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Borderline ovarian tumour		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm malignant		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer		
subjects affected / exposed	8 / 6465 (0.12%)	10 / 6452 (0.15%)
occurrences causally related to treatment / all	0 / 8	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer metastatic		
subjects affected / exposed	1 / 6465 (0.02%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 2
Bronchial carcinoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Central nervous system neoplasm		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar tumour		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Cervix carcinoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 1	1 / 1
Choroid melanoma		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
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	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia		
subjects affected / exposed	1 / 6465 (0.02%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	1 / 1
Clear cell renal cell carcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	4 / 6465 (0.06%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	9 / 6465 (0.14%)	12 / 6452 (0.19%)
occurrences causally related to treatment / all	1 / 9	2 / 12
deaths causally related to treatment / all	0 / 1	0 / 0
Colon cancer metastatic		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	1 / 1	0 / 0
Colorectal adenocarcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystadenocarcinoma ovary		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Desmoplastic melanoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Essential thrombocythaemia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibroma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		
subjects affected / exposed	6 / 6465 (0.09%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	1 / 6	2 / 7
deaths causally related to treatment / all	0 / 2	1 / 2
Gastric cancer stage I		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric neoplasm		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal cancer metastatic		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastrointestinal carcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrointestinal stromal cancer		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal tumour		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal tract adenoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma multiforme		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glottis carcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemangioma of liver		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer metastatic		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatocellular carcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large cell lung cancer stage IV		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
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 / 6465 (0.02%)	0 / 6452 (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 / 6465 (0.02%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal squamous cell carcinoma		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leiomyosarcoma metastatic		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Leukaemia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lip neoplasm malignant stage unspecified		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lip squamous cell carcinoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Lung cancer metastatic		
subjects affected / exposed	9 / 6465 (0.14%)	12 / 6452 (0.19%)
occurrences causally related to treatment / all	1 / 10	0 / 12
deaths causally related to treatment / all	0 / 7	0 / 8
Lung carcinoma cell type unspecified recurrent		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm malignant		
subjects affected / exposed	14 / 6465 (0.22%)	11 / 6452 (0.17%)
occurrences causally related to treatment / all	0 / 14	1 / 12
deaths causally related to treatment / all	0 / 4	1 / 7
Lung squamous cell carcinoma metastatic		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung squamous cell carcinoma stage I		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoma		
subjects affected / exposed	4 / 6465 (0.06%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant melanoma		
subjects affected / exposed	6 / 6465 (0.09%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 1
Malignant neoplasm of ampulla of Vater		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant neoplasm of unknown		

primary site			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Malignant neoplasm progression			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Melanoma recurrent			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma benign			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma malignant			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to bone			
subjects affected / exposed	3 / 6465 (0.05%)	3 / 6452 (0.05%)	
occurrences causally related to treatment / all	0 / 3	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Metastases to liver			

subjects affected / exposed	7 / 6465 (0.11%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	1 / 7	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1
Metastases to lung		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Metastases to lymph nodes		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Metastases to peritoneum		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to pleura		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastases to spine		
subjects affected / exposed	0 / 6465 (0.00%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic bronchial carcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic gastric cancer		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Metastatic lymphoma		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic malignant melanoma		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic neoplasm		
subjects affected / exposed	0 / 6465 (0.00%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	1 / 2
Metastatic renal cell carcinoma		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic squamous cell carcinoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic uterine cancer		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Myelodysplastic syndrome		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Myeloproliferative disorder		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm malignant		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neurilemmoma benign		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma of the skin		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine tumour		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Non-small cell lung cancer stage IIIB		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Non-small cell lung cancer metastatic		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Non-small cell lung cancer recurrent		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Oesophageal cancer metastatic		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1
Oesophageal carcinoma		
subjects affected / exposed	4 / 6465 (0.06%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	1 / 4	1 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Oral cavity cancer metastatic		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal cancer		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteosarcoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer metastatic		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Ovarian germ cell teratoma benign		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Pancreatic carcinoma metastatic		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Paraneoplastic syndrome		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Paraproteinaemia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Plasmacytoma		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pleomorphic adenoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polycythaemia vera		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Precursor B-lymphoblastic lymphoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Prostate cancer		
subjects affected / exposed	21 / 6465 (0.32%)	25 / 6452 (0.39%)
occurrences causally related to treatment / all	2 / 21	2 / 25
deaths causally related to treatment / all	0 / 1	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	2 / 6465 (0.03%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 2	2 / 7
deaths causally related to treatment / all	0 / 1	1 / 3
Prostate cancer recurrent		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	3 / 6465 (0.05%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	1 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Rectal cancer metastatic		
subjects affected / exposed	1 / 6465 (0.02%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 3
Rectosigmoid cancer		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	6 / 6465 (0.09%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Renal cancer metastatic		
subjects affected / exposed	1 / 6465 (0.02%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 3
Renal cell carcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma stage II		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal oncocytoma		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sarcoma metastatic		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1
Signet-ring cell carcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Skin cancer		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	1 / 6465 (0.02%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Small cell lung cancer metastatic		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Small intestine adenocarcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		

subjects affected / exposed	3 / 6465 (0.05%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Squamous cell carcinoma of skin		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
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 tongue		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
T-cell lymphoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Testis cancer		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thymoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer metastatic		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue cancer metastatic		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue carcinoma stage IV		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Tongue neoplasm malignant stage unspecified		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Tonsil cancer metastatic		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Tracheal neoplasm		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma		
subjects affected / exposed	3 / 6465 (0.05%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma metastatic		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Uterine cancer		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine leiomyoma		

subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal cancer			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiodysplasia			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	11 / 6465 (0.17%)	12 / 6452 (0.19%)	
occurrences causally related to treatment / all	0 / 11	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic dissection			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic occlusion			

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic stenosis		
subjects affected / exposed	7 / 6465 (0.11%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Aortic thrombosis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial disorder		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial haemorrhage		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial insufficiency		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial thrombosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis		

subjects affected / exposed	2 / 6465 (0.03%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Arteriovenous fistula		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Coeliac artery occlusion		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Deep vein thrombosis		
subjects affected / exposed	14 / 6465 (0.22%)	12 / 6452 (0.19%)
occurrences causally related to treatment / all	0 / 16	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic microangiopathy		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		
subjects affected / exposed	0 / 6465 (0.00%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery aneurysm		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery dissection		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery occlusion		
subjects affected / exposed	3 / 6465 (0.05%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	4 / 6465 (0.06%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Haemodynamic instability		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Haemorrhage		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Hypertension		
subjects affected / exposed	38 / 6465 (0.59%)	15 / 6452 (0.23%)
occurrences causally related to treatment / all	0 / 46	1 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	19 / 6465 (0.29%)	13 / 6452 (0.20%)
occurrences causally related to treatment / all	0 / 20	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	25 / 6465 (0.39%)	18 / 6452 (0.28%)
occurrences causally related to treatment / all	0 / 25	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery occlusion		
subjects affected / exposed	3 / 6465 (0.05%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery rupture		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	17 / 6465 (0.26%)	15 / 6452 (0.23%)
occurrences causally related to treatment / all	0 / 18	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic limb pain		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jugular vein thrombosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leriche syndrome		

subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphatic fistula		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphocele		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant hypertension		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	10 / 6465 (0.15%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	39 / 6465 (0.60%)	36 / 6452 (0.56%)
occurrences causally related to treatment / all	0 / 51	0 / 43
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	3 / 6465 (0.05%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery dissection		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		

subjects affected / exposed	15 / 6465 (0.23%)	25 / 6452 (0.39%)
occurrences causally related to treatment / all	0 / 16	0 / 32
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (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	15 / 6465 (0.23%)	17 / 6452 (0.26%)
occurrences causally related to treatment / all	0 / 22	0 / 20
deaths causally related to treatment / all	0 / 1	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	15 / 6465 (0.23%)	13 / 6452 (0.20%)
occurrences causally related to treatment / all	0 / 21	0 / 16
deaths causally related to treatment / all	0 / 1	0 / 0
Polyarteritis nodosa		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post thrombotic syndrome		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Reperfusion injury		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery stenosis		
subjects affected / exposed	3 / 6465 (0.05%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Temporal arteritis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis superficial		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose vein		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular insufficiency		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular occlusion		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pain		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stenosis			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Coronary angioplasty			
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery bypass			
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Percutaneous coronary intervention			
subjects affected / exposed	252 / 6465 (3.90%)	262 / 6452 (4.06%)	
occurrences causally related to treatment / all	0 / 258	0 / 279	
deaths causally related to treatment / all	0 / 0	0 / 1	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	4 / 6465 (0.06%)	6 / 6452 (0.09%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac death			
subjects affected / exposed	3 / 6465 (0.05%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 2	
Chest discomfort			
subjects affected / exposed	10 / 6465 (0.15%)	8 / 6452 (0.12%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	15 / 6465 (0.23%)	20 / 6452 (0.31%)	
occurrences causally related to treatment / all	0 / 16	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 1	
Death			
subjects affected / exposed	36 / 6465 (0.56%)	34 / 6452 (0.53%)	
occurrences causally related to treatment / all	0 / 36	1 / 34	
deaths causally related to treatment / all	0 / 36	1 / 34	
Device dislocation			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	0 / 6465 (0.00%)	3 / 6452 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	14 / 6465 (0.22%)	27 / 6452 (0.42%)	
occurrences causally related to treatment / all	0 / 14	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug withdrawal syndrome			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
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	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fatigue		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Gait disturbance		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
General physical health deterioration		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Hernia obstructive		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypothermia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired healing		
subjects affected / exposed	5 / 6465 (0.08%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inflammation		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza like illness		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Local swelling		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device complication		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mucosal haemorrhage		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multi-organ failure		
subjects affected / exposed	9 / 6465 (0.14%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 6	0 / 3
Nodule		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-cardiac chest pain		
subjects affected / exposed	298 / 6465 (4.61%)	248 / 6452 (3.84%)
occurrences causally related to treatment / all	1 / 387	0 / 331
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		

subjects affected / exposed	6 / 6465 (0.09%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pain		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Patient-device incompatibility		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic mass		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyserositis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pseudopolyp		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
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 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	11 / 6465 (0.17%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Stent malfunction		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stent-graft endoleak		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden cardiac death		
subjects affected / exposed	35 / 6465 (0.54%)	26 / 6452 (0.40%)
occurrences causally related to treatment / all	1 / 35	0 / 26
deaths causally related to treatment / all	1 / 35	0 / 26
Sudden death		
subjects affected / exposed	28 / 6465 (0.43%)	26 / 6452 (0.40%)
occurrences causally related to treatment / all	1 / 28	0 / 26
deaths causally related to treatment / all	1 / 28	0 / 26
Surgical failure		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic inflammatory response syndrome		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Thrombosis in device		
subjects affected / exposed	8 / 6465 (0.12%)	8 / 6452 (0.12%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0
Ulcer haemorrhage		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vessel puncture site thrombosis		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Allergy to arthropod sting			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	2 / 6465 (0.03%)	4 / 6452 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	4 / 6465 (0.06%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 4	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
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 phimosis			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balanoposthitis			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	12 / 6465 (0.19%)	9 / 6452 (0.14%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast pain			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix disorder			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			

subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erectile dysfunction		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Menometrorrhagia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metrorrhagia		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Organic erectile dysfunction		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cyst		
subjects affected / exposed	5 / 6465 (0.08%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Perineal fistula		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic disorder		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatitis		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectocele		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sperm granuloma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spermatocele		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine polyp		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine prolapse		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Uterovaginal prolapse		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vaginal haemorrhage		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	16 / 6465 (0.25%)	9 / 6452 (0.14%)	
occurrences causally related to treatment / all	1 / 18	0 / 11	
deaths causally related to treatment / all	1 / 3	0 / 3	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
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	10 / 6465 (0.15%)	7 / 6452 (0.11%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 3	0 / 3	
Alveolitis			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aspiration			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	6 / 6465 (0.09%)	3 / 6452 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma late onset			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	3 / 6465 (0.05%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	45 / 6465 (0.70%)	56 / 6452 (0.87%)
occurrences causally related to treatment / all	1 / 65	0 / 79
deaths causally related to treatment / all	0 / 1	0 / 2
Cough		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		
subjects affected / exposed	27 / 6465 (0.42%)	21 / 6452 (0.33%)
occurrences causally related to treatment / all	0 / 29	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 1
Dyspnoea exertional		
subjects affected / exposed	4 / 6465 (0.06%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea paroxysmal nocturnal		

subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Epistaxis		
subjects affected / exposed	13 / 6465 (0.20%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 14	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Granulomatous pneumonitis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	7 / 6465 (0.11%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemothorax		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrothorax		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	4 / 6465 (0.06%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		

subjects affected / exposed	0 / 6465 (0.00%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal oedema		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infiltration		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal congestion		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
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	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive airways disorder		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal pain		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		

subjects affected / exposed	8 / 6465 (0.12%)	14 / 6452 (0.22%)
occurrences causally related to treatment / all	0 / 8	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		
subjects affected / exposed	2 / 6465 (0.03%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuritic pain		
subjects affected / exposed	2 / 6465 (0.03%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	5 / 6465 (0.08%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 0
Pneumonitis		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	6 / 6465 (0.09%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		
subjects affected / exposed	9 / 6465 (0.14%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 11	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	22 / 6465 (0.34%)	28 / 6452 (0.43%)
occurrences causally related to treatment / all	0 / 23	0 / 28
deaths causally related to treatment / all	0 / 4	0 / 5
Pulmonary fibrosis		

subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary haemorrhage		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary hypertension		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary mass		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	18 / 6465 (0.28%)	15 / 6452 (0.23%)
occurrences causally related to treatment / all	0 / 18	0 / 16
deaths causally related to treatment / all	0 / 5	0 / 0
Pulmonary sarcoidosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary thrombosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory arrest		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Respiratory depression		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory disorder			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	11 / 6465 (0.17%)	11 / 6452 (0.17%)	
occurrences causally related to treatment / all	1 / 12	0 / 11	
deaths causally related to treatment / all	0 / 3	0 / 4	
Sleep apnoea syndrome			
subjects affected / exposed	3 / 6465 (0.05%)	4 / 6452 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sputum retention			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Affective disorder			
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			

subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Alcohol withdrawal syndrome		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Alcoholism		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety		
subjects affected / exposed	9 / 6465 (0.14%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety disorder		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar I disorder		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar disorder		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Completed suicide		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 1
Confusional state		

subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	14 / 6465 (0.22%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 15	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Depression suicidal		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Disorientation		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug abuse		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Emotional distress		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		

subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental disorder due to a general medical condition			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	4 / 6465 (0.06%)	5 / 6452 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mood disorder due to a general medical condition			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Psychotic disorder due to a general medical condition			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizophrenia, undifferentiated type			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Substance abuse			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	1 / 6465 (0.02%)	3 / 6452 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			

subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 6465 (0.06%)	6 / 6452 (0.09%)	
occurrences causally related to treatment / all	0 / 4	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ammonia increased			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
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	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium decreased			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium increased			

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
C-reactive protein increased		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac enzymes increased		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac output decreased		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac stress test abnormal		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium test positive		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction decreased		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram QT prolonged		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram ST segment depression		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram ST segment elevation		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Exercise test abnormal		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibrin D dimer increased		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoglobin decreased		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
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	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme abnormal		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme increased		

subjects affected / exposed	8 / 6465 (0.12%)	9 / 6452 (0.14%)	
occurrences causally related to treatment / all	2 / 8	4 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laboratory test abnormal			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count increased			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary function test decreased			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin I increased			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin T increased			

subjects affected / exposed	1 / 6465 (0.02%)	3 / 6452 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Troponin increased			
subjects affected / exposed	16 / 6465 (0.25%)	7 / 6452 (0.11%)	
occurrences causally related to treatment / all	0 / 18	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
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			
Accidental overdose			
subjects affected / exposed	3 / 6465 (0.05%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Afferent loop syndrome			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	0 / 6465 (0.00%)	5 / 6452 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 6465 (0.02%)	3 / 6452 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			

subjects affected / exposed	4 / 6465 (0.06%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial restenosis		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthropod sting		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (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	4 / 6465 (0.06%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Burns second degree		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burns third degree		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac function disturbance postoperative		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac procedure complication		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery restenosis		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral hyperperfusion syndrome		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical vertebral fracture		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle fracture		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Comminuted fracture		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Compression fracture		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Contrast media reaction		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	5 / 6465 (0.08%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery reocclusion		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery restenosis		
subjects affected / exposed	30 / 6465 (0.46%)	30 / 6452 (0.46%)
occurrences causally related to treatment / all	0 / 32	0 / 34
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis radiation		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dural tear		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electric shock		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exposure via inhalation		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
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	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	6 / 6465 (0.09%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0
Fat embolism		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	4 / 6465 (0.06%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	10 / 6465 (0.15%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		

subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	0 / 6465 (0.00%)	3 / 6452 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fractured ischium			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal injury			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	0 / 6465 (0.00%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gun shot wound			
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hand fracture			

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	4 / 6465 (0.06%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Heart injury		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heat exhaustion		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Heat stroke		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	10 / 6465 (0.15%)	11 / 6452 (0.17%)
occurrences causally related to treatment / all	0 / 10	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	5 / 6465 (0.08%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site pain		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Injury		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intentional overdose		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal anastomosis complication		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw fracture		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		
subjects affected / exposed	0 / 6465 (0.00%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney contusion		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laceration		

subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament rupture		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
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 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	4 / 6465 (0.06%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	3 / 6465 (0.05%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		
subjects affected / exposed	1 / 6465 (0.02%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mountain sickness acute		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple injuries		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Muscle rupture		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle strain		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Overdose		
subjects affected / exposed	4 / 6465 (0.06%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peroneal nerve injury		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumoconiosis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural complication		

subjects affected / exposed	4 / 6465 (0.06%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural contusion		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural fistula		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural myocardial infarction		
subjects affected / exposed	6 / 6465 (0.09%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic pain		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative ileus		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postpericardiotomy syndrome		

subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural complication		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Procedural haemorrhage		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural headache		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomeningocele		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary contusion		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		

subjects affected / exposed	2 / 6465 (0.03%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Renal haematoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
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 / 6465 (0.14%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	5 / 6465 (0.08%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 2
Scapula fracture		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal haematoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Seroma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shunt stenosis		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shunt thrombosis		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fracture		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fractured base		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column injury		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	1 / 6465 (0.02%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic injury		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sternal fracture		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous haematoma		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	6 / 6465 (0.09%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Subdural haemorrhage		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Tendon injury		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	1 / 6465 (0.02%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	4 / 6465 (0.06%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		

subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic shock		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic ulcer		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft complication		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft occlusion		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft thrombosis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular procedure complication		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		

subjects affected / exposed	8 / 6465 (0.12%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound necrosis			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal arteriovenous malformation			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Odontogenic cyst			
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	8 / 6465 (0.12%)	11 / 6452 (0.17%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 2	
Acute left ventricular failure			
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	446 / 6465 (6.90%)	432 / 6452 (6.70%)	
occurrences causally related to treatment / all	3 / 547	7 / 527	
deaths causally related to treatment / all	0 / 41	0 / 26	
Angina pectoris			
subjects affected / exposed	272 / 6465 (4.21%)	266 / 6452 (4.12%)	
occurrences causally related to treatment / all	0 / 319	1 / 293	
deaths causally related to treatment / all	0 / 3	0 / 0	
Angina unstable			
subjects affected / exposed	546 / 6465 (8.45%)	562 / 6452 (8.71%)	
occurrences causally related to treatment / all	4 / 704	5 / 711	
deaths causally related to treatment / all	0 / 4	0 / 3	
Aortic valve incompetence			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	3 / 6465 (0.05%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			

subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Arrhythmia supraventricular		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	5 / 6465 (0.08%)	11 / 6452 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 2
Arteriospasm coronary		
subjects affected / exposed	0 / 6465 (0.00%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		
subjects affected / exposed	108 / 6465 (1.67%)	76 / 6452 (1.18%)
occurrences causally related to treatment / all	2 / 129	0 / 101
deaths causally related to treatment / all	0 / 0	0 / 1
Atrial flutter		
subjects affected / exposed	14 / 6465 (0.22%)	13 / 6452 (0.20%)
occurrences causally related to treatment / all	0 / 15	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial thrombosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	2 / 6465 (0.03%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	14 / 6465 (0.22%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 14	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block first degree		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	4 / 6465 (0.06%)	10 / 6452 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Bradyarrhythmia		
subjects affected / exposed	0 / 6465 (0.00%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	9 / 6465 (0.14%)	21 / 6452 (0.33%)
occurrences causally related to treatment / all	0 / 9	1 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac aneurysm		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		

subjects affected / exposed	18 / 6465 (0.28%)	29 / 6452 (0.45%)
occurrences causally related to treatment / all	0 / 19	0 / 29
deaths causally related to treatment / all	0 / 14	0 / 23
Cardiac asthma		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac discomfort		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure		
subjects affected / exposed	176 / 6465 (2.72%)	170 / 6452 (2.63%)
occurrences causally related to treatment / all	2 / 233	1 / 245
deaths causally related to treatment / all	0 / 28	0 / 25
Cardiac failure acute		
subjects affected / exposed	21 / 6465 (0.32%)	20 / 6452 (0.31%)
occurrences causally related to treatment / all	0 / 27	1 / 35
deaths causally related to treatment / all	0 / 4	0 / 4
Cardiac failure chronic		
subjects affected / exposed	14 / 6465 (0.22%)	16 / 6452 (0.25%)
occurrences causally related to treatment / all	0 / 22	0 / 17
deaths causally related to treatment / all	0 / 3	0 / 1
Cardiac failure congestive		
subjects affected / exposed	101 / 6465 (1.56%)	107 / 6452 (1.66%)
occurrences causally related to treatment / all	2 / 165	0 / 173
deaths causally related to treatment / all	1 / 9	0 / 9
Cardiac tamponade		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		

subjects affected / exposed	9 / 6465 (0.14%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	1 / 9	0 / 5
deaths causally related to treatment / all	1 / 8	0 / 5
Cardiogenic shock		
subjects affected / exposed	5 / 6465 (0.08%)	10 / 6452 (0.15%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 4	0 / 8
Cardiomyopathy		
subjects affected / exposed	1 / 6465 (0.02%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 1	1 / 1
Cardiorenal syndrome		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular disorder		
subjects affected / exposed	11 / 6465 (0.17%)	10 / 6452 (0.15%)
occurrences causally related to treatment / all	0 / 11	0 / 10
deaths causally related to treatment / all	0 / 9	0 / 10
Cardiovascular insufficiency		
subjects affected / exposed	4 / 6465 (0.06%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 4	0 / 1
Chronotropic incompetence		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	145 / 6465 (2.24%)	139 / 6452 (2.15%)
occurrences causally related to treatment / all	1 / 165	0 / 149
deaths causally related to treatment / all	0 / 3	0 / 1
Coronary artery dissection		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery insufficiency		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery occlusion		
subjects affected / exposed	10 / 6465 (0.15%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 11	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery perforation		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	59 / 6465 (0.91%)	38 / 6452 (0.59%)
occurrences causally related to treatment / all	0 / 60	0 / 43
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery thrombosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Dilatation ventricular		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive heart disease		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Interventricular septum rupture		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracardiac thrombus		
subjects affected / exposed	2 / 6465 (0.03%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	5 / 6465 (0.08%)	8 / 6452 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	1 / 6465 (0.02%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Left ventricular failure		
subjects affected / exposed	4 / 6465 (0.06%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Microvascular coronary artery disease		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve disease		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	5 / 6465 (0.08%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial fibrosis		
subjects affected / exposed	4 / 6465 (0.06%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Myocardial infarction		
subjects affected / exposed	61 / 6465 (0.94%)	45 / 6452 (0.70%)
occurrences causally related to treatment / all	0 / 64	0 / 46
deaths causally related to treatment / all	0 / 22	0 / 17
Myocardial ischaemia		
subjects affected / exposed	53 / 6465 (0.82%)	47 / 6452 (0.73%)
occurrences causally related to treatment / all	0 / 56	0 / 49
deaths causally related to treatment / all	0 / 3	0 / 0
Myocardial rupture		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Myopericarditis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nodal rhythm		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
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 / 6465 (0.14%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 9	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Paroxysmal arrhythmia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		
subjects affected / exposed	4 / 6465 (0.06%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial haemorrhage		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	12 / 6465 (0.19%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuropericarditis		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postinfarction angina		
subjects affected / exposed	8 / 6465 (0.12%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Prinzmetal angina		
subjects affected / exposed	1 / 6465 (0.02%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pulseless electrical activity		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Restrictive cardiomyopathy		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Sick sinus syndrome		
subjects affected / exposed	10 / 6465 (0.15%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Sinoatrial block		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrhythmia		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	5 / 6465 (0.08%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus tachycardia		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stress cardiomyopathy		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular extrasystoles		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachyarrhythmia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		
subjects affected / exposed	11 / 6465 (0.17%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 15	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Tachyarrhythmia		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia paroxysmal		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Torsade de pointes		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Trifascicular block		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricle rupture		

subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	3 / 6465 (0.05%)	4 / 6452 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Ventricular dyssynchrony			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	4 / 6465 (0.06%)	5 / 6452 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	14 / 6465 (0.22%)	12 / 6452 (0.19%)	
occurrences causally related to treatment / all	0 / 14	0 / 13	
deaths causally related to treatment / all	0 / 8	0 / 3	
Ventricular tachyarrhythmia			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	28 / 6465 (0.43%)	19 / 6452 (0.29%)	
occurrences causally related to treatment / all	0 / 33	1 / 21	
deaths causally related to treatment / all	0 / 4	0 / 1	
Nervous system disorders			
Aphasia			
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			

subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Basilar migraine		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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 / 6465 (0.00%)	1 / 6452 (0.02%)
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	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Brain stem stroke		
subjects affected / exposed	0 / 6465 (0.00%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Carotid arteriosclerosis		
subjects affected / exposed	3 / 6465 (0.05%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery disease		
subjects affected / exposed	1 / 6465 (0.02%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery occlusion		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery stenosis		

subjects affected / exposed	34 / 6465 (0.53%)	27 / 6452 (0.42%)
occurrences causally related to treatment / all	0 / 37	1 / 27
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid sinus syndrome		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carpal tunnel syndrome		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar ataxia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cerebellar infarction		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral arteriosclerosis		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery embolism		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral circulatory failure		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	2 / 6465 (0.03%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 4
Cerebral infarction		
subjects affected / exposed	6 / 6465 (0.09%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ischaemia		
subjects affected / exposed	3 / 6465 (0.05%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	16 / 6465 (0.25%)	19 / 6452 (0.29%)
occurrences causally related to treatment / all	0 / 16	0 / 19
deaths causally related to treatment / all	0 / 2	0 / 4
Cerebrovascular disorder		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular insufficiency		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical myelopathy		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical neuritis		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical radiculopathy		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Complex regional pain syndrome		
subjects affected / exposed	0 / 6465 (0.00%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Convulsion		
subjects affected / exposed	8 / 6465 (0.12%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 8	1 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Dementia		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		

subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	7 / 6465 (0.11%)	13 / 6452 (0.20%)
occurrences causally related to treatment / all	0 / 7	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Dysaesthesia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic stroke		
subjects affected / exposed	4 / 6465 (0.06%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Encephalopathy		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	3 / 6465 (0.05%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Frontotemporal dementia		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Grand mal convulsion		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Haemorrhagic cerebral infarction		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Haemorrhagic stroke		
subjects affected / exposed	10 / 6465 (0.15%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	1 / 10	0 / 6
deaths causally related to treatment / all	1 / 4	0 / 5
Haemorrhagic transformation stroke		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Head discomfort		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		
subjects affected / exposed	4 / 6465 (0.06%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiplegia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiplegic migraine		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperaesthesia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	5 / 6465 (0.08%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic coma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic seizure		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotonia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intercostal neuralgia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial aneurysm		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial haematoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	9 / 6465 (0.14%)	14 / 6452 (0.22%)
occurrences causally related to treatment / all	0 / 10	0 / 15
deaths causally related to treatment / all	0 / 1	0 / 0
Ischaemic stroke		
subjects affected / exposed	86 / 6465 (1.33%)	93 / 6452 (1.44%)
occurrences causally related to treatment / all	0 / 89	0 / 101
deaths causally related to treatment / all	0 / 9	0 / 8
Lacunar infarction		
subjects affected / exposed	4 / 6465 (0.06%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lethargy		
subjects affected / exposed	1 / 6465 (0.02%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		

subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Monoparesis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Monoplegia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Motor neurone disease		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple sclerosis relapse		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Narcolepsy		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgia		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroglycopenia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Normal pressure hydrocephalus		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Occipital neuralgia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	2 / 6465 (0.03%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Paraplegia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paresis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral sensory neuropathy		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postictal paralysis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	12 / 6465 (0.19%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculopathy		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		
subjects affected / exposed	4 / 6465 (0.06%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Sensory disturbance		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
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 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Speech disorder		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal epidural haematoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitic myelopathy		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Status epilepticus		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	10 / 6465 (0.15%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 1
Syncope		
subjects affected / exposed	60 / 6465 (0.93%)	58 / 6452 (0.90%)
occurrences causally related to treatment / all	1 / 62	0 / 62
deaths causally related to treatment / all	0 / 0	0 / 0
Thalamic infarction		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transient global amnesia		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		

subjects affected / exposed	45 / 6465 (0.70%)	48 / 6452 (0.74%)	
occurrences causally related to treatment / all	0 / 51	1 / 53	
deaths causally related to treatment / all	0 / 1	0 / 0	
Trigeminal neuralgia			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIIth nerve paralysis			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery occlusion			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	6 / 6465 (0.09%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo CNS origin			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
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			
Agranulocytosis			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			

subjects affected / exposed	43 / 6465 (0.67%)	49 / 6452 (0.76%)
occurrences causally related to treatment / all	0 / 47	1 / 53
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia macrocytic		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aplastic anaemia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile neutropenia		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic anaemia		
subjects affected / exposed	3 / 6465 (0.05%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Heparin-induced thrombocytopenia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercoagulation		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		

subjects affected / exposed	7 / 6465 (0.11%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy mediastinal		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoid tissue hyperplasia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	2 / 6465 (0.03%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normochromic normocytic anaemia		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (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	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic infarction		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	2 / 6465 (0.03%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness neurosensory			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear haemorrhage			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hearing impaired			
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			

subjects affected / exposed	8 / 6465 (0.12%)	8 / 6452 (0.12%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Accommodation disorder			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Age-related macular degeneration			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amaurosis fugax			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			

subjects affected / exposed	4 / 6465 (0.06%)	12 / 6452 (0.19%)
occurrences causally related to treatment / all	0 / 4	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract nuclear		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinopathy		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ectropion		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Eye haemorrhage		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid cyst		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lens dislocation		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular hole		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Open angle glaucoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Optic neuropathy		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery occlusion		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal detachment		
subjects affected / exposed	2 / 6465 (0.03%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal haemorrhage		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinoschisis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Visual acuity reduced		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	1 / 6465 (0.02%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	1 / 6465 (0.02%)	6 / 6452 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	12 / 6465 (0.19%)	8 / 6452 (0.12%)	
occurrences causally related to treatment / all	2 / 13	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	9 / 6465 (0.14%)	8 / 6452 (0.12%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal strangulated hernia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abnormal faeces		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	2 / 6465 (0.03%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's oesophagus		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brunner's gland hyperplasia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Caecitis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coeliac artery stenosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	1 / 6465 (0.02%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 1	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic pseudo-obstruction		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		

subjects affected / exposed	2 / 6465 (0.03%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's disease		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gastroparesis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diaphragmatic hernia		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	8 / 6465 (0.12%)	14 / 6452 (0.22%)
occurrences causally related to treatment / all	0 / 8	2 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	0 / 6465 (0.00%)	8 / 6452 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	5 / 6465 (0.08%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal polyp		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	7 / 6465 (0.11%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	3 / 6465 (0.05%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenogastric reflux		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	5 / 6465 (0.08%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enteroceles		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterovesical fistula		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive oesophagitis		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Faeces discoloured		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral hernia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric disorder		

subjects affected / exposed	0 / 6465 (0.00%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	5 / 6465 (0.08%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric perforation		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	17 / 6465 (0.26%)	13 / 6452 (0.20%)
occurrences causally related to treatment / all	1 / 17	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1
Gastric ulcer haemorrhage		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	16 / 6465 (0.25%)	10 / 6452 (0.15%)
occurrences causally related to treatment / all	0 / 17	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis atrophic		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		

subjects affected / exposed	3 / 6465 (0.05%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal ulcer		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis haemorrhagic		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal disorder		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	26 / 6465 (0.40%)	18 / 6452 (0.28%)
occurrences causally related to treatment / all	0 / 27	0 / 23
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrointestinal pain		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	13 / 6465 (0.20%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 13	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophagitis		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	3 / 6465 (0.05%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic erosive gastritis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	3 / 6465 (0.05%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	4 / 6465 (0.06%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperchlorhydria		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileal perforation		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileal stenosis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	3 / 6465 (0.05%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus paralytic		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	17 / 6465 (0.26%)	16 / 6452 (0.25%)
occurrences causally related to treatment / all	0 / 17	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia, obstructive		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal infarction		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Intestinal ischaemia		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Intestinal obstruction		
subjects affected / exposed	3 / 6465 (0.05%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Intestinal perforation		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ulcer		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haemorrhage		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Irritable bowel syndrome		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal obstruction		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal ulcer		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		

subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	8 / 6465 (0.12%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	1 / 10	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	5 / 6465 (0.08%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-Weiss syndrome		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Megacolon		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	2 / 6465 (0.03%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery thrombosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Mesenteric vein thrombosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		

subjects affected / exposed	6 / 6465 (0.09%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	1 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Obstruction gastric		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Odynophagia		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal disorder		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal stenosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic disorder		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic pseudocyst		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	7 / 6465 (0.11%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	1 / 9	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatitis acute		
subjects affected / exposed	11 / 6465 (0.17%)	12 / 6452 (0.19%)
occurrences causally related to treatment / all	1 / 14	1 / 13
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatitis chronic		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis relapsing		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer perforation		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periproctitis		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal adhesions		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal mesothelial hyperplasia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumoperitoneum		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proctitis		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular cyst		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal fissure		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	9 / 6465 (0.14%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		

subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal ulcer haemorrhage		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Reflux gastritis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haematoma		
subjects affected / exposed	1 / 6465 (0.02%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haemorrhage		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Short-bowel syndrome		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal obstruction		
subjects affected / exposed	7 / 6465 (0.11%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal perforation		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestine polyp		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stomatitis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subileus		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia, obstructive		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	8 / 6465 (0.12%)	10 / 6452 (0.15%)
occurrences causally related to treatment / all	0 / 9	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Uraemic gastropathy		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Varices oesophageal		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vomiting		

subjects affected / exposed	6 / 6465 (0.09%)	4 / 6452 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Alcoholic liver disease			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune hepatitis			
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct obstruction			
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	3 / 6465 (0.05%)	4 / 6452 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dyskinesia			

subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	3 / 6465 (0.05%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis acute		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cholecystitis		
subjects affected / exposed	13 / 6465 (0.20%)	10 / 6452 (0.15%)
occurrences causally related to treatment / all	1 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	15 / 6465 (0.23%)	15 / 6452 (0.23%)
occurrences causally related to treatment / all	0 / 15	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis chronic		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	18 / 6465 (0.28%)	23 / 6452 (0.36%)
occurrences causally related to treatment / all	0 / 18	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 1
Cholestasis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug-induced liver injury		

subjects affected / exposed	3 / 6465 (0.05%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	2 / 3	4 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cyst		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	0 / 6465 (0.00%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic function abnormal		
subjects affected / exposed	5 / 6465 (0.08%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	1 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	1 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis acute		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis alcoholic		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis cholestatic		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis toxic		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular injury		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatorenal syndrome		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatotoxicity		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperbilirubinaemia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic hepatitis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice cholestatic		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Liver injury		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	3 / 6465 (0.05%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	1 / 4	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	8 / 6465 (0.12%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ulcer			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry gangrene			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage subcutaneous			

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperhidrosis		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pemphigus		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Photosensitivity reaction		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriasis		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rash maculo-papular		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rosacea		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin erosion		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	7 / 6465 (0.11%)	9 / 6452 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stasis dermatitis			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic skin eruption			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute prerenal failure			
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Azotaemia			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder outlet obstruction			
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder stenosis			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder			

subjects affected / exposed	0 / 6465 (0.00%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus ureteric		
subjects affected / exposed	2 / 6465 (0.03%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urethral		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		
subjects affected / exposed	3 / 6465 (0.05%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis haemorrhagic		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	13 / 6465 (0.20%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 1
Haemorrhage urinary tract		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive nephropathy		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Micturition disorder		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephritis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	9 / 6465 (0.14%)	8 / 6452 (0.12%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyuria		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery arteriosclerosis		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery occlusion		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	3 / 6465 (0.05%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	2 / 6465 (0.03%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	19 / 6465 (0.29%)	20 / 6452 (0.31%)
occurrences causally related to treatment / all	1 / 20	0 / 20
deaths causally related to treatment / all	0 / 2	0 / 0
Renal failure acute		
subjects affected / exposed	46 / 6465 (0.71%)	44 / 6452 (0.68%)
occurrences causally related to treatment / all	2 / 48	1 / 48
deaths causally related to treatment / all	0 / 2	0 / 1
Renal failure chronic		
subjects affected / exposed	5 / 6465 (0.08%)	16 / 6452 (0.25%)
occurrences causally related to treatment / all	0 / 5	0 / 17
deaths causally related to treatment / all	0 / 1	0 / 0
Renal haemorrhage		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal hypertension		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		
subjects affected / exposed	5 / 6465 (0.08%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Renal infarct		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular necrosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stress urinary incontinence		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric dilatation		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric haemorrhage		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral haemorrhage		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	2 / 6465 (0.03%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder haemorrhage			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	8 / 6465 (0.12%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 8	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinoma			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune thyroiditis			
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	4 / 6465 (0.06%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary hypothyroidism			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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			
Ankylosing spondylitis			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	6 / 6465 (0.09%)	7 / 6452 (0.11%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	10 / 6465 (0.15%)	8 / 6452 (0.12%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical spinal stenosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Compartment syndrome		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fistula		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture malunion		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture nonunion		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc disorder		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	11 / 6465 (0.17%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Joint instability		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb discomfort		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	1 / 6465 (0.02%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle disorder		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle haemorrhage		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle spasms		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	21 / 6465 (0.32%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 22	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		
subjects affected / exposed	6 / 6465 (0.09%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	3 / 6465 (0.05%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Myositis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neck pain		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	40 / 6465 (0.62%)	29 / 6452 (0.45%)
occurrences causally related to treatment / all	0 / 40	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondritis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondrosis		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporosis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	3 / 6465 (0.05%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 3	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in jaw		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plantar fascial fibromatosis		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthritis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyositis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriatic arthropathy		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		
subjects affected / exposed	3 / 6465 (0.05%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 3	1 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sensation of heaviness		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sjogren's syndrome		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column stenosis		
subjects affected / exposed	2 / 6465 (0.03%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	1 / 6465 (0.02%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		
subjects affected / exposed	2 / 6465 (0.03%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spondyloarthropathy		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolysis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sympathetic posterior cervical syndrome		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	1 / 6465 (0.02%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Abdominal infection			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	3 / 6465 (0.05%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess intestinal			

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abscess limb		
subjects affected / exposed	6 / 6465 (0.09%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Acarodermatitis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute tonsillitis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	6 / 6465 (0.09%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Appendiceal abscess		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	8 / 6465 (0.12%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		

subjects affected / exposed	1 / 6465 (0.02%)	3 / 6452 (0.05%)
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 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial prostatitis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone abscess		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	19 / 6465 (0.29%)	29 / 6452 (0.45%)
occurrences causally related to treatment / all	0 / 20	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchopneumonia		
subjects affected / exposed	10 / 6465 (0.15%)	9 / 6452 (0.14%)
occurrences causally related to treatment / all	0 / 11	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 2
Burkholderia pseudomallei infection		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Bursitis infective		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter infection		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	24 / 6465 (0.37%)	27 / 6452 (0.42%)
occurrences causally related to treatment / all	0 / 29	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis staphylococcal		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis suppurative		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis infective		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic sinusitis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	5 / 6465 (0.08%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		

subjects affected / exposed	7 / 6465 (0.11%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Creutzfeldt-Jakob disease		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cystitis		
subjects affected / exposed	6 / 6465 (0.09%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus infection		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
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	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	16 / 6465 (0.25%)	14 / 6452 (0.22%)
occurrences causally related to treatment / all	0 / 23	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema infected		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Empyema		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Endocarditis		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis enterococcal		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis infectious		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis infectious		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		

subjects affected / exposed	4 / 6465 (0.06%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder abscess		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
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 / 6465 (0.02%)	0 / 6452 (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	8 / 6465 (0.12%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 11	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric infection		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	20 / 6465 (0.31%)	18 / 6452 (0.28%)
occurrences causally related to treatment / all	1 / 21	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis clostridial		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis norovirus		

subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Graft infection		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Groin infection		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma infection		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter infection		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis C		

subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis E		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis infectious mononucleosis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Impetigo		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected dermal cyst		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected lymphocele		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
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	4 / 6465 (0.06%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		

subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Influenza		
subjects affected / exposed	4 / 6465 (0.06%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Klebsiella infection		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Klebsiella sepsis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Labyrinthitis		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lobar pneumonia		
subjects affected / exposed	4 / 6465 (0.06%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		

subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	2 / 6465 (0.03%)	4 / 6452 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lung abscess		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	2 / 6465 (0.03%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphangitis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malaria		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Mastoiditis		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinitis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis tuberculous		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Necrotising fasciitis		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroborreliosis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal candidiasis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	2 / 6465 (0.03%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis acute		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis chronic		
subjects affected / exposed	1 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic abscess		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis tuberculous		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillar abscess		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
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 / 6465 (0.02%)	0 / 6452 (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	113 / 6465 (1.75%)	130 / 6452 (2.01%)
occurrences causally related to treatment / all	0 / 124	0 / 139
deaths causally related to treatment / all	0 / 3	0 / 3
Pneumonia bacterial		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonia fungal		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia influenzal		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia legionella		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumonia pseudomonas aeruginosa		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumonia staphylococcal		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia streptococcal		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	0 / 6465 (0.00%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural pneumonia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural sepsis		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	4 / 6465 (0.06%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Pseudomembranous colitis		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonas infection		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
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 / 6465 (0.02%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pyelonephritis		
subjects affected / exposed	5 / 6465 (0.08%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	4 / 6465 (0.06%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyoderma streptococcal		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal abscess		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		
subjects affected / exposed	5 / 6465 (0.08%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Respiratory tract infection viral		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection bacterial		

subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Scrotal abscess		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	23 / 6465 (0.36%)	24 / 6452 (0.37%)
occurrences causally related to treatment / all	1 / 23	0 / 25
deaths causally related to treatment / all	1 / 5	0 / 9
Septic shock		
subjects affected / exposed	9 / 6465 (0.14%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 3
Sinusitis		
subjects affected / exposed	2 / 6465 (0.03%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Skin bacterial infection		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin infection		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal abscess		

subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Staphylococcal infection		
subjects affected / exposed	1 / 6465 (0.02%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Staphylococcal sepsis		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal skin infection		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal bacteraemia		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal sepsis		
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Subcutaneous abscess		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Superinfection		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Testicular abscess		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	1 / 6465 (0.02%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	6 / 6465 (0.09%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection bacterial		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	47 / 6465 (0.73%)	25 / 6452 (0.39%)
occurrences causally related to treatment / all	0 / 51	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection enterococcal		
subjects affected / exposed	2 / 6465 (0.03%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection pseudomonal		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	6 / 6465 (0.09%)	7 / 6452 (0.11%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Vestibular neuronitis		
subjects affected / exposed	2 / 6465 (0.03%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection		
subjects affected / exposed	4 / 6465 (0.06%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral upper respiratory tract infection		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection		
subjects affected / exposed	5 / 6465 (0.08%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection pseudomonas		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection staphylococcal			
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed	0 / 6465 (0.00%)	2 / 6452 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (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	18 / 6465 (0.28%)	19 / 6452 (0.29%)	
occurrences causally related to treatment / all	0 / 21	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetes mellitus inadequate control			
subjects affected / exposed	19 / 6465 (0.29%)	17 / 6452 (0.26%)	
occurrences causally related to treatment / all	0 / 21	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	3 / 6465 (0.05%)	4 / 6452 (0.06%)	
occurrences causally related to treatment / all	1 / 10	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid retention		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	3 / 6465 (0.05%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydraemia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	0 / 6465 (0.00%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	5 / 6465 (0.08%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	4 / 6465 (0.06%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 4	1 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Hyperlipidaemia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		

subjects affected / exposed	11 / 6465 (0.17%)	13 / 6452 (0.20%)
occurrences causally related to treatment / all	0 / 13	1 / 14
deaths causally related to treatment / all	0 / 0	0 / 1
Hypokalaemia		
subjects affected / exposed	7 / 6465 (0.11%)	5 / 6452 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	10 / 6465 (0.15%)	6 / 6452 (0.09%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hypophagia		
subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	2 / 6465 (0.03%)	3 / 6452 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Insulin-requiring type 2 diabetes mellitus		
subjects affected / exposed	1 / 6465 (0.02%)	0 / 6452 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malnutrition		
subjects affected / exposed	2 / 6465 (0.03%)	2 / 6452 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		

subjects affected / exposed	0 / 6465 (0.00%)	1 / 6452 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	21 / 6465 (0.32%)	21 / 6452 (0.33%)
occurrences causally related to treatment / all	1 / 21	2 / 21
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	3416 / 6465 (52.84%)	3698 / 6452 (57.32%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	409 / 6465 (6.33%)	370 / 6452 (5.73%)	
occurrences (all)	458	414	
Hypotension			
subjects affected / exposed	132 / 6465 (2.04%)	154 / 6452 (2.39%)	
occurrences (all)	139	163	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	398 / 6465 (6.16%)	363 / 6452 (5.63%)	
occurrences (all)	474	433	
Atrial fibrillation			
subjects affected / exposed	185 / 6465 (2.86%)	154 / 6452 (2.39%)	
occurrences (all)	213	183	
Nervous system disorders			
Dizziness			
subjects affected / exposed	357 / 6465 (5.52%)	354 / 6452 (5.49%)	
occurrences (all)	398	414	
Headache			
subjects affected / exposed	202 / 6465 (3.12%)	175 / 6452 (2.71%)	
occurrences (all)	220	198	
Blood and lymphatic system disorders			

Anaemia subjects affected / exposed occurrences (all)	187 / 6465 (2.89%) 195	184 / 6452 (2.85%) 195	
General disorders and administration site conditions			
Chest discomfort subjects affected / exposed occurrences (all)	111 / 6465 (1.72%) 123	134 / 6452 (2.08%) 153	
Fatigue subjects affected / exposed occurrences (all)	334 / 6465 (5.17%) 354	302 / 6452 (4.68%) 318	
Non-cardiac chest pain subjects affected / exposed occurrences (all)	431 / 6465 (6.67%) 499	414 / 6452 (6.42%) 476	
Oedema peripheral subjects affected / exposed occurrences (all)	245 / 6465 (3.79%) 274	239 / 6452 (3.70%) 267	
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	130 / 6465 (2.01%) 140	140 / 6452 (2.17%) 157	
Abdominal pain upper subjects affected / exposed occurrences (all)	128 / 6465 (1.98%) 137	135 / 6452 (2.09%) 145	
Abnormal faeces subjects affected / exposed occurrences (all)	64 / 6465 (0.99%) 64	525 / 6452 (8.14%) 551	
Constipation subjects affected / exposed occurrences (all)	174 / 6465 (2.69%) 177	165 / 6452 (2.56%) 175	
Diarrhoea subjects affected / exposed occurrences (all)	351 / 6465 (5.43%) 386	675 / 6452 (10.46%) 826	
Dyspepsia subjects affected / exposed occurrences (all)	116 / 6465 (1.79%) 123	130 / 6452 (2.01%) 139	
Large intestine polyp			

subjects affected / exposed occurrences (all)	130 / 6465 (2.01%) 139	127 / 6452 (1.97%) 145	
Nausea subjects affected / exposed occurrences (all)	176 / 6465 (2.72%) 194	198 / 6452 (3.07%) 219	
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	355 / 6465 (5.49%) 382	324 / 6452 (5.02%) 350	
Dyspnoea subjects affected / exposed occurrences (all)	310 / 6465 (4.80%) 342	286 / 6452 (4.43%) 307	
Skin and subcutaneous tissue disorders			
Skin odour abnormal subjects affected / exposed occurrences (all)	23 / 6465 (0.36%) 23	241 / 6452 (3.74%) 267	
Renal and urinary disorders			
Urine odour abnormal subjects affected / exposed occurrences (all)	65 / 6465 (1.01%) 65	344 / 6452 (5.33%) 353	
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	207 / 6465 (3.20%) 225	158 / 6452 (2.45%) 175	
Back pain subjects affected / exposed occurrences (all)	262 / 6465 (4.05%) 287	224 / 6452 (3.47%) 243	
Musculoskeletal pain subjects affected / exposed occurrences (all)	130 / 6465 (2.01%) 139	98 / 6452 (1.52%) 102	
Myalgia subjects affected / exposed occurrences (all)	186 / 6465 (2.88%) 203	215 / 6452 (3.33%) 231	
Pain in extremity subjects affected / exposed occurrences (all)	221 / 6465 (3.42%) 236	181 / 6452 (2.81%) 197	

Infections and infestations			
Bronchitis			
subjects affected / exposed	178 / 6465 (2.75%)	192 / 6452 (2.98%)	
occurrences (all)	214	212	
Influenza			
subjects affected / exposed	143 / 6465 (2.21%)	141 / 6452 (2.19%)	
occurrences (all)	159	159	
Nasopharyngitis			
subjects affected / exposed	279 / 6465 (4.32%)	273 / 6452 (4.23%)	
occurrences (all)	344	352	
Upper respiratory tract infection			
subjects affected / exposed	144 / 6465 (2.23%)	162 / 6452 (2.51%)	
occurrences (all)	163	191	
Urinary tract infection			
subjects affected / exposed	205 / 6465 (3.17%)	157 / 6452 (2.43%)	
occurrences (all)	253	196	
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	358 / 6465 (5.54%)	325 / 6452 (5.04%)	
occurrences (all)	373	340	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 November 2010	<p>The primary intent was to revise two exclusion criteria.</p> <p>1. The definition of liver disease was revised to remove AST from the list of required liver function tests, and participants (par.) with chronic stable hepatitis were allowed to be enrolled under certain circumstances.</p> <p>RATIONALE: AST was removed from the list of required liver function assessments during the screening phase to assess eligibility because the ALT assessment is much more specific for evaluating liver function abnormalities.</p> <p>2. The threshold for excluding par. of Japanese, Chinese, or Korean ancestry with plasma levels of Lp-PLA2 activity was revised from ≤ 10 to ≤ 20.0 nmol/min/mL.</p> <p>RATIONALE: The original text excluded Japanese, Chinese, and Korean par. 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 par. who would not be expected to produce circulating levels of the Lp-PLA2 enzyme. As par. who were homozygous for the 279F null allele would have no Lp-PLA2 enzyme to inhibit, it was important to identify these par. since there would be no clear rationale for exposing such par. to the investigational Lp-PLA2 inhibitor darapladib. Data from par. with chronic coronary heart disease in the STABILITY study (Study LPL100601) determined that Japanese, Chinese, and Korean par. 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 par. 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 par. who were homozygous for the 279F variant were not enrolled.</p>
26 April 2012	<p>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.</p> <p>RATIONALE: This change allowed collection of study endpoints/safety data in participants unable to attend a Follow-up clinic visit.</p>
22 October 2012	<p>The primary intent was to allow increased collection of data on new cancer, recurrence of cancer, or progression of cancer; and adjudication of all gastrointestinal (GI) neoplasms (malignant and benign) and all GI polyps (malignant, and benign, and non-neoplastic).</p> <p>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 LPL100601) 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.</p> <p>However, this protocol change was proposed and incorporated by the sponsor to allow a more thorough review of neoplasms reported in this study.</p>
29 November 2012	<p>This country-specific amendment for France was required by the French regulatory authority (ANSM). The amendment required participants diagnosed with inflammatory bowel disease (Crohn's disease or ulcerative colitis) be immediately discontinued from investigational product (IP).</p>

26 February 2014	<p>The primary reason for this amendment was to change the primary efficacy endpoint from Major Adverse Cardiovascular Events (MACE: cardiovascular death, non-fatal MI, or non-fatal stroke) to the previous secondary endpoint of Major Coronary Events (i.e., CHD death, non-fatal MI, or urgent coronary revascularization for myocardial ischemia).</p> <p>RATIONALE: The Executive Steering Committee of the SOLID-TIMI-52 trial (Study SB-480848/033) which was ongoing at that time met to review data from the STABILITY (Study LPL100601) trial (similar design as Study SB-480848/033, except in a chronic CHD population) and made the recommendation to GSK that the primary endpoint of the SOLID-TIMI-52 trial (Study SB-480848/033) be revised to Major Coronary Events (CHD death, non-fatal myocardial infarction, and urgent coronary revascularization for myocardial ischemia) from MACE (CV death, non-fatal myocardial infarction, and non-fatal stroke). Specifically, this change primarily removed both fatal and non-fatal stroke from the composite endpoint. In addition, data from genetic studies and epidemiologic data showed a lack of association between Lp-PLA2 activity and risk of stroke. The decision by GSK to follow the Executive Steering Committee's recommendation to amend the primary endpoint of the SOLID-TIMI 52 study was made prior to unblinding study data and without communication from the IDMC.</p>
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Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported