Clinical trial results:
A Long-Term Outcomes Study to Assess STatin Residual Risk Reduction with EpaNova in HiGh Cardiovascular Risk PatienTs with Hypertriglyceridemia (STRENGTH)

Summary

EudraCT number	2014-001069-28
Trial protocol	CZ GB EE LT HU IT DK NL PL BE
Global end of trial date	27 May 2020

Results information

Result version number	v2 (current)
This version publication date	26 September 2021
First version publication date	10 June 2021
Version creation reason	• Correction of full data set We revised FSR date.

Trial information

Trial identification

Sponsor protocol code	D5881C00004

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AstraZeneca AB
Sponsor organisation address	151 85, Södertälje, Sweden,
Public contact	AstraZenenca Information Center, AstraZeneca, +1 18772409479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca, +1 18772409479, information.center@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	22 July 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 May 2020
Global end of trial reached?	Yes
Global end of trial date	27 May 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate the effectiveness of adding Epanova to statin therapy (with or without ezetimibe) for lowering MACE (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, emergent/elective coronary revascularization, or hospitalization for unstable angina) in high cardiovascular risk patients with persistent hypertriglyceridemia and low high-density lipoprotein cholesterol.

Protection of trial subjects:

This study was performed in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with International Council for Harmonisation/GCP, applicable regulatory requirements, and the AstraZeneca policy on Bioethics and Human Biological Smaples.

Background therapy:

Background statin therapy

Evidence for comparator: -

Actual start date of recruitment	30 October 2014
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	Australia: 112
Country: Number of subjects enrolled	Belgium: 104
Country: Number of subjects enrolled	Canada: 364
Country: Number of subjects enrolled	Czechia: 228
Country: Number of subjects enrolled	Denmark: 121
Country: Number of subjects enrolled	Estonia: 110
Country: Number of subjects enrolled	Hungary: 1123
Country: Number of subjects enrolled	Italy: 67
Country: Number of subjects enrolled	Japan: 305
Country: Number of subjects enrolled	Lithuania: 363
Country: Number of subjects enrolled	Mexico: 307
Country: Number of subjects enrolled	Netherlands: 421
Country: Number of subjects enrolled	New Zealand: 151
Country: Number of subjects enrolled	Poland: 993
Country: Number of subjects enrolled	Russian Federation: 633
Country: Number of subjects enrolled	South Africa: 961

Country: Number of subjects enrolled	Korea, Republic of: 133
Country: Number of subjects enrolled	Taiwan: 59
Country: Number of subjects enrolled	Ukraine: 1964
Country: Number of subjects enrolled	United Kingdom: 759
Country: Number of subjects enrolled	United States: 3087
Country: Number of subjects enrolled	China: 713
Worldwide total number of subjects	13078
EEA total number of subjects	3530

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)	7459
From 65 to 84 years	5563
85 years and over	56

Subject disposition

Recruitment

Recruitment details:

686 study sites in 22 countries randomized subjects. The first patient was randomized on 11 November 2014. The last patient was randomized on 12 July 2017.

Pre-assignment

Screening details:

In total, 33047 patients were enrolled, with 13078 patients randomized (6539 patients were randomized to Epanova and 6539 to placebo). Among the randomized patients, 7 in the Epanova group and 4 in the placebo group did not receive study treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Epanova

Arm description:

Omega-3 carboxylic acid 4 x 1 gram capsule

Arm type	Experimental
Investigational medicinal product name	Omega-3 carboxylic acid
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4 x 1 gram capsule orally once daily

Arm title	Placebo

Arm description:

Corn oil 4 x 1 gram capsule

Arm type	Placebo
Investigational medicinal product name	corn oil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4 x 1 gram capsule orally once daily

Number of subjects in period 1	Epanova	Placebo
Started	6539	6539
Completed	80	92
Not completed	6459	6447
Adverse event, serious fatal	363	330
Consent withdrawn by subject	111	78
Study terminated by sponsor	5854	5901
Other reasons	128	135
Lost to follow-up	3	2
Protocol deviation	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Epanova
Reporting group description:	
Omega-3 carboxylic acid 4 x 1 gram capsule	
Reporting group title	Placebo
Reporting group description:	
Corn oil 4 x 1 gram capsule	

Reporting group values	Epanova	Placebo	Total
Number of subjects	6539	6539	13078
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	3756	3703	7459
From 65-84 years	2758	2805	5563
85 years and over	25	31	56
Age Continuous Units: years			
arithmetic mean	62.5	62.5	
standard deviation	± 8.98	± 8.98	-
Sex: Female, Male Units: Participants			
Male	4250	4260	8510
Female	2289	2279	4568
Race (NIH/OMB) Units: Subjects			
WHITE	5341	5382	10723
BLACK OR AFRICAN AMERICAN	180	166	346
ASIAN	698	657	1355
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	10	11	21
AMERICAN INDIAN OR ALASKA NATIVE	114	112	226
OTHER	159	154	313
MULTIPLE	33	47	80
UNKNOWN	4	10	14
NOT REPORTED	0	0	0
Region of Enrollment Units: Subjects			
Australia	58	54	112
Belgium	53	51	104

Canada	187	177	364
China	357	356	713
Czech Republic	120	108	228
Denmark	48	73	121
Estonia	57	53	110
Hungary	561	562	1123
Italy	33	34	67
Japan	166	139	305
Korea, Republic Of	68	65	133
Lithuania	170	193	363
Mexico	152	155	307
Netherlands	206	215	421
New Zealand	74	77	151
Poland	501	492	993
Russia	307	326	633
South Africa	471	490	961
Taiwan, Province Of China	28	31	59
Ukraine	1009	955	1964
United Kingdom	377	382	759
USA	1536	1551	3087

End points

End points reporting groups

Reporting group title	Epanova
Reporting group description:	
Omega-3 carboxylic acid 4 x 1 gram capsule	
Reporting group title	Placebo
Reporting group description:	
Corn oil 4 x 1 gram capsule	
Subject analysis set title	Full analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
Full analysis set contains all subjects who were randomised	
Subject analysis set title	Safety analysis set
Subject analysis set type	Safety analysis
Subject analysis set description:	
Safety analysis set contains all randomised subjects who received at least 1 dose of investigational product	

Primary: The primary outcome measure is the time to the first occurrence of any component of the composite of Major adverse cardiovascular events (MACE)

End point title	The primary outcome measure is the time to the first occurrence of any component of the composite of Major adverse cardiovascular events (MACE)
End point description:	
MACE components include: cardiovascular (CV) death, nonfatal myocardial infarction (MI), nonfatal stroke, emergent/elective coronary revascularization, or hospitalization for unstable angina.	
End point type	Primary
End point timeframe:	
From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure	

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants	785	795		

Statistical analyses

Statistical analysis title	Primary Endpoint Analysis
Statistical analysis description:	
Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region	
Comparison groups	Placebo v Epanova

Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.837 [1]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.09

Notes:

[1] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing.

Secondary: Time to the first occurrence of the composite measure of MACE in participants with established CV disease(CVD) at baseline

End point title	Time to the first occurrence of the composite measure of MACE in participants with established CV disease(CVD) at baseline

End point description:

Time to the first occurrence of the composite measure of MACE that includes the first occurrence of CV death, non-fatal MI, non-fatal stroke, emergent/elective coronary revascularization, or hospitalization for unstable angina in the subgroup of participants with established CVD at baseline

End point type	Secondary

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants				
Number of participants with events	785	795		
# of participants with events with CVD at baseline	569	610		

Statistical analyses

Statistical analysis title	Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), region and treatment by established CVD at baseline interaction

Comparison groups	Epanova v Placebo

Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.269 [2]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.05

Notes:

[2] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing.

Secondary: Time to the first occurrence of the composite measure of CV events that include the first occurrence of CV death, non-fatal MI and non-fatal stroke

End point title	Time to the first occurrence of the composite measure of CV events that include the first occurrence of CV death, non-fatal MI and non-fatal stroke

End point description:

Time to the first occurrence of the composite measure of CV events that include the first occurrence of CV death, non-fatal MI and non-fatal stroke

End point type	Secondary

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants	541	517		

Statistical analyses

Statistical analysis title	Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region

Comparison groups	Epanova v Placebo
Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.402 [3]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.05

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.19

Notes:

[3] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing

Secondary: Time to the first occurrence of the composite measure of CV events that include the first occurrence of CV death, non-fatal MI and non-fatal stroke in the subgroup of participants with established CVD at baseline

End point title	Time to the first occurrence of the composite measure of CV events that include the first occurrence of CV death, non-fatal MI and non-fatal stroke in the subgroup of participants with established CVD at baseline

End point description:

Time to the first occurrence of the composite measure of CV events that include the first occurrence of CV death, non-fatal MI and non-fatal stroke in the subgroup of participants with established CVD at baseline

End point type	Secondary

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants				
Number of participants with events	541	517		
# of participants with events with CVD at baseline	383	385		

Statistical analyses

Statistical analysis title	Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), region and treatment by established CVD at baseline interaction

Comparison groups	Epanova v Placebo
Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.94 [4]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.16

Notes:

[4] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing

Secondary: Time to the first occurrence of the composite measure of coronary events that include the first occurrence of cardiac death, non-fatal MI, emergent/elective coronary revascularization, or hospitalization for unstable angina

End point title	Time to the first occurrence of the composite measure of coronary events that include the first occurrence of cardiac death, non-fatal MI, emergent/elective coronary revascularization, or hospitalization for unstable angina

End point description:

Time to the first occurrence of the composite measure of coronary events that include the first occurrence of cardiac death (including death due to acute MI, sudden cardiac death and death due to CV procedure), non-fatal MI, emergent/elective coronary revascularization, or hospitalization for unstable angina

End point type	Secondary

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants	556	616		

Statistical analyses

Statistical analysis title	Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region

Comparison groups	Epanova v Placebo
Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.092 [5]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.02

Notes:

[5] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing

Secondary: Time to 1st occurrence of a composite measure of coronary events (includes cardiac death, non-fatal MI, emergent/elective coronary revascularization, or hospitalization for unstable angina) in the subgroup of participants with established CVD at baseline

End point title	Time to 1st occurrence of a composite measure of coronary events (includes cardiac death, non-fatal MI, emergent/elective coronary revascularization, or hospitalization for unstable angina) in the subgroup of participants with established CVD at baseline

End point description:

Time to the first occurrence of the composite measure of coronary events that include the first occurrence of cardiac death (including death due to acute MI, sudden cardiac death and death due to CV procedures), non-fatal MI, emergent/elective coronary revascularization, or hospitalization for unstable angina in the subgroup of participants with established CVD at baseline

End point type	Secondary

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants				
Number of participants with events	556	616		
# of participants with events with CVD at baseline	417	493		

Statistical analyses

Statistical analysis title	Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), region and treatment by established CVD at baseline interaction

Comparison groups	Epanova v Placebo

Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.016 [6]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	0.97

Notes:

[6] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing.

Secondary: Time to the first occurrence of CV death

End point title	Time to the first occurrence of CV death

End point description:

The time to the first occurrence of CV death

End point type	Secondary

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants	228	211		

Statistical analyses

Statistical analysis title	Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region

Comparison groups	Epanova v Placebo
Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.372 [7]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.09

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.31

Notes:

[7] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing

Secondary: The time to first occurrence of CV death in the subgroup of participants with established CVD at baseline

End point title	The time to first occurrence of CV death in the subgroup of participants with established CVD at baseline

End point description:

The time to the first occurrence of CV death in the subgroup of participants with established CVD at baseline

End point type	Secondary

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants				
Number of participants with events	228	211		
# of participants with events with CVD at baseline	152	138		

Statistical analyses

Statistical analysis title	Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), region and treatment by established CVD at baseline interaction

Comparison groups	Epanova v Placebo
Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.336 [8]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.41

Notes:

[8] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing.

Secondary: Time to the first occurrence of all-cause death

End point title	Time to the first occurrence of all-cause death

End point description:

Time to the first occurrence of death from any cause.

End point type	Secondary

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants	373	333		

Statistical analyses

Statistical analysis title	Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region

Comparison groups	Epanova v Placebo
Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.112 [9]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.31

Notes:

[9] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing.

Secondary: Time to the first occurrence of all-cause death in the subgroup of participants with established CVD at baseline

End point title	Time to the first occurrence of all-cause death in the subgroup of participants with established CVD at baseline

End point description:

Time to the first occurrence of death of any cause in the subgroup of participants with established CVD at baseline

End point type	Secondary

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants				
Number of participants with events	373	333		
# of participants with events with CVD at baseline	234	202		

Statistical analyses

Statistical analysis title	Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), region and treatment by established CVD at baseline interaction

Comparison groups	Epanova v Placebo
Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.091 [10]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.42

Notes:

[10] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing.

Other pre-specified: Time to emergent/elective coronary revascularization

End point title	Time to emergent/elective coronary revascularization

End point description:

Time to emergent/elective coronary revascularization

End point type	Other pre-specified

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants				
Number of participants with events	414	441		

Statistical analyses

Statistical analysis title	Other Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region

Comparison groups	Epanova v Placebo
Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.408 [11]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.08

Notes:

[11] - This endpoint was not in the testing sequence and therefore not under type I error control.

Other pre-specified: Time to hospitalization for unstable angina

End point title	Time to hospitalization for unstable angina

End point description:

Time to hospitalization for unstable angina

End point type	Other pre-specified

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants				
Number of participants with events	87	104		

Statistical analyses

Statistical analysis title	Other Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region

Comparison groups	Epanova v Placebo
Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.233 [12]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	1.12

Notes:

[12] - This endpoint was not in the testing sequence and therefore not under type I error control.

Other pre-specified: Time to non-fatal myocardial infarction

End point title	Time to non-fatal myocardial infarction

End point description:

Time to non-fatal myocardial infarction

End point type	Other pre-specified

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants				
Number of participants with events	218	226		

Statistical analyses

Statistical analysis title	Other Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region

Comparison groups	Epanova v Placebo
Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.77 [13]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.17

Notes:

[13] - This endpoint was not in the testing sequence and therefore not under type I error control.

Other pre-specified: Time to non-fatal stroke

End point title	Time to non-fatal stroke

End point description:

Time to non-fatal stoke

End point type	Other pre-specified

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

End point values	Epanova	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6539	6539		
Units: Participants				
Number of participants with events	142	125		

Statistical analyses

Statistical analysis title	Other Secondary Endpoint Analysis

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region

Comparison groups	Epanova v Placebo

Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.278 [14]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.45

Notes:

[14] - This endpoint was not in the testing sequence and therefore not under type I error control.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious Adverse Events will be recorded at all visits for the patients who prematurely discontinue IP. Non Serious Adverse Events will be collected until the final visit but no more than 30 days after the last dose of IP.

Adverse event reporting additional description:

Only Adverse Events that are considered serious, lead to discontinuation of IP or result in a dose modification, overdose, new onset of diabetes mellitus, TIA, PHL cases or bleeding related events will be captured starting after randomization through the final visit.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Epanova
Reporting group description: -	
Reporting group title	Placebo

Reporting group description: -

Serious adverse events	Epanova	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	2259 / 6532 (34.58%)	2195 / 6535 (33.59%)	
number of deaths (all causes)	371	333	
number of deaths resulting from adverse events	334	299	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute lymphocytic leukaemia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	

Acute promyelocytic leukaemia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma gastric			
subjects affected / exposed	3 / 6532 (0.05%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	4 / 6532 (0.06%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenocarcinoma pancreas			
subjects affected / exposed	4 / 6532 (0.06%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adrenal adenoma			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal cancer			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiomyolipoma			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anogenital warts			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell prolymphocytic leukaemia			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
B-cell small lymphocytic lymphoma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	15 / 6532 (0.23%)	17 / 6535 (0.26%)	
occurrences causally related to treatment / all	0 / 15	1 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign bone neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of adrenal gland			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of bladder			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of eyelid			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of thyroid gland			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign pancreatic neoplasm			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct cancer			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder cancer			
subjects affected / exposed	9 / 6532 (0.14%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer recurrent			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			
subjects affected / exposed	3 / 6532 (0.05%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder squamous cell carcinoma stage unspecified			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			

subjects affected / exposed	3 / 6532 (0.05%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone cancer			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			
subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain cancer metastatic			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm malignant			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	8 / 6532 (0.12%)	17 / 6535 (0.26%)	
occurrences causally related to treatment / all	0 / 9	0 / 17	
deaths causally related to treatment / all	0 / 1	0 / 2	
Breast cancer female			
subjects affected / exposed	3 / 6532 (0.05%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Breast cancer metastatic			

subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial carcinoma			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	1 / 2	0 / 1	
Bronchioloalveolar carcinoma			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carcinoid tumour pulmonary			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac neoplasm malignant			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Castleman's disease			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix carcinoma			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			

subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Chronic lymphocytic leukaemia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	3 / 6532 (0.05%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	10 / 6532 (0.15%)	20 / 6535 (0.31%)	
occurrences causally related to treatment / all	0 / 11	0 / 21	
deaths causally related to treatment / all	0 / 2	0 / 6	
Colon cancer metastatic			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Colon cancer stage 0			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon neoplasm			

subjects affected / exposed	5 / 6532 (0.08%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Colorectal adenocarcinoma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer metastatic			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Craniopharyngioma			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial adenocarcinoma			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential thrombocythaemia			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female reproductive neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder cancer			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric adenoma			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	3 / 6532 (0.05%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Gastrointestinal carcinoma			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma multiforme			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma of bone			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head and neck cancer metastatic			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	3 / 6532 (0.05%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 4	
Hepatic neoplasm			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	4 / 6532 (0.06%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Intestinal adenocarcinoma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal papilloma of breast			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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 / 6532 (0.02%)	0 / 6535 (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	4 / 6532 (0.06%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratinising squamous cell carcinoma of nasopharynx			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine benign neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			
subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Laryngeal neoplasm			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal squamous cell carcinoma			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lentigo maligna			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	7 / 6532 (0.11%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 9	1 / 11	
deaths causally related to treatment / all	0 / 1	0 / 3	
Lung adenocarcinoma recurrent			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Lung neoplasm			
subjects affected / exposed	3 / 6532 (0.05%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung neoplasm malignant			
subjects affected / exposed	8 / 6532 (0.12%)	12 / 6535 (0.18%)	
occurrences causally related to treatment / all	0 / 8	0 / 12	
deaths causally related to treatment / all	0 / 5	0 / 7	
Lymphoma			

subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant melanoma			
subjects affected / exposed	11 / 6532 (0.17%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	0 / 12	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant neoplasm of eye			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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 renal pelvis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of spinal cord			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant pleural effusion			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant polyp			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mantle cell lymphoma			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			

subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma benign			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Metastases to liver			
subjects affected / exposed	3 / 6532 (0.05%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Metastases to lung			
subjects affected / exposed	4 / 6532 (0.06%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Metastases to lymph nodes			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to peritoneum			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to pleura			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to rectum			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to soft tissue			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastasis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic gastric cancer			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic malignant melanoma			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic neoplasm			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Metastatic squamous cell carcinoma			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic uterine cancer			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Mucoepidermoid carcinoma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelofibrosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neoplasm malignant			
subjects affected / exposed	4 / 6532 (0.06%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 3	
Neoplasm of appendix			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm prostate			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm skin			

subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Neuroendocrine carcinoma metastatic			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma of the skin			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine tumour			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodular melanoma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	0 / 6532 (0.00%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer metastatic			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal adenocarcinoma			

subjects affected / exposed	3 / 6532 (0.05%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal cancer metastatic			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	6 / 6532 (0.09%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 5	0 / 0	
Oesophageal papilloma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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 / 6532 (0.02%)	0 / 6535 (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	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ovarian adenoma			

subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian endometrioid carcinoma			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian granulosa cell tumour			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paget's disease of the vulva			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	12 / 6532 (0.18%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 12	0 / 6	
deaths causally related to treatment / all	0 / 6	0 / 3	
Pancreatic carcinoma metastatic			
subjects affected / exposed	4 / 6532 (0.06%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 4	0 / 2	
Papillary renal cell carcinoma			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			

subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid tumour benign			
subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary tumour benign			
subjects affected / exposed	0 / 6532 (0.00%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Plasma cell myeloma			
subjects affected / exposed	2 / 6532 (0.03%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasmacytoma			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	34 / 6532 (0.52%)	33 / 6535 (0.50%)	
occurrences causally related to treatment / all	0 / 34	0 / 34	
deaths causally related to treatment / all	0 / 2	0 / 2	
Prostate cancer metastatic			
subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Prostate cancer recurrent			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Queyrat erythroplasia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma			
subjects affected / exposed	0 / 6532 (0.00%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rectal cancer			
subjects affected / exposed	2 / 6532 (0.03%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer metastatic			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Rectal neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid cancer			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer metastatic			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	6 / 6532 (0.09%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 7	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland adenoma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schwannoma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Secretory adenoma of pituitary			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinonasal papilloma			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin cancer			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Small cell lung cancer metastatic			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Small intestine carcinoma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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 / 6532 (0.02%)	0 / 6535 (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	3 / 6532 (0.05%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Squamous cell carcinoma of lung			

subjects affected / exposed	6 / 6532 (0.09%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Squamous cell carcinoma of skin			
subjects affected / exposed	4 / 6532 (0.06%)	8 / 6535 (0.12%)	
occurrences causally related to treatment / all	0 / 4	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superficial spreading melanoma stage unspecified			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
T-cell lymphoma			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid adenoma			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			
subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer metastatic			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	4 / 6532 (0.06%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric cancer			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract neoplasm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	4 / 6532 (0.06%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	1 / 6532 (0.02%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal adenocarcinoma			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer stage I, with cancer in situ			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage I			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage II			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer stage IV			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune reconstitution inflammatory syndrome associated Kaposi's sarcoma			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung carcinoma cell type unspecified stage II			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Malignant melanoma stage IV			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Non-Hodgkin's lymphoma			
subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Non-Hodgkin's lymphoma stage I			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer stage IIIA			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer stage IV			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma stage IV			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Prostate cancer stage IV			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer stage IV			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal cell carcinoma stage IV			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal cancer stage I			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	16 / 6532 (0.24%)	11 / 6535 (0.17%)	
occurrences causally related to treatment / all	0 / 16	0 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	5 / 6532 (0.08%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Aortic embolus			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	8 / 6532 (0.12%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	1 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial occlusive disease			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial stenosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure inadequately controlled			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			
subjects affected / exposed	3 / 6532 (0.05%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Deep vein thrombosis			
subjects affected / exposed	14 / 6532 (0.21%)	15 / 6535 (0.23%)	
occurrences causally related to treatment / all	0 / 15	1 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic vascular disorder			

subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry gangrene			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism venous			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential hypertension			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	2 / 6532 (0.03%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery perforation			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	5 / 6532 (0.08%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemodynamic instability			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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 / 6532 (0.46%)	31 / 6535 (0.47%)	
occurrences causally related to treatment / all	2 / 33	1 / 35	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypertensive crisis			
subjects affected / exposed	15 / 6532 (0.23%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 19	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	1 / 6532 (0.02%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive urgency			
subjects affected / exposed	6 / 6532 (0.09%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	11 / 6532 (0.17%)	10 / 6535 (0.15%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	1 / 6532 (0.02%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Iliac artery occlusion			
subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iliac artery stenosis			

subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inferior vena cava perforation			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent claudication			
subjects affected / exposed	4 / 6532 (0.06%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jugular vein thrombosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leriche syndrome			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoedema			
subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant hypertension			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurogenic shock			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	4 / 6532 (0.06%)	10 / 6535 (0.15%)	
occurrences causally related to treatment / all	0 / 4	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	30 / 6532 (0.46%)	45 / 6535 (0.69%)	
occurrences causally related to treatment / all	2 / 39	0 / 52	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peripheral artery aneurysm			
subjects affected / exposed	3 / 6532 (0.05%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery aneurysm rupture			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	7 / 6532 (0.11%)	8 / 6535 (0.12%)	
occurrences causally related to treatment / all	0 / 8	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	7 / 6532 (0.11%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral coldness			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			

subjects affected / exposed	16 / 6532 (0.24%)	11 / 6535 (0.17%)	
occurrences causally related to treatment / all	2 / 21	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	13 / 6532 (0.20%)	12 / 6535 (0.18%)	
occurrences causally related to treatment / all	0 / 20	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral venous disease			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian artery stenosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian steal syndrome			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subclavian vein thrombosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adverse event			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cardiac death			
subjects affected / exposed	3 / 6532 (0.05%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 3	
Catheter site haemorrhage			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	2 / 6532 (0.03%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	10 / 6532 (0.15%)	23 / 6535 (0.35%)	
occurrences causally related to treatment / all	0 / 10	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyst			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	57 / 6532 (0.87%)	38 / 6535 (0.58%)	
occurrences causally related to treatment / all	4 / 57	4 / 38	
deaths causally related to treatment / all	4 / 57	4 / 38	
Decreased activity			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related thrombosis			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drowning			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Drug intolerance			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exercise tolerance decreased			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
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	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised oedema			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site haematoma			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site inflammation			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injection site phlebitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site haematoma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal inflammation			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ disorder			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	5 / 6532 (0.08%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 4	0 / 1	
No adverse event			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodule			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	51 / 6532 (0.78%)	51 / 6535 (0.78%)	
occurrences causally related to treatment / all	2 / 69	0 / 53	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organ failure			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic mass			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perforation			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	3 / 6532 (0.05%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retention cyst			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stent-graft endoleak			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	5 / 6532 (0.08%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 5	0 / 4	
Sudden death			
subjects affected / exposed	4 / 6532 (0.06%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	1 / 4	0 / 3	
deaths causally related to treatment / all	1 / 4	0 / 3	
Surgical failure			

subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcer haemorrhage			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unevaluable event			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	1 / 6532 (0.02%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			

subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contrast media allergy			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart transplant rejection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney transplant rejection			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Aborted pregnancy			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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 hydrocele			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenomyosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adnexal torsion			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balanoposthitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	11 / 6532 (0.17%)	18 / 6535 (0.28%)	
occurrences causally related to treatment / all	1 / 13	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast discharge			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast disorder			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast hyperplasia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast pain			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	4 / 6532 (0.06%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial thickening			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometriosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymal cyst			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female genital tract fistula			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital leukoplakia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic ovarian cyst			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic congestion			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fluid collection			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic prolapse			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal cyst			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peyronie's disease			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic disorder			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seminal vesiculitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spermatocele			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular cyst			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular mass			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			

subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal fistula			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Acute respiratory failure			
subjects affected / exposed	23 / 6532 (0.35%)	15 / 6535 (0.23%)	
occurrences causally related to treatment / all	0 / 29	0 / 16	
deaths causally related to treatment / all	0 / 4	0 / 1	
Asphyxia			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Aspiration			

subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	8 / 6532 (0.12%)	11 / 6535 (0.17%)	
occurrences causally related to treatment / all	0 / 8	1 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial hyperreactivity			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis chronic			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	31 / 6532 (0.47%)	38 / 6535 (0.58%)	
occurrences causally related to treatment / all	0 / 35	0 / 42	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic respiratory failure			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chylothorax			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphonia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	11 / 6532 (0.17%)	15 / 6535 (0.23%)	
occurrences causally related to treatment / all	0 / 11	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 2	
Dyspnoea exertional			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottic cyst			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			

subjects affected / exposed	13 / 6532 (0.20%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	1 / 13	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	3 / 6532 (0.05%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercapnia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity pneumonitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal oedema			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngospasm			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal congestion			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal septum deviation			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organising pneumonia			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal stenosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pickwickian syndrome			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	4 / 6532 (0.06%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			

subjects affected / exposed	6 / 6532 (0.09%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 2	
Pneumonitis			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial hypertension			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
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	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	23 / 6532 (0.35%)	20 / 6535 (0.31%)	
occurrences causally related to treatment / all	0 / 23	0 / 20	
deaths causally related to treatment / all	0 / 3	0 / 1	
Pulmonary haemorrhage			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hypertension			

subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Pulmonary infarction			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	7 / 6532 (0.11%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 0	
Respiratory arrest			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory distress			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	6 / 6532 (0.09%)	12 / 6535 (0.18%)	
occurrences causally related to treatment / all	0 / 7	0 / 17	
deaths causally related to treatment / all	0 / 1	0 / 5	
Sleep apnoea syndrome			
subjects affected / exposed	7 / 6532 (0.11%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	1 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillar disorder			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord polyp			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	0 / 6532 (0.00%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Borderline personality disorder			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 2	
Confusional state			

subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conversion disorder			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressed mood			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	10 / 6532 (0.15%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 14	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression suicidal			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Insomnia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	6 / 6532 (0.09%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mania			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental disorder			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	4 / 6532 (0.06%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mood disorder due to a general medical condition			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organic brain syndrome			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post-traumatic stress disorder			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizophrenia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device lead damage			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device power source issue			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis in device			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	4 / 6532 (0.06%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 6	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract disorder			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	6 / 6532 (0.09%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 6	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	13 / 6532 (0.20%)	17 / 6535 (0.26%)	
occurrences causally related to treatment / all	0 / 13	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cholecystitis acute			

subjects affected / exposed	20 / 6532 (0.31%)	12 / 6535 (0.18%)	
occurrences causally related to treatment / all	2 / 20	3 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			
subjects affected / exposed	4 / 6532 (0.06%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 4	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	27 / 6532 (0.41%)	15 / 6535 (0.23%)	
occurrences causally related to treatment / all	0 / 28	1 / 16	
deaths causally related to treatment / all	0 / 1	0 / 0	
Chronic hepatitis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Hepatic failure			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatic steatosis			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic hepatitis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-alcoholic steatohepatitis			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nonalcoholic fatty liver disease			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post cholecystectomy syndrome			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level above therapeutic			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level increased			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood calcium decreased			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Blood glucose abnormal			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose decreased			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose fluctuation			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose increased			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood lactic acid increased			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure increased			
subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
C-reactive protein increased			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram change			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate irregular			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular pressure increased			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic specific antigen increased			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus rhythm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transplant evaluation			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trial of void			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			

subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight increased			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin I increased			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	3 / 6532 (0.05%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	2 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Airway complication of anaesthesia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal bite			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	5 / 6532 (0.08%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial bypass occlusion			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial bypass stenosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back injury			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone contusion			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain contusion			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbon monoxide poisoning			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery restenosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chest injury			
subjects affected / exposed	0 / 6532 (0.00%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery restenosis			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cystitis radiation			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epicondylitis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid injury			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	15 / 6532 (0.23%)	10 / 6535 (0.15%)	
occurrences causally related to treatment / all	0 / 19	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	9 / 6532 (0.14%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	1 / 9	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Femur fracture			

subjects affected / exposed	8 / 6532 (0.12%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	3 / 6532 (0.05%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body aspiration			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body in gastrointestinal tract			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture displacement			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Frostbite			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	5 / 6532 (0.08%)	8 / 6535 (0.12%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hip fracture			
subjects affected / exposed	4 / 6532 (0.06%)	11 / 6535 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	5 / 6532 (0.08%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hyphaema			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	5 / 6532 (0.08%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation of wound			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intentional overdose			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	0 / 6532 (0.00%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb traumatic amputation			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	3 / 6532 (0.05%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			

subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallet finger			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	4 / 6532 (0.06%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	3 / 6532 (0.05%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle injury			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle rupture			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle strain			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck injury			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Patella fracture			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic organ injury			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery restenosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve injury			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal contusion			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poisoning			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Post concussion syndrome			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post laminectomy syndrome			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural fever			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	1 / 6532 (0.02%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 1	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematuria			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	7 / 6532 (0.11%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	1 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural swelling			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative delirium			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative hypotension			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative ileus			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative respiratory failure			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative thoracic procedure complication			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural hypotension			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural nausea			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	1 / 6532 (0.02%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomeningocele			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary contusion			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation dysphagia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation injury			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	0 / 6532 (0.00%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			

subjects affected / exposed	7 / 6532 (0.11%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Road traffic accident			
subjects affected / exposed	6 / 6532 (0.09%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Scapula fracture			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shunt thrombosis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skeletal injury			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin abrasion			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			
subjects affected / exposed	2 / 6532 (0.03%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fracture			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fractured base			

subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue injury			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	9 / 6532 (0.14%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord injury			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic injury			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic rupture			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress fracture			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous haematoma			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	11 / 6532 (0.17%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 14	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Subdural haemorrhage			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suture related complication			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon injury			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	6 / 6532 (0.09%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			

subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	2 / 6532 (0.03%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic arthrosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic ulcer			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral injury			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft occlusion			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular procedure complication			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Arteriovenous malformation			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial septal defect			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular arteriovenous malformation			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Familial mediterranean fever			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal arteriovenous malformation			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Porokeratosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyloric stenosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	13 / 6532 (0.20%)	8 / 6535 (0.12%)	
occurrences causally related to treatment / all	0 / 13	0 / 8	
deaths causally related to treatment / all	0 / 4	0 / 2	
Acute left ventricular failure			

subjects affected / exposed	16 / 6532 (0.24%)	8 / 6535 (0.12%)	
occurrences causally related to treatment / all	0 / 16	0 / 9	
deaths causally related to treatment / all	0 / 2	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	40 / 6532 (0.61%)	45 / 6535 (0.69%)	
occurrences causally related to treatment / all	0 / 53	1 / 47	
deaths causally related to treatment / all	0 / 5	0 / 6	
Angina pectoris			
subjects affected / exposed	92 / 6532 (1.41%)	102 / 6535 (1.56%)	
occurrences causally related to treatment / all	1 / 110	0 / 113	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	112 / 6532 (1.71%)	141 / 6535 (2.16%)	
occurrences causally related to treatment / all	7 / 125	19 / 162	
deaths causally related to treatment / all	0 / 1	0 / 0	
Anginal equivalent			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (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	6 / 6532 (0.09%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			

subjects affected / exposed	12 / 6532 (0.18%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 12	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arteriosclerosis coronary artery			
subjects affected / exposed	19 / 6532 (0.29%)	15 / 6535 (0.23%)	
occurrences causally related to treatment / all	6 / 23	3 / 20	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arteriospasm coronary			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	150 / 6532 (2.30%)	89 / 6535 (1.36%)	
occurrences causally related to treatment / all	2 / 188	2 / 103	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atrial flutter			
subjects affected / exposed	14 / 6532 (0.21%)	17 / 6535 (0.26%)	
occurrences causally related to treatment / all	1 / 20	1 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	7 / 6532 (0.11%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block first degree			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	4 / 6532 (0.06%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 4	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular dissociation			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	8 / 6532 (0.12%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac aneurysm			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	19 / 6532 (0.29%)	11 / 6535 (0.17%)	
occurrences causally related to treatment / all	0 / 19	0 / 11	
deaths causally related to treatment / all	0 / 11	0 / 9	
Cardiac asthma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac discomfort			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorder			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	90 / 6532 (1.38%)	92 / 6535 (1.41%)	
occurrences causally related to treatment / all	0 / 117	10 / 132	
deaths causally related to treatment / all	0 / 12	0 / 12	
Cardiac failure acute			
subjects affected / exposed	27 / 6532 (0.41%)	21 / 6535 (0.32%)	
occurrences causally related to treatment / all	0 / 35	0 / 25	
deaths causally related to treatment / all	0 / 4	0 / 5	
Cardiac failure chronic			
subjects affected / exposed	18 / 6532 (0.28%)	21 / 6535 (0.32%)	
occurrences causally related to treatment / all	0 / 21	2 / 26	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cardiac failure congestive			
subjects affected / exposed	60 / 6532 (0.92%)	59 / 6535 (0.90%)	
occurrences causally related to treatment / all	0 / 83	0 / 77	
deaths causally related to treatment / all	0 / 9	0 / 9	
Cardiac tamponade			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ventricular thrombosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardio-respiratory distress			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiogenic shock			
subjects affected / exposed	6 / 6532 (0.09%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 5	0 / 1	
Cardiomyopathy			
subjects affected / exposed	9 / 6532 (0.14%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 9	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	3 / 6532 (0.05%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 3	0 / 5	
Cardiovascular deconditioning			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular disorder			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular insufficiency			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	82 / 6532 (1.26%)	61 / 6535 (0.93%)	
occurrences causally related to treatment / all	10 / 89	19 / 72	
deaths causally related to treatment / all	0 / 7	0 / 2	
Coronary artery insufficiency			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Coronary artery occlusion			
subjects affected / exposed	3 / 6532 (0.05%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	3 / 6532 (0.05%)	8 / 6535 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery thrombosis			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diastolic dysfunction			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrasystoles			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive heart disease			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracardiac thrombus			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	4 / 6532 (0.06%)	10 / 6535 (0.15%)	
occurrences causally related to treatment / all	0 / 5	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 1	
Left ventricular dysfunction			
subjects affected / exposed	3 / 6532 (0.05%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Left ventricular failure			
subjects affected / exposed	6 / 6532 (0.09%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metabolic cardiomyopathy			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve disease			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	2 / 6532 (0.03%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial fibrosis			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myocardial infarction			
subjects affected / exposed	39 / 6532 (0.60%)	51 / 6535 (0.78%)	
occurrences causally related to treatment / all	0 / 43	1 / 51	
deaths causally related to treatment / all	0 / 10	1 / 22	
Myocardial ischaemia			
subjects affected / exposed	27 / 6532 (0.41%)	16 / 6535 (0.24%)	
occurrences causally related to treatment / all	0 / 28	0 / 17	
deaths causally related to treatment / all	0 / 6	0 / 2	
Myocarditis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal arrhythmia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal rhythm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paroxysmal atrioventricular block			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
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 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 6532 (0.02%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuropericarditis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postinfarction angina			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary valve stenosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulseless electrical activity			
subjects affected / exposed	0 / 6532 (0.00%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Right ventricular failure			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Silent myocardial infarction			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinoatrial block			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus arrest			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus bradycardia			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	6 / 6532 (0.09%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular extrasystoles			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	6 / 6532 (0.09%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			

subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular dysfunction			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	5 / 6532 (0.08%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	1 / 5	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	7 / 6532 (0.11%)	8 / 6535 (0.12%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
Ventricular tachycardia			
subjects affected / exposed	13 / 6532 (0.20%)	14 / 6535 (0.21%)	
occurrences causally related to treatment / all	0 / 14	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adams-Stokes syndrome			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amnesia			

subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aphasia			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autonomic nervous system imbalance			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance disorder			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia infarction			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basilar artery aneurysm			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basilar artery stenosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem ischaemia			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem stroke			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid arteriosclerosis			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery disease			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	17 / 6532 (0.26%)	14 / 6535 (0.21%)	
occurrences causally related to treatment / all	1 / 18	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	3 / 6532 (0.05%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar stroke			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery stenosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebral infarction			
subjects affected / exposed	12 / 6532 (0.18%)	17 / 6535 (0.26%)	
occurrences causally related to treatment / all	2 / 12	7 / 18	
deaths causally related to treatment / all	0 / 2	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	6 / 6532 (0.09%)	12 / 6535 (0.18%)	
occurrences causally related to treatment / all	0 / 6	2 / 15	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebral small vessel ischaemic disease			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral venous sinus thrombosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebrovascular accident			

subjects affected / exposed	45 / 6532 (0.69%)	42 / 6535 (0.64%)	
occurrences causally related to treatment / all	0 / 46	0 / 43	
deaths causally related to treatment / all	0 / 5	0 / 12	
Cerebrovascular insufficiency			
subjects affected / exposed	4 / 6532 (0.06%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	2 / 4	1 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cerebrovascular stenosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (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	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cluster headache			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	4 / 6532 (0.06%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Demyelination			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic autonomic neuropathy			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic coma			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetic neuropathy			
subjects affected / exposed	6 / 6532 (0.09%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	1 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	6 / 6532 (0.09%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	1 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness postural			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Encephalopathy			
subjects affected / exposed	3 / 6532 (0.05%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			

subjects affected / exposed	4 / 6532 (0.06%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential tremor			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			
subjects affected / exposed	10 / 6532 (0.15%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	1 / 10	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paresis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	4 / 6532 (0.06%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	1 / 4	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Haemorrhagic transformation stroke			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			

subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive encephalopathy			
subjects affected / exposed	3 / 6532 (0.05%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotonia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial mass			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cerebral infarction			

subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	30 / 6532 (0.46%)	24 / 6535 (0.37%)	
occurrences causally related to treatment / all	0 / 33	0 / 24	
deaths causally related to treatment / all	0 / 3	0 / 3	
Lacunar infarction			
subjects affected / exposed	3 / 6532 (0.05%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	1 / 3	3 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar stroke			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	3 / 6532 (0.05%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbosacral plexus lesion			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbosacral radiculopathy			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Memory impairment			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental impairment			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoplegia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Motor neurone disease			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple sclerosis			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Multiple sclerosis relapse			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myasthenia gravis			

subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelopathy			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myoclonus			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve compression			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurological symptom			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	1 / 6532 (0.02%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normal pressure hydrocephalus			

subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraparesis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraplegia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinsonism			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			

subjects affected / exposed	8 / 6532 (0.12%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radial nerve palsy			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radicular pain			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	6 / 6532 (0.09%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	4 / 6532 (0.06%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	4 / 6532 (0.06%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord haematoma			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord herniation			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord infarction			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord ischaemia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal vascular disorder			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitic myelopathy			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	5 / 6532 (0.08%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	32 / 6532 (0.49%)	15 / 6535 (0.23%)	
occurrences causally related to treatment / all	1 / 33	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamic infarction			

subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient aphasia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	41 / 6532 (0.63%)	41 / 6535 (0.63%)	
occurrences causally related to treatment / all	1 / 46	4 / 45	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	9 / 6532 (0.14%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 9	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular headache			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	4 / 6532 (0.06%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	1 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar stroke			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord paralysis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia Alzheimer's type			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
IIIrd nerve paralysis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	15 / 6532 (0.23%)	19 / 6535 (0.29%)	
occurrences causally related to treatment / all	2 / 17	0 / 25	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia macrocytic			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Antiphospholipid syndrome			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	9 / 6532 (0.14%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	9 / 6532 (0.14%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	1 / 10	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic anaemia			

subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrogenic anaemia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normocytic anaemia			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic thrombosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenomegaly			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			

subjects affected / exposed	3 / 6532 (0.05%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness neurosensory			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otolithiasis			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			

subjects affected / exposed	12 / 6532 (0.18%)	11 / 6535 (0.17%)	
occurrences causally related to treatment / all	1 / 13	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	29 / 6532 (0.44%)	20 / 6535 (0.31%)	
occurrences causally related to treatment / all	1 / 35	2 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctival erosion			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivochalasis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal erosion			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryostenosis acquired			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exophthalmos			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid ptosis			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	1 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iridocyclitis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular hole			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Maculopathy			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery embolism			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal tear			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein occlusion			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinopathy			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhegmatogenous retinal detachment			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tractional retinal detachment			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous detachment			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous disorder			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	5 / 6532 (0.08%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia obstructive			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal incarcerated hernia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	8 / 6532 (0.12%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 9	1 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	3 / 6532 (0.05%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic pancreatitis			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal haemorrhage			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal stenosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anogenital dysplasia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Barrett's oesophagus			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	3 / 6532 (0.05%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	0 / 3	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coeliac artery stenosis			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	7 / 6532 (0.11%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	1 / 7	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic fistula			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	6 / 6532 (0.09%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	1 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental cyst			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gastroparesis			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gastropathy			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic hernia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	21 / 6532 (0.32%)	10 / 6535 (0.15%)	
occurrences causally related to treatment / all	9 / 21	5 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dieulafoy's vascular malformation			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			
subjects affected / exposed	3 / 6532 (0.05%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal perforation			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal polyp			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	5 / 6532 (0.08%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	1 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	4 / 6532 (0.06%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Duodenal ulcer perforation			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenogastric reflux			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysbiosis			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical fistula			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecaloma			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Functional gastrointestinal disorder			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric disorder			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastric polyps			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	5 / 6532 (0.08%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer perforation			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastritis			
subjects affected / exposed	9 / 6532 (0.14%)	8 / 6535 (0.12%)	
occurrences causally related to treatment / all	0 / 9	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			

subjects affected / exposed	6 / 6532 (0.09%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	1 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroduodenal ulcer			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorder			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal erosion			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	24 / 6532 (0.37%)	10 / 6535 (0.15%)	
occurrences causally related to treatment / all	1 / 31	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 1	
Gastrointestinal inflammation			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal polyp haemorrhage			

subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal ulcer haemorrhage			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal vascular malformation haemorrhagic			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	7 / 6532 (0.11%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingival bleeding			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic erosive gastritis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			

subjects affected / exposed	2 / 6532 (0.03%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	5 / 6532 (0.08%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 5	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	3 / 6532 (0.05%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	18 / 6532 (0.28%)	11 / 6535 (0.17%)	
occurrences causally related to treatment / all	0 / 19	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intestinal mass			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	7 / 6532 (0.11%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal polyp			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal haemorrhage			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable bowel syndrome			

subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal stenosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	14 / 6532 (0.21%)	13 / 6535 (0.20%)	
occurrences causally related to treatment / all	1 / 15	2 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (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	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery stenosis			

subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric haemorrhage			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric vascular insufficiency			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Mouth haemorrhage			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	4 / 6532 (0.06%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	1 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Noninfective sialoadenitis			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedematous pancreatitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal achalasia			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal spasm			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal stenosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic disorder			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	11 / 6532 (0.17%)	10 / 6535 (0.15%)	
occurrences causally related to treatment / all	1 / 11	1 / 10	
deaths causally related to treatment / all	1 / 1	0 / 1	
Pancreatitis acute			
subjects affected / exposed	12 / 6532 (0.18%)	11 / 6535 (0.17%)	
occurrences causally related to treatment / all	3 / 16	3 / 11	
deaths causally related to treatment / all	0 / 2	0 / 0	
Pancreatitis chronic			

subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			
subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer haemorrhage			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngo-oesophageal diverticulum			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumatosis intestinalis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	7 / 6532 (0.11%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal prolapse			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reflux gastritis			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal fibrosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haematoma			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Retroperitoneal mass			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	5 / 6532 (0.08%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis mesenteric vessel			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tongue cyst			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	5 / 6532 (0.08%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	12 / 6532 (0.18%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	1 / 12	1 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Volvulus			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus of small bowel			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	8 / 6532 (0.12%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	1 / 9	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Acanthosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alopecia scarring			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			

subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal cyst			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis contact			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatomyositis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetic foot			
subjects affected / exposed	6 / 6532 (0.09%)	14 / 6535 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema multiforme			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Granuloma annulare			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hidradenitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity vasculitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic skin ulcer			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panniculitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pruritus			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin necrosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			

subjects affected / exposed	8 / 6532 (0.12%)	12 / 6535 (0.18%)	
occurrences causally related to treatment / all	0 / 9	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Henoch-Schonlein purpura			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	46 / 6532 (0.70%)	53 / 6535 (0.81%)	
occurrences causally related to treatment / all	0 / 54	0 / 59	
deaths causally related to treatment / all	0 / 2	0 / 3	
Azotaemia			
subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bladder mass			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder outlet obstruction			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder prolapse			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder			

subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	3 / 6532 (0.05%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	15 / 6532 (0.23%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	0 / 16	0 / 8	
deaths causally related to treatment / all	0 / 3	0 / 2	
Cystitis haemorrhagic			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	1 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	4 / 6532 (0.06%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 6	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Genitourinary symptom			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			

subjects affected / exposed	8 / 6532 (0.12%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	1 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	6 / 6532 (0.09%)	2 / 6535 (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 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertonic bladder			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketonuria			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower urinary tract symptoms			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	15 / 6532 (0.23%)	20 / 6535 (0.31%)	
occurrences causally related to treatment / all	0 / 18	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			

subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery arteriosclerosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stenosis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery thrombosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	3 / 6532 (0.05%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal embolism			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	17 / 6532 (0.26%)	16 / 6535 (0.24%)	
occurrences causally related to treatment / all	0 / 18	0 / 17	
deaths causally related to treatment / all	0 / 3	0 / 3	
Renal haematoma			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal haemorrhage			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	6 / 6532 (0.09%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Renal injury			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal ischaemia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal mass			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stag horn calculus			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	8 / 6532 (0.12%)	8 / 6535 (0.12%)	
occurrences causally related to treatment / all	1 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral haemorrhage			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary fistula			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			

subjects affected / exposed	6 / 6532 (0.09%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Acromegaly			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal mass			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			
subjects affected / exposed	4 / 6532 (0.06%)	8 / 6535 (0.12%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism primary			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid disorder			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid mass			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	10 / 6532 (0.15%)	12 / 6535 (0.18%)	
occurrences causally related to treatment / all	0 / 11	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	8 / 6532 (0.12%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	8 / 6532 (0.12%)	11 / 6535 (0.17%)	
occurrences causally related to treatment / all	0 / 10	1 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone lesion			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	6 / 6532 (0.09%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrocalcinosis pyrophosphate			

subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment syndrome			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crystal arthropathy			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibromyalgia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	4 / 6532 (0.06%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture nonunion			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin pain			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma muscle			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal mass			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc displacement			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	13 / 6532 (0.20%)	17 / 6535 (0.26%)	
occurrences causally related to treatment / all	0 / 13	1 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
Joint ankylosis			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint effusion			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb deformity			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb discomfort			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb mass			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	18 / 6532 (0.28%)	11 / 6535 (0.17%)	
occurrences causally related to treatment / all	0 / 18	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mandibular mass			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscal degeneration			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mobility decreased			

subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	7 / 6532 (0.11%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	3 / 6532 (0.05%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myopathy			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic arthropathy			

subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	66 / 6532 (1.01%)	58 / 6535 (0.89%)	
occurrences causally related to treatment / all	0 / 69	0 / 67	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis of jaw			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	6 / 6532 (0.09%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periarthritis			

subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (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	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatic disorder			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	0 / 6532 (0.00%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	6 / 6532 (0.09%)	10 / 6535 (0.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal instability			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			

subjects affected / exposed	17 / 6532 (0.26%)	8 / 6535 (0.12%)	
occurrences causally related to treatment / all	2 / 17	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	4 / 6532 (0.06%)	11 / 6535 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	4 / 6532 (0.06%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolysis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon disorder			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic spinal stenosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	4 / 6532 (0.06%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acarodermatitis			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acquired immunodeficiency syndrome			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenovirus infection			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	9 / 6532 (0.14%)	14 / 6535 (0.21%)	
occurrences causally related to treatment / all	0 / 9	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	5 / 6532 (0.08%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 6532 (0.00%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			

subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical pneumonia			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bacteraemia			
subjects affected / exposed	4 / 6532 (0.06%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial colitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial prostatitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Beta haemolytic streptococcal infection			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary sepsis			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Borrelia infection			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast abscess			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	10 / 6532 (0.15%)	23 / 6535 (0.35%)	
occurrences causally related to treatment / all	0 / 11	2 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis viral			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis infective			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter colitis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter gastroenteritis			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida pneumonia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbuncle			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	39 / 6532 (0.60%)	46 / 6535 (0.70%)	
occurrences causally related to treatment / all	1 / 46	0 / 52	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis of male external genital organ			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis staphylococcal			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest wall abscess			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis infective			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			

subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cystitis			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis infected			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetic foot infection			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			

subjects affected / exposed	13 / 6532 (0.20%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 16	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysentery			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysematous pyelonephritis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Empyema			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis bacterial			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal sepsis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epidemic pleurodynia			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	6 / 6532 (0.09%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	0 / 10	2 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia pyelonephritis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
External ear cellulitis			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural abscess			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Folliculitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fournier's gangrene			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Fungal infection			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder abscess			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder empyema			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	7 / 6532 (0.11%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastroenteritis			

subjects affected / exposed	15 / 6532 (0.23%)	20 / 6535 (0.31%)	
occurrences causally related to treatment / all	0 / 16	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis clostridial			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	4 / 6532 (0.06%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal viral infection			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genitourinary tract infection			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Graft infection			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin abscess			
subjects affected / exposed	3 / 6532 (0.05%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma infection			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter gastritis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cyst infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	4 / 6532 (0.06%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site infection			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site cellulitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected cyst			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected dermal cyst			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (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 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective aneurysm			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective tenosynovitis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	12 / 6532 (0.18%)	15 / 6535 (0.23%)	
occurrences causally related to treatment / all	0 / 13	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral discitis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal gangrene			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Localised infection			
subjects affected / exposed	1 / 6532 (0.02%)	5 / 6535 (0.08%)	
occurrences causally related to treatment / all	0 / 1	2 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	8 / 6532 (0.12%)	12 / 6535 (0.18%)	
occurrences causally related to treatment / all	0 / 8	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection bacterial			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lyme disease			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphangitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site abscess			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site joint infection			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis bacterial			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Meningoencephalitis herpetic			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Moraxella infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycetoma mycotic			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising fasciitis			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal candidiasis			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			

subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	9 / 6532 (0.14%)	12 / 6535 (0.18%)	
occurrences causally related to treatment / all	0 / 11	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis acute			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis chronic			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis externa			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media acute			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media bacterial			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media chronic			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae virus infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotitis			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal abscess			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirectal abscess			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillitis			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pilonidal cyst			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	113 / 6532 (1.73%)	126 / 6535 (1.93%)	
occurrences causally related to treatment / all	5 / 130	3 / 135	
deaths causally related to treatment / all	1 / 11	0 / 14	
Pneumonia bacterial			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia haemophilus			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia legionella			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia pseudomonal			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia staphylococcal			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia streptococcal			

subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural cellulitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural sepsis			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Postoperative abscess			
subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (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	8 / 6532 (0.12%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonas infection			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoas abscess			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary nocardiosis			

subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pyelonephritis			
subjects affected / exposed	9 / 6532 (0.14%)	12 / 6535 (0.18%)	
occurrences causally related to treatment / all	0 / 9	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	7 / 6532 (0.11%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	1 / 9	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis chronic			
subjects affected / exposed	5 / 6532 (0.08%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal abscess			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal abscess			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			

subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory tract infection viral			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotavirus infection			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
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 / 6532 (0.02%)	0 / 6535 (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 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	49 / 6532 (0.75%)	43 / 6535 (0.66%)	
occurrences causally related to treatment / all	0 / 51	0 / 47	
deaths causally related to treatment / all	0 / 8	0 / 11	
Septic necrosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	8 / 6532 (0.12%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 10	
deaths causally related to treatment / all	0 / 4	0 / 3	
Sinobronchitis			

subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal abscess			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	1 / 6532 (0.02%)	4 / 6535 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal abscess			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			

subjects affected / exposed	2 / 6532 (0.03%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 6532 (0.02%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	1 / 1	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	24 / 6532 (0.37%)	36 / 6535 (0.55%)	
occurrences causally related to treatment / all	0 / 26	0 / 40	
deaths causally related to treatment / all	0 / 0	0 / 1	
Urosepsis			

subjects affected / exposed	9 / 6532 (0.14%)	9 / 6535 (0.14%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vestibular neuronitis			
subjects affected / exposed	3 / 6532 (0.05%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	1 / 6532 (0.02%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	1 / 6532 (0.02%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	0 / 1	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection bacterial			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatitis B			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIV infection			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis C			

subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Cardiometabolic syndrome			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central obesity			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	8 / 6532 (0.12%)	12 / 6535 (0.18%)	
occurrences causally related to treatment / all	0 / 9	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	43 / 6532 (0.66%)	49 / 6535 (0.75%)	
occurrences causally related to treatment / all	4 / 47	7 / 50	
deaths causally related to treatment / all	0 / 1	0 / 1	
Diabetes mellitus inadequate control			
subjects affected / exposed	26 / 6532 (0.40%)	24 / 6535 (0.37%)	
occurrences causally related to treatment / all	2 / 29	3 / 32	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic complication			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			

subjects affected / exposed	6 / 6532 (0.09%)	6 / 6535 (0.09%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 2	
Diabetic ketosis			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Diabetic metabolic decompensation			
subjects affected / exposed	16 / 6532 (0.24%)	13 / 6535 (0.20%)	
occurrences causally related to treatment / all	0 / 16	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid overload			
subjects affected / exposed	3 / 6532 (0.05%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			
subjects affected / exposed	6 / 6532 (0.09%)	7 / 6535 (0.11%)	
occurrences causally related to treatment / all	1 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			

subjects affected / exposed	13 / 6532 (0.20%)	12 / 6535 (0.18%)	
occurrences causally related to treatment / all	1 / 13	1 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperhomocysteinaemia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	5 / 6532 (0.08%)	13 / 6535 (0.20%)	
occurrences causally related to treatment / all	0 / 5	1 / 13	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hypertriglyceridaemia			
subjects affected / exposed	2 / 6532 (0.03%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	0 / 6532 (0.00%)	2 / 6535 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	14 / 6532 (0.21%)	16 / 6535 (0.24%)	
occurrences causally related to treatment / all	0 / 15	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			

subjects affected / exposed	2 / 6532 (0.03%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	1 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	0 / 6532 (0.00%)	3 / 6535 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	4 / 6532 (0.06%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketoacidosis			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	1 / 6532 (0.02%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	0 / 6532 (0.00%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	2 / 6532 (0.03%)	1 / 6535 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Obesity			

subjects affected / exposed	6 / 6532 (0.09%)	10 / 6535 (0.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	28 / 6532 (0.43%)	18 / 6535 (0.28%)	
occurrences causally related to treatment / all	4 / 32	1 / 19	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vitamin B12 deficiency			
subjects affected / exposed	1 / 6532 (0.02%)	0 / 6535 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Epanova	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1689 / 6532 (25.86%)	964 / 6535 (14.75%)	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	87 / 6532 (1.33%)	35 / 6535 (0.54%)	
occurrences (all)	102	38	
Abdominal pain			
subjects affected / exposed	90 / 6532 (1.38%)	54 / 6535 (0.83%)	
occurrences (all)	104	61	
Abdominal pain upper			
subjects affected / exposed	80 / 6532 (1.22%)	59 / 6535 (0.90%)	
occurrences (all)	99	68	
Diarrhoea			
subjects affected / exposed	765 / 6532 (11.71%)	316 / 6535 (4.84%)	
occurrences (all)	1049	386	
Dyspepsia			
subjects affected / exposed	89 / 6532 (1.36%)	41 / 6535 (0.63%)	
occurrences (all)	104	53	
Nausea			

subjects affected / exposed	204 / 6532 (3.12%)	110 / 6535 (1.68%)	
occurrences (all)	229	126	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	97 / 6532 (1.48%)	75 / 6535 (1.15%)	
occurrences (all)	193	145	
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	147 / 6532 (2.25%)	121 / 6535 (1.85%)	
occurrences (all)	150	122	
Type 2 diabetes mellitus			
subjects affected / exposed	130 / 6532 (1.99%)	153 / 6535 (2.34%)	
occurrences (all)	131	155	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 July 2014	To enrich CV risk in the study population by adding low HDL-C criterion. Additions based on FDA recommendations. Low HDL inclusion criterion added: HDL-C <40 mg/dL (1.03 mmol/L) for men or HDL-C <45 mg/dL (1.16 mmol/L) for women. Added FDA recommendations from SPA: 1) Impaired renal function change from MDRD to CKD-EPI formula, 2) High-intensity statin treatment clarified specifically as atorvastatin 40 or 80 mg and rosuvastatin 20 or 40 mg, 3) Added exclusion criterion of known hypersensitivity to fish and/or shellfish. ITT and safety population analysis sets clarified. Added interim analyses. Removed sample size re-estimation. Clarified time to CV death as the third key secondary endpoint. TIA added as an AE to the predefined list of selective AEs for collection.
09 September 2014	Allow for enhanced recruitment without changing CV risk profile substantially. Clarified key secondary endpoint throughout the CSP. Food questionnaire removed. Biobank samples changed to include US patients only. Number of lipid markers were reduced.
30 May 2015	Allow for enhanced recruitment without changing CV risk profile substantially. Thresholds for TG and HDL-C changed from TG ≥200 and <500 mg/dL and HDL-C <40 mg/dL for males or <45 mg/dL for female to TG ≥180 and <500 mg/dL and HDL-C <42 mg/dL for males, <47 mg/dL for females. First key secondary outcome measure changed from composite of CV death, non-fatal MI, non-fatal stroke to composite of cardiac death, non-fatal MI and non-fatal stroke. Other clarifications: Carotid stenting added as established atherosclerotic CVD. Definition of family history of premature CHD clarified. Niacin dose clarified. HbA1c exclusion criterion changed from >10% to >12% at visit 1. Clarified use of omega-3 dietary supplements. Clarified time windows for selected exclusion criteria.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported