Clinical trial results:
A randomised, double-blind, parallel group, multicentre phase IIIb study to compare ticagrelor with clopidogrel treatment on the risk of cardiovascular death, myocardial infarction and ischaemic stroke in patients with established Peripheral Artery Disease (EUCLID – Examining Use of tiCagreLor In paD)

Summary

EudraCT number	2011-004616-36
Trial protocol	SK NL PL GB SE ES DE HU BG CZ IT FR
Global end of trial date	27 September 2016

Results information

Result version number	v1 (current)
This version publication date	29 July 2017
First version publication date	29 July 2017

Trial information

Trial identification

Sponsor protocol code	D5135C00001

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AstraZeneca R&D
Sponsor organisation address	Pepparedsleden 1, Mölndal, Sweden, 431 83
Public contact	Brilinta Global Clinical Lead, AstraZeneca R&D, +46 31 776 10 00, ClinicalTrialTransparency@astrazeneca.com
Scientific contact	Brilinta Global Clinical Lead, AstraZeneca R&D, +46 31 776 10 00, ClinicalTrialTransparency@astrazeneca.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 October 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 September 2016
Global end of trial reached?	Yes
Global end of trial date	27 September 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to compare the effect of long-term treatment with ticagrelor versus clopidogrel on the event rate of the composite of CV death, MI, and ischaemic stroke (defined as any stroke not demonstrated to be primarily haemorrhagic) in patients with established PAD.

The primary efficacy variable was time from randomisation to first occurrence of any event in the composite of CV death, MI, and ischaemic stroke.

Protection of trial subjects:

The PI at each centre ensured that the patient was given full and adequate oral and written information about the nature, purpose, possible benefit and risk of the study. The Investigator also notified patients that they were free to withdraw from the study at any time. The Investigator gave the patient the opportunity to ask questions and time to consider the information provided. The Investigator obtained the patient's signed and dated ICF before conducting any procedure specifically for the study. The Investigator stored the original, signed ICF, and gave a copy to the patient. The Investigator also ensured that any incentives for patients who participated in the study, as well as any provisions for patients harmed as a consequence of study participation, were described in the ICF that was approved by an IRB/IEC. The ICF incorporated (or, in some cases, was accompanied by a separate document incorporating) wording that complied with relevant data protection and privacy legislation.

Samples of written patient information and consent forms are provided in Appendix 12.1.3.2.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 December 2012
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	Argentina: 567
Country: Number of subjects enrolled	Brazil: 643
Country: Number of subjects enrolled	Bulgaria: 678
Country: Number of subjects enrolled	Canada: 430
Country: Number of subjects enrolled	Chile: 161
Country: Number of subjects enrolled	China: 423
Country: Number of subjects enrolled	Czech Republic: 723
Country: Number of subjects enrolled	France: 371
Country: Number of subjects enrolled	Germany: 623
Country: Number of subjects enrolled	Hungary: 580
Country: Number of subjects enrolled	Italy: 285

Country: Number of subjects enrolled	Japan: 420
Country: Number of subjects enrolled	Mexico: 369
Country: Number of subjects enrolled	Netherlands: 234
Country: Number of subjects enrolled	Philippines: 128
Country: Number of subjects enrolled	Poland: 609
Country: Number of subjects enrolled	Romania: 508
Country: Number of subjects enrolled	Russian Federation: 935
Country: Number of subjects enrolled	Slovakia: 419
Country: Number of subjects enrolled	Korea, Republic of: 214
Country: Number of subjects enrolled	Spain: 323
Country: Number of subjects enrolled	Sweden: 240
Country: Number of subjects enrolled	Thailand: 122
Country: Number of subjects enrolled	Turkey: 137
Country: Number of subjects enrolled	United States: 2615
Country: Number of subjects enrolled	Ukraine: 536
Country: Number of subjects enrolled	United Kingdom: 297
Country: Number of subjects enrolled	Vietnam: 295
Worldwide total number of subjects	13885
EEA total number of subjects	5890

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)	5885
From 65 to 84 years	7754
85 years and over	246

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 821 centres randomising patients across 28 countries. The first patient was enrolled on 04 December 2012. The last visit of the last patient took place on 26 September 2016. In total, 16237 patients were enrolled.

Pre-assignment

Screening details:

Enrolled patients randomised to study drug: 85.5%; n=13885
Patients who were not randomised: 14.5%; n=2352
Patients with inclusion criteria for symptomatic lower extremity PAD failed: n=489
Patients with poor metabolizer status for CYP2C19: n=616
Patients with other reason: n=1374

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Ticagrelor 90 mg bd

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Ticagrelor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

90 mg twice daily

Arm title	Clopidogrel 75 mg od

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Clopidogrel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

75 mg once daily

Number of subjects in period 1	Ticagrelor 90 mg bd	Clopidogrel 75 mg od
Started	6930	6955
Completed	6807	6842
Not completed	123	113
Consent withdrawn by subject	123	113

Baseline characteristics

Reporting groups	
Reporting group title	Ticagrelor 90 mg bd
Reporting group description: -	
Reporting group title	Clopidogrel 75 mg od
Reporting group description: -	

Reporting group values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od	Total
Number of subjects	6930	6955	13885
Age Categorical Units: Subjects			
<65 years	2900	2985	5885
Between 65 and 75 years	2925	2850	5775
>75 years	1105	1120	2225
Age Continuous Units: Years			
arithmetic mean	66.6	66.5	
standard deviation	± 8.4	± 8.5	-
Gender, Male/Female Units: Subjects			
Female	1908	1980	3888
Male	5022	4975	9997
Ethnicity, Customized Units: Subjects			
Hispanic Or Latino	1046	1067	2113
Not Hispanic Or Latino	5884	5888	11772
Race, Customized Units: Subjects			
American Indian Or Alaska Native	63	62	125
Asian	824	810	1634
Black Or African American	280	289	569
Native Hawaiian Or Other Pacific Islander	2	3	5
Other	110	132	242
White	5651	5659	11310

End points

End points reporting groups	
Reporting group title	Ticagrelor 90 mg bd
Reporting group description: -	
Reporting group title	Clopidogrel 75 mg od
Reporting group description: -	

Primary: Composite of CV death/MI/ischemic stroke	
End point title	Composite of CV death/MI/ischemic stroke
End point description:	
Participants with CV death, MI or ischemic stroke. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, non-CV death date)	
End point type	Primary
End point timeframe:	
From randomization to PACD	

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participants	751	740		

Statistical analyses

Statistical analysis title	Composite of CV death/MI/ischemic stroke
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.65 [1]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.13

Notes:

[1] - The hypothesis will be tested at the 4.94% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

Secondary: Composite of CV death, MI, ischemic stroke, and ALI

End point title	Composite of CV death, MI, ischemic stroke, and ALI

End point description:

Participants with CV death, MI, ischemic stroke or ALI. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, non-CV death date)

End point type	Secondary

End point timeframe:

From randomization to PACD

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	839	833		

Statistical analyses

Statistical analysis title	Composite of CV death/MI/ischemic stroke/ALI
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.738 [2]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.12

Notes:

[2] - The hypothesis will be tested at the 4.94% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

Secondary: CV death

End point title	CV death

End point description:

Participants with CV death. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, non-CV death date)

End point type	Secondary

End point timeframe:

From randomization to PACD

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	363	343		

Statistical analyses

Statistical analysis title	CV death
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4 [3]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.23

Notes:

[3] - The hypothesis will be tested at the 4.94% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

Secondary: MI

End point title	MI

End point description:

Participants with MI. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, death date)

End point type	Secondary

End point timeframe:

From randomization to PACD

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	349	334		

Statistical analyses

Statistical analysis title	MI
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od

Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.482 [4]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.23

Notes:

[4] - The hypothesis will be tested at the 4.94% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

Secondary: All-cause mortality

End point title	All-cause mortality

End point description:

Participants with all-cause death. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date)

End point type	Secondary

End point timeframe:

From randomization to PACD

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	628	635		

Statistical analyses

Statistical analysis title	All-cause mortality
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.913 [5]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.11

Notes:

[5] - The hypothesis will be tested at the 4.94% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

Secondary: Composite of CV death, MI, and all-cause stroke (ischemic or hemorrhagic)

End point title	Composite of CV death, MI, and all-cause stroke (ischemic or hemorrhagic)

End point description:

Participants with CV death, MI or all-cause stroke. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, non-CV death date)

End point type	Secondary

End point timeframe:

From randomization to PACD

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	766	759		

Statistical analyses

Statistical analysis title	Composite of CV death, MI, and all-cause stroke
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.724 [6]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.13

Notes:

[6] - The hypothesis will be tested at the 4.94% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

Secondary: ALI

End point title	ALI

End point description:

Participants with ALI. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, death date)

End point type	Secondary

End point timeframe:

From randomization to PACD

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	117	115		

Statistical analyses

Statistical analysis title	ALI
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.846 [7]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.33

Notes:

[7] - The hypothesis will be tested at the 4.94% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

Secondary: Lower extremity revascularization

End point title	Lower extremity revascularization

End point description:

Participants with LER. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, death date)

End point type	Secondary

End point timeframe:

From randomization to PACD

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	846	892		

Statistical analyses

Statistical analysis title	Lower extremity revascularization
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.298 [8]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.05

Notes:

[8] - The hypothesis will be tested at the 4.94% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

Secondary: Any revascularisation (coronary, peripheral [limb, mesenteric, renal, carotid and other])

End point title	Any revascularisation (coronary, peripheral [limb, mesenteric, renal, carotid and other])

End point description:

Participants with any revascularization. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, death date)

End point type	Secondary

End point timeframe:

From randomization to PACD

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	1211	1250		

Statistical analyses

Statistical analysis title	Any revascularisation
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.462 [9]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.05

Notes:

[9] - The hypothesis will be tested at the 4.94% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

Other pre-specified: Net clinical benefit (composite of CV death/MI/ischemic stroke/fatal bleeding/intracranial bleeding)

End point title	Net clinical benefit (composite of CV death/MI/ischemic stroke/fatal bleeding/intracranial bleeding)

End point description:

Participants with CV death, MI, ischemic stroke, fatal bleeding or intracranial bleeding. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, non-CV death date)

End point type	Other pre-specified

End point timeframe:

From randomization to PACD

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	789	786		

Statistical analyses

Statistical analysis title	Net clinical benefit 1
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.793
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.12

Other pre-specified: Net clinical benefit (composite of all-cause mortality/MI/ischemic stroke/fatal bleeding/intracranial bleeding)

End point title	Net clinical benefit (composite of all-cause mortality/MI/ischemic stroke/fatal bleeding/intracranial bleeding)

End point description:

Participants with all-cause death, MI, ischemic stroke, fatal bleeding or intracranial bleeding. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date)

End point type	Other pre-specified

End point timeframe:

From randomization to PACD

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	983	992		

Statistical analyses

Statistical analysis title	Net clinical benefit 2
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.09

Other pre-specified: Net clinical benefit (composite of all-cause mortality/MI/ischemic stroke/ALI/major amputation/fatal bleeding/intracranial

bleeding)	
End point title	Net clinical benefit (composite of all-cause mortality/MI/ischemic stroke/ALI/major amputation/fatal bleeding/intracranial bleeding)
End point description:	
Participants with all-cause death, MI, ischemic stroke, ALI, major amputation, fatal bleeding or intracranial bleeding. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date)	
End point type	Other pre-specified
End point timeframe:	
From randomization to PACD	

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	1119	1140		

Statistical analyses

Statistical analysis title	Net clinical benefit 3
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.829
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.08

Other pre-specified: Net clinical benefit (composite of all-cause mortality/MI/ischemic stroke/ALI/major amputation/TIMI major bleeding)	
End point title	Net clinical benefit (composite of all-cause mortality/MI/ischemic stroke/ALI/major amputation/TIMI major bleeding)
End point description:	
Participants with all-cause death, MI, ischemic stroke, ALI, major amputation or TIMI major bleeding. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date)	
End point type	Other pre-specified
End point timeframe:	
From randomization to PACD	

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	1183	1199		

Statistical analyses

Statistical analysis title	Net clinical benefit 4
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.949
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.08

Other pre-specified: Non-CV death	
End point title	Non-CV death
End point description:	
Participants with non-CV death. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, CV death)	
End point type	Other pre-specified
End point timeframe:	
From randomization to PACD	

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	250	272		

Statistical analyses

Statistical analysis title	Non-CV death
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.377
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.1

Other pre-specified: Change in ABI/TBI

End point title	Change in ABI/TBI
End point description: Change in ABI/TBI from baseline	
End point type	Other pre-specified
End point timeframe: From randomization to PACD	

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6908	6940		
Units: Change in ABI/TBI				
arithmetic mean (standard deviation)				
ABI - 6 months N = 6184(Tica , 6319(Clopi)	0.016 (± 0.136)	0.011 (± 0.134)		
ABI - End of treatment N = 4951(Tica), 5073(Clopi)	0.022 (± 0.167)	0.016 (± 0.167)		
TBI - 6 months N = 55(Tica), 48(Clopi)	0.05 (± 0.132)	0.036 (± 0.137)		
TBI - End of treatment N = 36(Tica), 21(Clopi)	0.059 (± 0.115)	-0.065 (± 0.304)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Any amputation caused by PAD

End point title	Any amputation caused by PAD

End point description:	
Participants with any amputation caused by PAD. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, death date)	
End point type	Other pre-specified
End point timeframe:	
From randomization to PACD	

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	179	208		

Statistical analyses

Statistical analysis title	Any amputation caused by PAD
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.164
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.06

Other pre-specified: Major amputation caused by PAD	
End point title	Major amputation caused by PAD
End point description:	
Participants with major amputation caused by PAD. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, death date)	
End point type	Other pre-specified
End point timeframe:	
From randomization to PACD	

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	100	116		

Statistical analyses

Statistical analysis title	Major amputation caused by PAD
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.306
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.14

Other pre-specified: CV-related hospitalization

End point title	CV-related hospitalization

End point description:

Participants with hospitalization associated with CV death, hospitalization due to MI, ischemic stroke, lower extremity revascularization, major amputation due to PAD, TIA, coronary revascularization or unstable angina. If no event, censoring occures at the minimum of (PACD, last endpoint assessment date, death date)

End point type	Other pre-specified

End point timeframe:

From randomization to PACD

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6930	6955		
Units: Participant	1312	1314		

Statistical analyses

Statistical analysis title	CV-related hospitalization
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.887
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.09

Other pre-specified: TIMI major bleeding events	
End point title	TIMI major bleeding events
End point description:	
Participants with TIMI major bleeding event. If no event, censoring occures at the minimum of (last endpoint assessment date, death date, 7 days after last dose of study drug)	
End point type	Other pre-specified
End point timeframe:	
From the date of first dose and up to and including 7 days following the date of last dose of study drug	

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6910	6932		
Units: Participant	113	109		

Statistical analyses

Statistical analysis title	TIMI major bleeding events
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13842
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.489
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.43

Other pre-specified: TIMI major or minor bleeding events

End point title	TIMI major or minor bleeding events

End point description:

Participants with TIMI major or minor bleeding event. If no event, censoring occures at the minimum of (last endpoint assessment date, death date, 7 days after last dose of study drug)

End point type	Other pre-specified

End point timeframe:

From the date of first dose and up to and including 7 days following the date of last dose of study drug

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6910	6932		
Units: Participant	193	175		

Statistical analyses

Statistical analysis title	TIMI major or minor bleeding events
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13842
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.138
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.43

Other pre-specified: PLATO major bleeding events

End point title	PLATO major bleeding events

End point description:

Participants with PLATO major bleeding event. If no event, censoring occures at the minimum of (last

endpoint assessment date, death date, 7 days after last dose of study drug)

End point type	Other pre-specified

End point timeframe:

From the date of first dose and up to and including 7 days following the date of last dose of study drug

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6910	6932		
Units: Participant	206	188		

Statistical analyses

Statistical analysis title	PLATO major bleeding events
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13842
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.139
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.41

Other pre-specified: Premature permanent discontinuation of study drug due to any bleeding event

End point title	Premature permanent discontinuation of study drug due to any bleeding event

End point description:

Participants with a permanent discontinuation of study drug due to any bleeding event. If no event, censoring occures at the minimum of (last endpoint assessment date, death date, 7 days after last dose of study drug)

End point type	Other pre-specified

End point timeframe:

From the date of first dose and up to and including 7 days following the date of last dose of study drug

End point values	Ticagrelor 90 mg bd	Clopidogrel 75 mg od		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6910	6932		
Units: Participant	168	112		

Statistical analyses

Statistical analysis title	Permanent discontinuations due to bleedings
Comparison groups	Ticagrelor 90 mg bd v Clopidogrel 75 mg od
Number of subjects included in analysis	13842
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.24
upper limit	2

Adverse events

Adverse events information

Timeframe for reporting adverse events:

On or after the date of first dose and up to and including 7 days following the date of last dose of study medication

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Clopidogrel 75mg od
Reporting group description: -	
Reporting group title	Ticagrelor 90mg bd

Reporting group description: -

Serious adverse events	Clopidogrel 75mg od	Ticagrelor 90mg bd	
Total subjects affected by serious adverse events			
subjects affected / exposed	1788 / 6932 (25.79%)	1716 / 6910 (24.83%)	
number of deaths (all causes)	290	271	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	9 / 6932 (0.13%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	1 / 9	1 / 8	
deaths causally related to treatment / all	1 / 4	0 / 3	
Adenocarcinoma of colon			
subjects affected / exposed	7 / 6932 (0.10%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma of salivary gland			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma pancreas			

subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Adenoma benign			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal gland cancer metastatic			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell lymphoma			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell lymphoma stage IV			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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 / 6932 (0.06%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign bone neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign ovarian tumour			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign renal neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign salivary gland neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct cancer			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Bladder cancer			
subjects affected / exposed	12 / 6932 (0.17%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 12	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder cancer recurrent			
subjects affected / exposed	3 / 6932 (0.04%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer stage IV			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Bladder neoplasm			

subjects affected / exposed	4 / 6932 (0.06%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bladder transitional cell carcinoma stage III			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone cancer			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bone cancer metastatic			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bone neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			
subjects affected / exposed	3 / 6932 (0.04%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Brain neoplasm benign			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Breast cancer			
subjects affected / exposed	1 / 6932 (0.01%)	9 / 6910 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Breast cancer metastatic			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer recurrent			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial carcinoma			
subjects affected / exposed	1 / 6932 (0.01%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bronchial neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix cancer metastatic			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cervix carcinoma stage III			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholesteatoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrosarcoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chronic myelomonocytic leukaemia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			

subjects affected / exposed	7 / 6932 (0.10%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colon cancer metastatic			
subjects affected / exposed	3 / 6932 (0.04%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Colon cancer recurrent			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer metastatic			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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 stage IV			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated large cell lymphoma			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ear neoplasm			
subjects affected / exposed	0 / 6932 (0.00%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer recurrent			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Fibrosarcoma			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder adenocarcinoma			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Gallbladder cancer			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			
subjects affected / exposed	8 / 6932 (0.12%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	1 / 8	2 / 8	
deaths causally related to treatment / all	1 / 4	0 / 2	
Gastric neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal carcinoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stromal tumour			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal tract adenoma			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gliomatosis cerebri			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangiopericytoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head and neck cancer metastatic			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic cancer			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	1 / 2	0 / 0	
Hepatic cancer metastatic			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	3 / 6932 (0.04%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hodgkin's disease			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Huerthle cell carcinoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insulinoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular melanoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive breast carcinoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	3 / 6932 (0.04%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large cell lung cancer			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Large intestine benign neoplasm			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			
subjects affected / exposed	10 / 6932 (0.14%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 3	
Laryngeal squamous cell carcinoma			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lip and/or oral cavity cancer			
subjects affected / exposed	4 / 6932 (0.06%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Lip squamous cell carcinoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	11 / 6932 (0.16%)	11 / 6910 (0.16%)	
occurrences causally related to treatment / all	0 / 11	1 / 11	
deaths causally related to treatment / all	0 / 5	1 / 3	
Lung adenocarcinoma metastatic			

subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung adenocarcinoma stage II			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma stage III			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma stage IV			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung cancer metastatic			
subjects affected / exposed	10 / 6932 (0.14%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 7	0 / 7	
Lung carcinoma cell type unspecified stage 0			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Lung neoplasm			
subjects affected / exposed	8 / 6932 (0.12%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 8	0 / 1	
deaths causally related to treatment / all	0 / 5	0 / 0	
Lung neoplasm malignant			

subjects affected / exposed	22 / 6932 (0.32%)	27 / 6910 (0.39%)	
occurrences causally related to treatment / all	0 / 22	0 / 27	
deaths causally related to treatment / all	0 / 8	0 / 13	
Lung squamous cell carcinoma stage I			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung squamous cell carcinoma stage II			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant melanoma			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant middle ear neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of eyelid			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of pleura			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant neoplasm of unknown primary site			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant neoplasm progression			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Meningioma			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma benign			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to bone			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Metastases to liver			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to lung			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to lymph nodes			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic bronchial carcinoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic gastric cancer			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic malignant melanoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic neoplasm			
subjects affected / exposed	4 / 6932 (0.06%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 2	
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			

subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myeloproliferative neoplasm			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal sinus cancer			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Neuroendocrine carcinoma metastatic			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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			
subjects affected / exposed	6 / 6932 (0.09%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 1	
Non-small cell lung cancer metastatic			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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 stage IV			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Nonkeratinising carcinoma of nasopharynx			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular neoplasm			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal adenocarcinoma			
subjects affected / exposed	3 / 6932 (0.04%)	0 / 6910 (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 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	5 / 6932 (0.07%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	1 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophageal neoplasm			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal squamous cell carcinoma			

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Oral neoplasm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal cancer			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal squamous cell carcinoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ovarian adenoma			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	6 / 6932 (0.09%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 6	0 / 2	
Pancreatic carcinoma metastatic			
subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 3	
Pancreatic neoplasm			
subjects affected / exposed	0 / 6932 (0.00%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Papillary cystadenoma lymphomatosum			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraneoplastic syndrome			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid tumour benign			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion malignant			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal cancer			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal neoplasm			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary tumour benign			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Plasmacytoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	19 / 6932 (0.27%)	15 / 6910 (0.22%)	
occurrences causally related to treatment / all	0 / 19	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer metastatic			
subjects affected / exposed	1 / 6932 (0.01%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage III			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic adenoma			
subjects affected / exposed	3 / 6932 (0.04%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			
subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rectal cancer metastatic			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rectal neoplasm			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid cancer			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid cancer metastatic			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal cancer			
subjects affected / exposed	3 / 6932 (0.04%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal cancer metastatic			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Renal cell carcinoma			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal neoplasm			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland cancer			

subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin cancer			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer			
subjects affected / exposed	5 / 6932 (0.07%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Small cell lung cancer metastatic			
subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Small intestine adenocarcinoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spindle cell sarcoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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 / 6932 (0.01%)	2 / 6910 (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	8 / 6932 (0.12%)	12 / 6910 (0.17%)	
occurrences causally related to treatment / all	0 / 8	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 5	
Squamous cell carcinoma of pharynx			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Squamous cell carcinoma of the oral cavity				
subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)		
occurrences causally related to treatment / all	0 / 1	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
Squamous cell carcinoma of the tongue				
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
T-cell lymphoma				
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Throat cancer				
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Tongue cancer metastatic				
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)		
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 / 6932 (0.01%)	0 / 6910 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Tonsil cancer				
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Transitional cell cancer of the renal				

pelvis and ureter			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell cancer of the renal pelvis and ureter recurrent			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	7 / 6932 (0.10%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric cancer			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral cancer			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal cancer stage 0			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Waldenstrom's macroglobulinaemia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Kaposi's sarcoma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer recurrent			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm ruptured			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic aneurysm			

subjects affected / exposed	12 / 6932 (0.17%)	9 / 6910 (0.13%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	12 / 6932 (0.17%)	7 / 6910 (0.10%)	
occurrences causally related to treatment / all	0 / 12	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic thrombosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aorto-duodenal fistula			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Behcet's syndrome			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brachiocephalic artery stenosis			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	11 / 6932 (0.16%)	12 / 6910 (0.17%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery aneurysm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	8 / 6932 (0.12%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	5 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	30 / 6932 (0.43%)	20 / 6910 (0.29%)	
occurrences causally related to treatment / all	1 / 32	1 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			

subjects affected / exposed	9 / 6932 (0.13%)	10 / 6910 (0.14%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	4 / 6932 (0.06%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	3 / 6932 (0.04%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	1 / 3	0 / 2	
deaths causally related to treatment / all	1 / 2	0 / 1	
Iliac artery perforation			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphatic fistula			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphocele			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
May-Thurner syndrome			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	5 / 6932 (0.07%)	7 / 6910 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery aneurysm			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis superficial			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renovascular hypertension			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subclavian artery occlusion			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian artery stenosis			
subjects affected / exposed	3 / 6932 (0.04%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian steal syndrome			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporal arteritis			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thromboangiitis obliterans			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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 / 6932 (0.00%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicophlebitis			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein ruptured			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vena cava thrombosis			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous perforation			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 6932 (0.04%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	7 / 6932 (0.10%)	9 / 6910 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication of device removal			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyst			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Drowning			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	2 / 2	0 / 0	
Face oedema			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised oedema			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing			
subjects affected / exposed	3 / 6932 (0.04%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site erosion			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	5 / 6932 (0.07%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 4	0 / 6	
Non-cardiac chest pain			
subjects affected / exposed	37 / 6932 (0.53%)	37 / 6910 (0.54%)	
occurrences causally related to treatment / all	0 / 38	0 / 40	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Puncture site haemorrhage			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			

subjects affected / exposed	2 / 6932 (0.03%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	1 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue inflammation			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated hernia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent restenosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vessel puncture site haematoma			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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 sting			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Allergy to chemicals			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overlap syndrome			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			

Acquired phimosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	13 / 6932 (0.19%)	10 / 6910 (0.14%)	
occurrences causally related to treatment / all	0 / 13	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast enlargement			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast hyperplasia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast mass			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymal cyst			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peyronie's disease			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular atrophy			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal cyst			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine pain			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			

subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal pain			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	6 / 6932 (0.09%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Acute respiratory failure			
subjects affected / exposed	6 / 6932 (0.09%)	17 / 6910 (0.25%)	
occurrences causally related to treatment / all	0 / 6	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 2	
Alveolitis allergic			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asphyxia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asthma			

subjects affected / exposed	6 / 6932 (0.09%)	8 / 6910 (0.12%)		
occurrences causally related to treatment / all	0 / 8	0 / 9		
deaths causally related to treatment / all	0 / 0	0 / 0		
Asthma-chronic obstructive pulmonary disease overlap syndrome				
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Atelectasis				
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Bronchiectasis				
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Bronchitis chronic				
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Bronchopneumopathy				
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)		
occurrences causally related to treatment / all	0 / 1	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Bronchostenosis				
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Chronic obstructive pulmonary disease				
subjects affected / exposed	71 / 6932 (1.02%)	87 / 6910 (1.26%)		
occurrences causally related to treatment / all	3 / 100	3 / 113		
deaths causally related to treatment / all	0 / 3	1 / 4		
Chronic respiratory failure				

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	4 / 6932 (0.06%)	11 / 6910 (0.16%)	
occurrences causally related to treatment / all	1 / 5	9 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea at rest			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	0 / 6932 (0.00%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	3 / 6932 (0.04%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	1 / 3	4 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	3 / 6932 (0.04%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 3	3 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cyst			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal dysplasia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cyst			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinal cyst			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal polyps			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal septum deviation			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal spasm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal stenosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	7 / 6932 (0.10%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	6 / 6932 (0.09%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 3	
Pneumothorax			
subjects affected / exposed	4 / 6932 (0.06%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial hypertension			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	15 / 6932 (0.22%)	18 / 6910 (0.26%)	
occurrences causally related to treatment / all	0 / 15	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary granuloma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hilum mass			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hypertension			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	3 / 6932 (0.04%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary oedema			

subjects affected / exposed	3 / 6932 (0.04%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (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	12 / 6932 (0.17%)	12 / 6910 (0.17%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 3	0 / 3	
Respiratory tract inflammation			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	5 / 6932 (0.07%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord polyp			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agitation			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			

subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder due to a general medical condition			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular somatic symptom disorder			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 2	
Delirium			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			

subjects affected / exposed	8 / 6932 (0.12%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 8	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug abuse			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug dependence			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental disorder due to a general medical condition			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	3 / 6932 (0.04%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			

subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device leakage			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood creatine phosphokinase MB increased			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose fluctuation			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood urea increased			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-reactive protein increased			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Computerised tomogram thorax abnormal			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram ST segment depression			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin increased			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	4 / 6932 (0.06%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza A virus test positive			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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 increased			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic specific antigen increased			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonella test positive			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stool analysis abnormal			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid function test abnormal			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	2 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic haemorrhage			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer haemorrhage			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	4 / 6932 (0.06%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod sting			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Avulsion fracture			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns second degree			

subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery restenosis			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Comminuted fracture			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			

subjects affected / exposed	8 / 6932 (0.12%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	0 / 8	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	11 / 6932 (0.16%)	12 / 6910 (0.17%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	13 / 6932 (0.19%)	11 / 6910 (0.16%)	
occurrences causally related to treatment / all	0 / 13	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body in eye			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft haemorrhage			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gun shot wound			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Head injury			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Heat exhaustion			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heat illness			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	13 / 6932 (0.19%)	12 / 6910 (0.17%)	
occurrences causally related to treatment / all	0 / 13	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
Humerus fracture			
subjects affected / exposed	10 / 6932 (0.14%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypobarism			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site erythema			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	6 / 6932 (0.09%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional overdose			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laceration			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			

subjects affected / exposed	3 / 6932 (0.04%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	6 / 6932 (0.09%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbosacral plexus injury			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	3 / 6932 (0.04%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle rupture			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve injury			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open globe injury			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprosthetic fracture			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax traumatic			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post concussion syndrome			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	0 / 6932 (0.00%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematuria			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			

subjects affected / exposed	7 / 6932 (0.10%)	14 / 6910 (0.20%)	
occurrences causally related to treatment / all	1 / 7	4 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative ileus			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural complication			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	11 / 6932 (0.16%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	2 / 12	2 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural hypotension			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural nausea			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pneumothorax			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pubis fracture			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation fibrosis			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	7 / 6932 (0.10%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Scapula fracture			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seroma			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin injury			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin wound			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	3 / 6932 (0.04%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord injury			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Spinal fracture			
subjects affected / exposed	1 / 6932 (0.01%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous haematoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	7 / 6932 (0.10%)	9 / 6910 (0.13%)	
occurrences causally related to treatment / all	4 / 7	3 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			

subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	5 / 6932 (0.07%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic fracture			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haemorrhage			
subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft complication			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	5 / 6932 (0.07%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Arteriovenous malformation			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal dystrophy			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			

Angina pectoris			
subjects affected / exposed	18 / 6932 (0.26%)	32 / 6910 (0.46%)	
occurrences causally related to treatment / all	0 / 20	0 / 34	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	6 / 6932 (0.09%)	10 / 6910 (0.14%)	
occurrences causally related to treatment / all	0 / 8	1 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	8 / 6932 (0.12%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia supraventricular			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriospasm coronary			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	67 / 6932 (0.97%)	69 / 6910 (1.00%)	
occurrences causally related to treatment / all	0 / 69	1 / 69	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	6 / 6932 (0.09%)	11 / 6910 (0.16%)	
occurrences causally related to treatment / all	0 / 6	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	4 / 6932 (0.06%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	4 / 6932 (0.06%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	1 / 4	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block first degree			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	2 / 6932 (0.03%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 2	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			

subjects affected / exposed	4 / 6932 (0.06%)	9 / 6910 (0.13%)	
occurrences causally related to treatment / all	1 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	8 / 6932 (0.12%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block left			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	3 / 6932 (0.04%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	23 / 6932 (0.33%)	28 / 6910 (0.41%)	
occurrences causally related to treatment / all	1 / 29	1 / 30	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			
subjects affected / exposed	3 / 6932 (0.04%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure chronic			
subjects affected / exposed	6 / 6932 (0.09%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	88 / 6932 (1.27%)	68 / 6910 (0.98%)	
occurrences causally related to treatment / all	2 / 108	1 / 81	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiogenic shock			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular insufficiency			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic left ventricular failure			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive cardiomyopathy			

subjects affected / exposed	0 / 6932 (0.00%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	4 / 6932 (0.06%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery dissection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart valve stenosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive heart disease			
subjects affected / exposed	0 / 6932 (0.00%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	4 / 6932 (0.06%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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 / 6932 (0.07%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal arrhythmia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
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	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	5 / 6932 (0.07%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular extrasystoles			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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	4 / 6932 (0.06%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia paroxysmal			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (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 / 6932 (0.04%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	3 / 6932 (0.04%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular hypokinesia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachyarrhythmia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	5 / 6932 (0.07%)	10 / 6910 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			

subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia infarction			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery aneurysm			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery disease			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	2 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	60 / 6932 (0.87%)	56 / 6910 (0.81%)	
occurrences causally related to treatment / all	0 / 64	1 / 58	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda equina syndrome			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar haemorrhage			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 2	
Cerebral atrophy			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	3 / 6932 (0.04%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	2 / 3	2 / 2	
deaths causally related to treatment / all	2 / 2	1 / 1	
Cerebral infarction			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 6932 (0.00%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebrovascular insufficiency			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical myelopathy			

subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicobrachial syndrome			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cranial nerve disorder			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressed level of consciousness			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic coma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathy			

subjects affected / exposed	4 / 6932 (0.06%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	6 / 6932 (0.09%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug withdrawal convulsions			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysaesthesia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	4 / 6932 (0.06%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	0 / 6932 (0.00%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	6 / 6932 (0.09%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	2 / 6	1 / 4	
deaths causally related to treatment / all	1 / 4	0 / 1	
Haemorrhagic cerebral infarction			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	6 / 6932 (0.09%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	3 / 6	2 / 5	
deaths causally related to treatment / all	2 / 4	1 / 1	
Headache			
subjects affected / exposed	6 / 6932 (0.09%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemianopia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	0 / 6932 (0.00%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiplegia			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
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 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic coma			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic seizure			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
IIIrd nerve paralysis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Internal carotid artery kinking			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			

subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cerebral infarction			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar infarction			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			
subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbosacral plexopathy			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoplegia			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple sclerosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple system atrophy			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myoclonus			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve compression			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve root compression			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			

subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraparesis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinsonism			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post stroke epilepsy			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	5 / 6932 (0.07%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radial nerve compression			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radicular pain			

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radicular syndrome			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Restless legs syndrome			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ruptured cerebral aneurysm			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sciatica			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	7 / 6932 (0.10%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep paralysis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			

subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitic myelopathy			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	7 / 6932 (0.10%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 7	2 / 4	
deaths causally related to treatment / all	0 / 1	2 / 3	
Syncope			
subjects affected / exposed	18 / 6932 (0.26%)	26 / 6910 (0.38%)	
occurrences causally related to treatment / all	0 / 18	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamus haemorrhage			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic encephalopathy			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			

subjects affected / exposed	6 / 6932 (0.09%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	2 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wernicke's encephalopathy			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	38 / 6932 (0.55%)	39 / 6910 (0.56%)	
occurrences causally related to treatment / all	8 / 40	14 / 43	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia macrocytic			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia of chronic disease			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aplastic anaemia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune aplastic anaemia			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Febrile neutropenia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic anaemia			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypochromic anaemia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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	4 / 6932 (0.06%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	1 / 4	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenitis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	1 / 2	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 6932 (0.00%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	1 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Acute vestibular syndrome			
subjects affected / exposed	3 / 6932 (0.04%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniere's disease			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Middle ear effusion			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	7 / 6932 (0.10%)	9 / 6910 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Angle closure glaucoma			

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	14 / 6932 (0.20%)	14 / 6910 (0.20%)	
occurrences causally related to treatment / all	0 / 17	1 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctival haemorrhage			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	3 / 6932 (0.04%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exophthalmos			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye haemorrhage			
subjects affected / exposed	4 / 6932 (0.06%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	3 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular hole			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery embolism			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal degeneration			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
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	6 / 6932 (0.09%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein occlusion			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinoschisis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uveitis			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	1 / 6932 (0.01%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	9 / 6932 (0.13%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	0 / 9	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abdominal pain upper			
subjects affected / exposed	3 / 6932 (0.04%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma			

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acid peptic disease			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute abdomen			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic pancreatitis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal haemorrhage			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal incontinence			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Barrett's oesophagus			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	4 / 6932 (0.06%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	1 / 6932 (0.01%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 2	
Constipation			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	4 / 6932 (0.06%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	1 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	3 / 6932 (0.04%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	1 / 3	3 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal polyp			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	1 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 3	1 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Duodenitis			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	4 / 6932 (0.06%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis haemorrhagic			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epigastric discomfort			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive duodenitis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive oesophagitis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric disorder			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	3 / 6932 (0.04%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	3 / 3	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric polyps			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	4 / 6932 (0.06%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	2 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	5 / 6932 (0.07%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	4 / 5	5 / 6	
deaths causally related to treatment / all	1 / 1	0 / 0	
Gastric ulcer perforation			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	10 / 6932 (0.14%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	0 / 10	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastritis alcoholic			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroduodenal ulcer			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia haemorrhagic			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorder			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	38 / 6932 (0.55%)	34 / 6910 (0.49%)	
occurrences causally related to treatment / all	29 / 41	22 / 39	
deaths causally related to treatment / all	2 / 2	0 / 0	
Gastrointestinal inflammation			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal obstruction			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal pain			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal polyp haemorrhage			

subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal ulcer haemorrhage			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	6 / 6932 (0.09%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	2 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			

subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia oral			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	3 / 6932 (0.04%)	10 / 6910 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ileus paralytic			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	3 / 6932 (0.04%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	22 / 6932 (0.32%)	20 / 6910 (0.29%)	
occurrences causally related to treatment / all	0 / 23	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia strangulated			

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal infarction			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Intestinal ischaemia			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intestinal perforation			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal polyp			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal haematoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable bowel syndrome			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal haemorrhage			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal ulcer haemorrhage			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Large intestine polyp			
subjects affected / exposed	15 / 6932 (0.22%)	14 / 6910 (0.20%)	
occurrences causally related to treatment / all	3 / 16	1 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	2 / 6932 (0.03%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	1 / 2	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mechanical ileus			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery stenosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery thrombosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric panniculitis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric vein thrombosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth haemorrhage			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedematous pancreatitis			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal achalasia			

subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal fistula			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal spasm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer haemorrhage			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis haemorrhagic			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis ulcerative			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic cyst			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic mass			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic pseudocyst			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	8 / 6932 (0.12%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatitis acute			
subjects affected / exposed	9 / 6932 (0.13%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 12	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis relapsing			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer haemorrhage			

subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontal disease			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal haemorrhage			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	6 / 6932 (0.09%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	3 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reflux gastritis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haematoma			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage			

subjects affected / exposed	3 / 6932 (0.04%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	1 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	4 / 6932 (0.06%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal perforation			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal stenosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated umbilical hernia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue dysplasia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			

subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	7 / 6932 (0.10%)	9 / 6910 (0.13%)	
occurrences causally related to treatment / all	4 / 7	7 / 9	
deaths causally related to treatment / all	1 / 2	1 / 1	
Volvulus			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Alcoholic liver disease			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune hepatitis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct obstruction			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	3 / 6932 (0.04%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			

subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dyskinesia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiolitis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	8 / 6932 (0.12%)	14 / 6910 (0.20%)	
occurrences causally related to treatment / all	0 / 9	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cholecystitis acute			
subjects affected / exposed	10 / 6932 (0.14%)	11 / 6910 (0.16%)	
occurrences causally related to treatment / all	2 / 10	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			

subjects affected / exposed	13 / 6932 (0.19%)	14 / 6910 (0.20%)	
occurrences causally related to treatment / all	0 / 13	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cirrhosis alcoholic			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatty liver alcoholic			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder perforation			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	2 / 6932 (0.03%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Hepatic cyst			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic haematoma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis alcoholic			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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			
Actinic keratosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal cyst			

subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	3 / 6932 (0.04%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	8 / 6932 (0.12%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug eruption			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkeratosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrobiosis lipoidica diabeticorum			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panniculitis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pemphigoid			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash generalised			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer haemorrhage			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stasis dermatitis			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subacute cutaneous lupus erythematosus			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swelling face			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic epidermal necrolysis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	32 / 6932 (0.46%)	48 / 6910 (0.69%)	
occurrences causally related to treatment / all	0 / 32	2 / 52	
deaths causally related to treatment / all	0 / 1	0 / 2	
Acute prerenal failure			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Azotaemia			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder prolapse			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	13 / 6932 (0.19%)	20 / 6910 (0.29%)	
occurrences causally related to treatment / all	0 / 14	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cystitis haemorrhagic			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic nephropathy			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	10 / 6932 (0.14%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	5 / 11	4 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage urinary tract			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	6 / 6932 (0.09%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive nephropathy			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephritis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	5 / 6932 (0.07%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy toxic			

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perinephritis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proteinuria			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal aneurysm			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal arteriosclerosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stenosis			
subjects affected / exposed	4 / 6932 (0.06%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal atrophy			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			

subjects affected / exposed	2 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	19 / 6932 (0.27%)	14 / 6910 (0.20%)	
occurrences causally related to treatment / all	0 / 19	0 / 14	
deaths causally related to treatment / all	0 / 4	0 / 3	
Renal impairment			
subjects affected / exposed	7 / 6932 (0.10%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular necrosis			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	2 / 6932 (0.03%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral obstruction			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urge incontinence			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 6932 (0.00%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urogenital haemorrhage			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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	0 / 6932 (0.00%)	2 / 6910 (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	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			

subjects affected / exposed	1 / 6932 (0.01%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cyst			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroiditis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	2 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthrofibrosis			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	7 / 6932 (0.10%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondritis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment syndrome			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dupuytren's contracture			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facet joint syndrome			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	3 / 6932 (0.04%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			

subjects affected / exposed	4 / 6932 (0.06%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	15 / 6932 (0.22%)	12 / 6910 (0.17%)	
occurrences causally related to treatment / all	0 / 15	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw cyst			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	6 / 6932 (0.09%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle haemorrhage			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			

subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic arthropathy			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	41 / 6932 (0.59%)	40 / 6910 (0.58%)	
occurrences causally related to treatment / all	0 / 45	0 / 41	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteolysis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			

subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporotic fracture			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	2 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periarthritis			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudarthrosis			
subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriatic arthropathy			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			

subjects affected / exposed	1 / 6932 (0.01%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatic disorder			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	3 / 6932 (0.04%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	7 / 6932 (0.10%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	1 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scleroderma			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue haemorrhage			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	7 / 6932 (0.10%)	7 / 6910 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal instability			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal ligament ossification			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	5 / 6932 (0.07%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	1 / 6932 (0.01%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	3 / 6932 (0.04%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial disorder			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic sclerosis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	2 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigger finger			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess intestinal			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess jaw			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess of salivary gland			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatitis B			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Anal abscess			
subjects affected / exposed	2 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	9 / 6932 (0.13%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous graft site infection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical mycobacterial pneumonia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bacteraemia			
subjects affected / exposed	0 / 6932 (0.00%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract infection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	19 / 6932 (0.27%)	23 / 6910 (0.33%)	
occurrences causally related to treatment / all	0 / 19	2 / 24	
deaths causally related to treatment / all	0 / 1	0 / 0	
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbuncle			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	26 / 6932 (0.38%)	27 / 6910 (0.39%)	
occurrences causally related to treatment / all	0 / 28	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis infective			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
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 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Chronic hepatitis C			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	3 / 6932 (0.04%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	8 / 6932 (0.12%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	2 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic abscess			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corynebacterium bacteraemia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	0 / 6932 (0.00%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			

subjects affected / exposed	6 / 6932 (0.09%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	7 / 6932 (0.10%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	3 / 6932 (0.04%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	1 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Echinococciasis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysematous cholecystitis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			

subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis enterococcal			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottitis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	4 / 6932 (0.06%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia infection			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder abscess			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder empyema			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	13 / 6932 (0.19%)	12 / 6910 (0.17%)	
occurrences causally related to treatment / all	0 / 13	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis salmonella			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (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 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft infection			
subjects affected / exposed	3 / 6932 (0.04%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin abscess			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin infection			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma infection			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes virus infection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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 / 6932 (0.04%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impetigo			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site infection			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site infection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
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	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected seroma			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious colitis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	6 / 6932 (0.09%)	8 / 6910 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral discitis			

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney infection			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			
subjects affected / exposed	1 / 6932 (0.01%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			

subjects affected / exposed	2 / 6932 (0.03%)	7 / 6910 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphangitis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site infection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis tuberculous			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle abscess			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycobacterium avium complex infection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Necrotising fasciitis			

subjects affected / exposed	1 / 6932 (0.01%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal candidiasis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	9 / 6932 (0.13%)	7 / 6910 (0.10%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis chronic			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paronychia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontitis			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	6 / 6932 (0.09%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	164 / 6932 (2.37%)	137 / 6910 (1.98%)	
occurrences causally related to treatment / all	0 / 175	0 / 141	
deaths causally related to treatment / all	0 / 28	0 / 15	
Pneumonia bacterial			
subjects affected / exposed	1 / 6932 (0.01%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia klebsiella			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural cellulitis			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Postoperative abscess			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (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	10 / 6932 (0.14%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 10	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	3 / 6932 (0.04%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pyelonephritis			
subjects affected / exposed	4 / 6932 (0.06%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	3 / 6932 (0.04%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 3	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis chronic			

subjects affected / exposed	1 / 6932 (0.01%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal abscess			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	5 / 6932 (0.07%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotavirus infection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonellosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal abscess			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	21 / 6932 (0.30%)	21 / 6910 (0.30%)	
occurrences causally related to treatment / all	0 / 22	0 / 21	
deaths causally related to treatment / all	0 / 7	0 / 5	
Septic shock			
subjects affected / exposed	13 / 6932 (0.19%)	11 / 6910 (0.16%)	
occurrences causally related to treatment / all	0 / 14	0 / 11	
deaths causally related to treatment / all	0 / 7	0 / 9	
Sialoadenitis			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue infection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic abscess			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	3 / 6932 (0.04%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal bacteraemia			
subjects affected / exposed	0 / 6932 (0.00%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdiaphragmatic abscess			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tetanus			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tracheostomy infection			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed	0 / 6932 (0.00%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculous pleurisy			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	4 / 6932 (0.06%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stricture post infection			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (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	40 / 6932 (0.58%)	32 / 6910 (0.46%)	
occurrences causally related to treatment / all	0 / 48	1 / 34	
deaths causally related to treatment / all	0 / 0	0 / 1	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection fungal			

subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	4 / 6932 (0.06%)	13 / 6910 (0.19%)	
occurrences causally related to treatment / all	0 / 4	0 / 15	
deaths causally related to treatment / all	0 / 1	0 / 2	
Varicella zoster virus infection			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular neuronitis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	2 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection bacterial			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	3 / 6932 (0.04%)	4 / 6910 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 3	
Dehydration			

subjects affected / exposed	9 / 6932 (0.13%)	10 / 6910 (0.14%)	
occurrences causally related to treatment / all	0 / 10	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	10 / 6932 (0.14%)	14 / 6910 (0.20%)	
occurrences causally related to treatment / all	1 / 12	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	18 / 6932 (0.26%)	11 / 6910 (0.16%)	
occurrences causally related to treatment / all	0 / 22	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	3 / 6932 (0.04%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetic metabolic decompensation			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	2 / 6932 (0.03%)	3 / 6910 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	2 / 6932 (0.03%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gout			
subjects affected / exposed	5 / 6932 (0.07%)	2 / 6910 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			

subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	9 / 6932 (0.13%)	15 / 6910 (0.22%)	
occurrences causally related to treatment / all	1 / 10	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	3 / 6932 (0.04%)	5 / 6910 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperosmolar hyperglycaemic state			
subjects affected / exposed	2 / 6932 (0.03%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hyperuricaemia			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	12 / 6932 (0.17%)	17 / 6910 (0.25%)	
occurrences causally related to treatment / all	1 / 14	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	5 / 6932 (0.07%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			

subjects affected / exposed	10 / 6932 (0.14%)	6 / 6910 (0.09%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metabolic disorder			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metabolic syndrome			
subjects affected / exposed	2 / 6932 (0.03%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock hypoglycaemic			
subjects affected / exposed	1 / 6932 (0.01%)	0 / 6910 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 6932 (0.00%)	1 / 6910 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Clopidogrel 75mg od	Ticagrelor 90mg bd	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	989 / 6932 (14.27%)	1682 / 6910 (24.34%)	
Vascular disorders			
Haemorrhage			
subjects affected / exposed	787 / 6932 (11.35%)	997 / 6910 (14.43%)	
occurrences (all)	1078	1451	
Respiratory, thoracic and mediastinal			

disorders Dyspnoea subjects affected / exposed	264 / 6932 (3.81%)	817 / 6910 (11.82%)	
occurrences (all)	289	968	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 September 2013	The sample size increased from 11500 to 13500 patients; ALI requiring hospitalization added as exploratory endpoint; time period for ESTV changed from "within 15 days after PACD" to "as soon as possible but not later than 60 days after PACD"; updated contact information for medical emergencies
03 March 2015	Secondary objectives changed, "Composite of CV death and MI" revised to "Composite of CV death, MI, Ischemic Stroke and Acute Limb Ischemia (ALI) requiring hospitalization", "ALI requiring hospitalization" changed from other objective to secondary objective, "All Lower Extremity Revascularization" added, "All revascularization (coronary and peripheral [limb, mesenteric, renal, carotid and other])" revised to "All revascularization procedures"; Other objectives changed, "Net clinical benefit composed of primary outcome events and fatal or intracranial bleeding" added, "Lower extremity revascularisation" removed, "All amputations due to PAD" added; expected study duration increased, minimum from 18 to 25 months, maximum from 36 to 40 months, median from 27 to 32; reduction in power from 90% to 85%; predetermined number of events decreased from 1596 to 1364; updated contact information for medical emergencies

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported