

**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	v1
This version publication date	10 June 2021
First version publication date	10 June 2021

**Trial information****Trial identification**

Sponsor protocol code	D5881C00004
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**Additional study identifiers**

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

Notes:

**Sponsors**

Sponsor organisation name	AstraZeneca AB
Sponsor organisation address	151 85, Södertälje, Sweden,
Public contact	AstraZeneca 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 Samples.

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:

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### 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 14 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
<b>Arm title</b>	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

<b>Arm title</b>	Placebo
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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

<b>Number of subjects in period 1</b>	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 <sup>[1]</sup>
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
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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
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End point timeframe:

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

<b>End point values</b>	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**

<b>Statistical analysis title</b>	Secondary Endpoint Analysis
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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
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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
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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
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End point timeframe:

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

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

### **Statistical analyses**

<b>Statistical analysis title</b>	Secondary Endpoint Analysis
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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
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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
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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
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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
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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
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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
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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 <sup>[5]</sup>
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
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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
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End point timeframe:

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

<b>End point values</b>	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**

<b>Statistical analysis title</b>	Secondary Endpoint Analysis
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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
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Number of subjects included in analysis	13078
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.016 <sup>[6]</sup>
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

<b>Statistical analysis title</b>	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 <sup>[7]</sup>
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
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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
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End point timeframe:

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

<b>End point values</b>	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**

<b>Statistical analysis title</b>	Secondary Endpoint Analysis
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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
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Number of subjects included in analysis	13078
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Analysis specification	Pre-specified
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Analysis type	superiority
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P-value	= 0.336 [8]
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Method	Regression, Cox
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Parameter estimate	Hazard ratio (HR)
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Point estimate	1.12
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Confidence interval

level	95 %
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sides	2-sided
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lower limit	0.89
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upper limit	1.41
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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
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End point description:

Time to the first occurrence of death from any cause.

End point type	Secondary
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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
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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
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Number of subjects included in analysis	13078
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Analysis specification	Pre-specified
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Analysis type	superiority
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P-value	= 0.112 [9]
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Method	Regression, Cox
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Parameter estimate	Hazard ratio (HR)
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Point estimate	1.13
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Confidence interval

level	95 %
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sides	2-sided
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lower limit	0.97
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upper limit	1.31
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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
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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	

<b>End point values</b>	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

<b>Statistical analysis title</b>	Secondary Endpoint Analysis
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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 <sup>[10]</sup>
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
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End point description:

Time to emergent/elective coronary revascularization

End point type	Other pre-specified
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End point timeframe:

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

<b>End point values</b>	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

<b>Statistical analysis title</b>	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 <sup>[11]</sup>
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	

<b>End point values</b>	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

<b>Statistical analysis title</b>	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 <sup>[12]</sup>
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

<b>End point title</b>	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	

<b>End point values</b>	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

<b>Statistical analysis title</b>	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 stroke	
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

<b>Statistical analysis title</b>	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 <sup>[14]</sup>
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
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.1
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### Reporting groups

Reporting group title	Placebo
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Reporting group description: -

Reporting group title	Epanova
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Reporting group description: -

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

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

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

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

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

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

subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		
subjects affected / exposed	2 / 6535 (0.03%)	3 / 6532 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	4 / 6535 (0.06%)	3 / 6532 (0.05%)
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	20 / 6535 (0.31%)	10 / 6532 (0.15%)
occurrences causally related to treatment / all	0 / 21	0 / 11
deaths causally related to treatment / all	0 / 6	0 / 2
Colon cancer metastatic		
subjects affected / exposed	1 / 6535 (0.02%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Colon neoplasm		
subjects affected / exposed	0 / 6535 (0.00%)	5 / 6532 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Colon cancer stage 0		

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

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

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head and neck cancer metastatic			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	5 / 6535 (0.08%)	3 / 6532 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 4	0 / 0	
Hepatic neoplasm			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	3 / 6535 (0.05%)	4 / 6532 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Intestinal adenocarcinoma			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (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	0 / 6535 (0.00%)	1 / 6532 (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	0 / 6535 (0.00%)	1 / 6532 (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	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	5 / 6535 (0.08%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Intraductal proliferative breast lesion		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (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	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Keratinising squamous cell carcinoma of nasopharynx		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		
subjects affected / exposed	3 / 6535 (0.05%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Laryngeal neoplasm		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal squamous cell carcinoma		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leukaemia		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		
subjects affected / exposed	2 / 6535 (0.03%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	9 / 6535 (0.14%)	7 / 6532 (0.11%)
occurrences causally related to treatment / all	1 / 11	0 / 9
deaths causally related to treatment / all	0 / 3	0 / 1
Lung adenocarcinoma recurrent		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic		
subjects affected / exposed	2 / 6535 (0.03%)	3 / 6532 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 2
Lung neoplasm		
subjects affected / exposed	3 / 6535 (0.05%)	3 / 6532 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Lung neoplasm malignant		
subjects affected / exposed	12 / 6535 (0.18%)	8 / 6532 (0.12%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 7	0 / 5
Lymphoma		

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

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

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

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

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

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

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

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

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Queyrat erythroplasia		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	4 / 6535 (0.06%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Rectal cancer		
subjects affected / exposed	4 / 6535 (0.06%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer metastatic		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Rectal neoplasm		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectosigmoid cancer		
subjects affected / exposed	1 / 6535 (0.02%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	1 / 6535 (0.02%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer metastatic		

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

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

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

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

subjects affected / exposed	5 / 6535 (0.08%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage I, with cancer in situ		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer stage I		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer stage II		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer stage IV		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Diffuse large B-cell lymphoma		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Immune reconstitution inflammatory syndrome associated Kaposi's sarcoma		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage II		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1

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

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

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

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

subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertension</b>		
subjects affected / exposed	31 / 6535 (0.47%)	30 / 6532 (0.46%)
occurrences causally related to treatment / all	1 / 35	2 / 33
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Hypertensive emergency</b>		
subjects affected / exposed	4 / 6535 (0.06%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertensive crisis</b>		
subjects affected / exposed	9 / 6535 (0.14%)	15 / 6532 (0.23%)
occurrences causally related to treatment / all	0 / 12	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypotension</b>		
subjects affected / exposed	10 / 6535 (0.15%)	11 / 6532 (0.17%)
occurrences causally related to treatment / all	0 / 12	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypertensive urgency</b>		
subjects affected / exposed	4 / 6535 (0.06%)	6 / 6532 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypovolaemic shock</b>		
subjects affected / exposed	4 / 6535 (0.06%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Iliac artery occlusion</b>		
subjects affected / exposed	3 / 6535 (0.05%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Iliac artery stenosis</b>		

subjects affected / exposed	2 / 6535 (0.03%)	3 / 6532 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Inferior vena cava perforation		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	4 / 6535 (0.06%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Jugular vein thrombosis		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leriche syndrome		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		
subjects affected / exposed	3 / 6535 (0.05%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant hypertension		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neurogenic shock		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		

subjects affected / exposed	10 / 6535 (0.15%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 11	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	45 / 6535 (0.69%)	30 / 6532 (0.46%)
occurrences causally related to treatment / all	0 / 52	2 / 39
deaths causally related to treatment / all	0 / 1	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	3 / 6535 (0.05%)	3 / 6532 (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	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	8 / 6535 (0.12%)	7 / 6532 (0.11%)
occurrences causally related to treatment / all	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	3 / 6535 (0.05%)	7 / 6532 (0.11%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	1 / 6535 (0.02%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral coldness		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		

subjects affected / exposed	11 / 6535 (0.17%)	16 / 6532 (0.24%)
occurrences causally related to treatment / all	0 / 13	2 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	12 / 6535 (0.18%)	13 / 6532 (0.20%)
occurrences causally related to treatment / all	0 / 16	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral venous disease		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery stenosis		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (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	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		
subjects affected / exposed	3 / 6535 (0.05%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian steal syndrome		

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (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 / 6535 (0.02%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	2 / 6535 (0.03%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

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

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

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

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

subjects affected / exposed	3 / 6535 (0.05%)	4 / 6532 (0.06%)	
occurrences causally related to treatment / all	0 / 3	1 / 4	
deaths causally related to treatment / all	0 / 3	1 / 4	
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcer haemorrhage			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unevaluable event			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	2 / 6535 (0.03%)	3 / 6532 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	5 / 6535 (0.08%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	3 / 6535 (0.05%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			

subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart transplant rejection			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	1 / 6535 (0.02%)	2 / 6532 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney transplant rejection			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Aborted pregnancy			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			

Acquired hydrocele			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenomyosis			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adnexal torsion			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balanoposthitis			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	18 / 6535 (0.28%)	11 / 6532 (0.17%)	
occurrences causally related to treatment / all	0 / 18	1 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast discharge			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast disorder			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast hyperplasia			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast mass			

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast pain		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial hyperplasia		
subjects affected / exposed	0 / 6535 (0.00%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial thickening		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometriosis		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymal cyst		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (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	0 / 6535 (0.00%)	1 / 6532 (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	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic ovarian cyst		

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

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

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

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

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

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

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal congestion		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum deviation		
subjects affected / exposed	3 / 6535 (0.05%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Organising pneumonia		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pickwickian syndrome		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	3 / 6535 (0.05%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuritic pain		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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	7 / 6535 (0.11%)	6 / 6532 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 1
Pneumonitis		
subjects affected / exposed	2 / 6535 (0.03%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		
subjects affected / exposed	3 / 6535 (0.05%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax spontaneous		
subjects affected / exposed	0 / 6535 (0.00%)	3 / 6532 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary arterial hypertension		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	20 / 6535 (0.31%)	23 / 6532 (0.35%)
occurrences causally related to treatment / all	0 / 20	0 / 23
deaths causally related to treatment / all	0 / 1	0 / 3
Pulmonary haemorrhage		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		

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

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord polyp			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	2 / 6535 (0.03%)	2 / 6532 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			
subjects affected / exposed	2 / 6535 (0.03%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	4 / 6535 (0.06%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Borderline personality disorder			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	2 / 6535 (0.03%)	2 / 6532 (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	2 / 6535 (0.03%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Conversion disorder		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	3 / 6535 (0.05%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depressed mood		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	9 / 6535 (0.14%)	10 / 6532 (0.15%)
occurrences causally related to treatment / all	0 / 11	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Depression suicidal		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Insomnia		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		
subjects affected / exposed	3 / 6535 (0.05%)	6 / 6532 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Mania		

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

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

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

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

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

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

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

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

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

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

subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Animal bite</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ankle fracture</b>		
subjects affected / exposed	9 / 6535 (0.14%)	5 / 6532 (0.08%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arterial bypass occlusion</b>		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arterial bypass stenosis</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Back injury</b>		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone contusion</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain contusion</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Burns second degree</b>		

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carbon monoxide poisoning		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery restenosis		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical vertebral fracture		
subjects affected / exposed	1 / 6535 (0.02%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Chest injury		
subjects affected / exposed	5 / 6535 (0.08%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle fracture		
subjects affected / exposed	3 / 6535 (0.05%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	2 / 6535 (0.03%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery restenosis		

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

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

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

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

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

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

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

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

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

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

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

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

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

subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (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 / 6535 (0.02%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral injury			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (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 / 6535 (0.03%)	2 / 6532 (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	0 / 6535 (0.00%)	2 / 6532 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	3 / 6535 (0.05%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Arteriovenous malformation			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial septal defect			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Familial mediterranean fever			

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

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

subjects affected / exposed	5 / 6535 (0.08%)	12 / 6532 (0.18%)
occurrences causally related to treatment / all	1 / 5	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	15 / 6535 (0.23%)	19 / 6532 (0.29%)
occurrences causally related to treatment / all	3 / 20	6 / 23
deaths causally related to treatment / all	0 / 0	0 / 1
Arteriospasm coronary		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		
subjects affected / exposed	89 / 6535 (1.36%)	150 / 6532 (2.30%)
occurrences causally related to treatment / all	2 / 103	2 / 188
deaths causally related to treatment / all	0 / 0	0 / 1
Atrial flutter		
subjects affected / exposed	17 / 6535 (0.26%)	14 / 6532 (0.21%)
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	3 / 6535 (0.05%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	1 / 6535 (0.02%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	7 / 6535 (0.11%)	7 / 6532 (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	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	4 / 6535 (0.06%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular dissociation		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (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	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	9 / 6535 (0.14%)	8 / 6532 (0.12%)
occurrences causally related to treatment / all	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac aneurysm		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	11 / 6535 (0.17%)	19 / 6532 (0.29%)
occurrences causally related to treatment / all	0 / 11	0 / 19
deaths causally related to treatment / all	0 / 9	0 / 11
Cardiac asthma		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac discomfort		

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

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cardio-respiratory distress		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiogenic shock		
subjects affected / exposed	1 / 6535 (0.02%)	6 / 6532 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 5
Cardiomyopathy		
subjects affected / exposed	2 / 6535 (0.03%)	9 / 6532 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		
subjects affected / exposed	5 / 6535 (0.08%)	3 / 6532 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 5	0 / 3
Cardiovascular deconditioning		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular disorder		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular insufficiency		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Congestive cardiomyopathy		

subjects affected / exposed	2 / 6535 (0.03%)	2 / 6532 (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	61 / 6535 (0.93%)	82 / 6532 (1.26%)
occurrences causally related to treatment / all	19 / 72	10 / 89
deaths causally related to treatment / all	0 / 2	0 / 7
Coronary artery insufficiency		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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	7 / 6535 (0.11%)	3 / 6532 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery thrombosis		
subjects affected / exposed	2 / 6535 (0.03%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Coronary artery stenosis		
subjects affected / exposed	8 / 6535 (0.12%)	3 / 6532 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diastolic dysfunction		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extrasystoles		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intracardiac thrombus</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ischaemic cardiomyopathy</b>		
subjects affected / exposed	10 / 6535 (0.15%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Left ventricular dysfunction</b>		
subjects affected / exposed	4 / 6535 (0.06%)	3 / 6532 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Left ventricular failure</b>		
subjects affected / exposed	7 / 6535 (0.11%)	6 / 6532 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Metabolic cardiomyopathy</b>		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mitral valve disease</b>		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mitral valve incompetence</b>		
subjects affected / exposed	4 / 6535 (0.06%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocardial fibrosis</b>		

subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Myocardial infarction</b>		
subjects affected / exposed	51 / 6535 (0.78%)	39 / 6532 (0.60%)
occurrences causally related to treatment / all	1 / 51	0 / 43
deaths causally related to treatment / all	1 / 22	0 / 10
<b>Myocardial ischaemia</b>		
subjects affected / exposed	16 / 6535 (0.24%)	27 / 6532 (0.41%)
occurrences causally related to treatment / all	0 / 17	0 / 28
deaths causally related to treatment / all	0 / 2	0 / 6
<b>Myocarditis</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nodal arrhythmia</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nodal rhythm</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Palpitations</b>		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Paroxysmal atrioventricular block</b>		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericardial effusion</b>		

subjects affected / exposed	3 / 6535 (0.05%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	5 / 6535 (0.08%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleuropericarditis		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postinfarction angina		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary valve stenosis		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulseless electrical activity		
subjects affected / exposed	4 / 6535 (0.06%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Right ventricular failure		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Silent myocardial infarction		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinoatrial block		

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

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

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

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

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

subjects affected / exposed	42 / 6535 (0.64%)	45 / 6532 (0.69%)
occurrences causally related to treatment / all	0 / 43	0 / 46
deaths causally related to treatment / all	0 / 12	0 / 5
Cerebrovascular insufficiency		
subjects affected / exposed	4 / 6535 (0.06%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	1 / 4	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Cerebrovascular stenosis		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical radiculopathy		
subjects affected / exposed	2 / 6535 (0.03%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cluster headache		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	3 / 6535 (0.05%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Demyelination		

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

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

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

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

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

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

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

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

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

subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thalamic infarction		
subjects affected / exposed	1 / 6535 (0.02%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		
subjects affected / exposed	41 / 6535 (0.63%)	41 / 6532 (0.63%)
occurrences causally related to treatment / all	4 / 45	1 / 46
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Transient global amnesia		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular encephalopathy		
subjects affected / exposed	1 / 6535 (0.02%)	9 / 6532 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular dementia		
subjects affected / exposed	0 / 6535 (0.00%)	3 / 6532 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Vascular headache		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency		

subjects affected / exposed	2 / 6535 (0.03%)	4 / 6532 (0.06%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vertebrobasilar stroke</b>			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vocal cord paralysis</b>			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Dementia Alzheimer's type</b>			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>IIIrd nerve paralysis</b>			
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood and lymphatic system disorders</b>			
<b>Agranulocytosis</b>			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anaemia</b>			
subjects affected / exposed	19 / 6535 (0.29%)	15 / 6532 (0.23%)	
occurrences causally related to treatment / all	0 / 25	2 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anaemia macrocytic</b>			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Blood loss anaemia</b>			

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

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

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

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

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Exophthalmos		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid ptosis		
subjects affected / exposed	2 / 6535 (0.03%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	1 / 6535 (0.02%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 1	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Iridocyclitis		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular hole		
subjects affected / exposed	0 / 6535 (0.00%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Maculopathy		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Open angle glaucoma		

subjects affected / exposed	0 / 6535 (0.00%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Optic ischaemic neuropathy		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery embolism		
subjects affected / exposed	0 / 6535 (0.00%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery occlusion		
subjects affected / exposed	1 / 6535 (0.02%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal detachment		
subjects affected / exposed	2 / 6535 (0.03%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal haemorrhage		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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	0 / 6535 (0.00%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vein occlusion		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinopathy		

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retroperitoneal fibrosis</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retroperitoneal haematoma</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retroperitoneal haemorrhage</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Retroperitoneal mass</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Small intestinal obstruction</b>		
subjects affected / exposed	9 / 6535 (0.14%)	5 / 6532 (0.08%)
occurrences causally related to treatment / all	0 / 12	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Thrombosis mesenteric vessel</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Tongue cyst</b>		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Umbilical hernia</b>		

subjects affected / exposed	2 / 6535 (0.03%)	5 / 6532 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	3 / 6535 (0.05%)	12 / 6532 (0.18%)	
occurrences causally related to treatment / all	1 / 3	1 / 12	
deaths causally related to treatment / all	0 / 1	0 / 2	
Volvulus			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus of small bowel			
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 6535 (0.02%)	8 / 6532 (0.12%)	
occurrences causally related to treatment / all	0 / 1	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Acanthosis			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alopecia scarring			
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	1 / 6535 (0.02%)	2 / 6532 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			

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

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

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

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

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

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

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal haematoma</b>		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal impairment</b>		
subjects affected / exposed	2 / 6535 (0.03%)	6 / 6532 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Renal injury</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal ischaemia</b>		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal mass</b>		
subjects affected / exposed	1 / 6535 (0.02%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stress urinary incontinence</b>		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stag horn calculus</b>		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ureteric stenosis</b>		

subjects affected / exposed	0 / 6535 (0.00%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ureterolithiasis		
subjects affected / exposed	8 / 6535 (0.12%)	8 / 6532 (0.12%)
occurrences causally related to treatment / all	0 / 9	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stenosis		
subjects affected / exposed	0 / 6535 (0.00%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral haemorrhage		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary bladder haemorrhage		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention		
subjects affected / exposed	5 / 6535 (0.08%)	6 / 6532 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary fistula		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary incontinence		

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

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

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

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

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

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

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

subjects affected / exposed	2 / 6535 (0.03%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		
subjects affected / exposed	2 / 6535 (0.03%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriatic arthropathy		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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 / 6535 (0.02%)	1 / 6532 (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	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	4 / 6535 (0.06%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	10 / 6535 (0.15%)	6 / 6532 (0.09%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal instability		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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	8 / 6535 (0.12%)	17 / 6532 (0.26%)
occurrences causally related to treatment / all	0 / 8	2 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		
subjects affected / exposed	1 / 6535 (0.02%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal stenosis		
subjects affected / exposed	11 / 6535 (0.17%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 11	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	3 / 6535 (0.05%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolysis		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial cyst		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon disorder		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tenosynovitis		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendonitis		

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

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

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

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

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

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

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

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

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

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

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter gastritis		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cyst infection		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	4 / 6535 (0.06%)	4 / 6532 (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	2 / 6535 (0.03%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site cellulitis		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected cyst		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected dermal cyst		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		

subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious pleural effusion		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective aneurysm		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	3 / 6535 (0.05%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infective tenosynovitis		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	15 / 6535 (0.23%)	12 / 6532 (0.18%)
occurrences causally related to treatment / all	0 / 15	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal gangrene		

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

subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lyme disease		
subjects affected / exposed	0 / 6535 (0.00%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphangitis		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mastitis		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinitis		
subjects affected / exposed	0 / 6535 (0.00%)	2 / 6532 (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 abscess		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site infection		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (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	0 / 6535 (0.00%)	1 / 6532 (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	2 / 6535 (0.03%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Meningitis</b>		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Moraxella infection</b>		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meningoencephalitis herpetic</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mycetoma mycotic</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nasopharyngitis</b>		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Necrotising fasciitis</b>		
subjects affected / exposed	0 / 6535 (0.00%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Orchitis</b>		
subjects affected / exposed	1 / 6535 (0.02%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal candidiasis</b>		

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

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

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

subjects affected / exposed	0 / 6535 (0.00%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	0 / 6535 (0.00%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural cellulitis		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural sepsis		
subjects affected / exposed	1 / 6535 (0.02%)	4 / 6532 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Postoperative abscess		
subjects affected / exposed	0 / 6535 (0.00%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	2 / 6535 (0.03%)	8 / 6532 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonas infection		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoas abscess		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (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 / 6535 (0.02%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary nocardiosis		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	3 / 6535 (0.05%)	7 / 6532 (0.11%)
occurrences causally related to treatment / all	0 / 3	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		
subjects affected / exposed	1 / 6535 (0.02%)	5 / 6532 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	12 / 6535 (0.18%)	9 / 6532 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal abscess		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal abscess		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (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	2 / 6535 (0.03%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Renal cyst infection		

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

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

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

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

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

subjects affected / exposed	6 / 6535 (0.09%)	6 / 6532 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 0
Diabetic ketosis		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	13 / 6535 (0.20%)	16 / 6532 (0.24%)
occurrences causally related to treatment / all	0 / 14	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	1 / 6535 (0.02%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		
subjects affected / exposed	3 / 6535 (0.05%)	3 / 6532 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Failure to thrive		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	12 / 6535 (0.18%)	13 / 6532 (0.20%)
occurrences causally related to treatment / all	1 / 14	1 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	2 / 6535 (0.03%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		

subjects affected / exposed	7 / 6535 (0.11%)	6 / 6532 (0.09%)
occurrences causally related to treatment / all	0 / 9	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	0 / 6535 (0.00%)	1 / 6532 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperhomocysteinaemia		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	13 / 6535 (0.20%)	5 / 6532 (0.08%)
occurrences causally related to treatment / all	1 / 13	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Hypertriglyceridaemia		
subjects affected / exposed	2 / 6535 (0.03%)	2 / 6532 (0.03%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypervolaemia		
subjects affected / exposed	1 / 6535 (0.02%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	2 / 6535 (0.03%)	0 / 6532 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	16 / 6535 (0.24%)	14 / 6532 (0.21%)
occurrences causally related to treatment / all	0 / 18	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		

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

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

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

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

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

## 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 $\geq$ 200 and <500 mg/dL and HDL-C <40 mg/dL for males or <45 mg/dL for female to TG $\geq$ 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:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported