



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
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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
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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 ^[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
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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
Dictionary version	16.1

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	
Postpericardiectomy 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	
VIIIth 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	
Enterocoele			
subjects affected / exposed	1 / 6465 (0.02%)	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	130 / 6465 (2.01%)	127 / 6452 (1.97%)	
occurrences (all)	139	145	
Nausea			
subjects affected / exposed	176 / 6465 (2.72%)	198 / 6452 (3.07%)	
occurrences (all)	194	219	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	355 / 6465 (5.49%)	324 / 6452 (5.02%)	
occurrences (all)	382	350	
Dyspnoea			
subjects affected / exposed	310 / 6465 (4.80%)	286 / 6452 (4.43%)	
occurrences (all)	342	307	
Skin and subcutaneous tissue disorders			
Skin odour abnormal			
subjects affected / exposed	23 / 6465 (0.36%)	241 / 6452 (3.74%)	
occurrences (all)	23	267	
Renal and urinary disorders			
Urine odour abnormal			
subjects affected / exposed	65 / 6465 (1.01%)	344 / 6452 (5.33%)	
occurrences (all)	65	353	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	207 / 6465 (3.20%)	158 / 6452 (2.45%)	
occurrences (all)	225	175	
Back pain			
subjects affected / exposed	262 / 6465 (4.05%)	224 / 6452 (3.47%)	
occurrences (all)	287	243	
Musculoskeletal pain			
subjects affected / exposed	130 / 6465 (2.01%)	98 / 6452 (1.52%)	
occurrences (all)	139	102	
Myalgia			
subjects affected / exposed	186 / 6465 (2.88%)	215 / 6452 (3.33%)	
occurrences (all)	203	231	
Pain in extremity			
subjects affected / exposed	221 / 6465 (3.42%)	181 / 6452 (2.81%)	
occurrences (all)	236	197	

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