



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
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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
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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 occurs 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 occurs 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 occurs 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 occurs 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 occurs 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 occurs 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 occurs 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 occurs 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 occurs 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 occurs 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)
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End point description:

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

End point type	Other pre-specified
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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 occurs 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 occurs 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 occurs 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
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End point description:

Participants with any amputation caused by PAD. If no event, censoring occurs 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 occurs 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 occurs 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 occurs 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 occurs 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 occurs 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 occurs 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
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Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Clopidogrel 75mg od
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Reporting group description: -

Reporting group title	Ticagrelor 90mg bd
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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
Bradycardia		

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 diabetorum		
subjects affected / exposed	1 / 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
Echinococcosis		
subjects affected / exposed	1 / 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