Clinical trial results:
A randomized, double-blind, placebo-controlled, event-driven trial of quarterly subcutaneous canakinumab in the prevention of recurrent cardiovascular events among stable post-myocardial infarction patients with elevated hsCRP

Summary

EudraCT number	2010-022970-14
Trial protocol	SK DE HU SE PL LV LT AT GB EE GR IS BE NO CZ IT BG SI
Global end of trial date	14 April 2019

Results information

Result version number	v1 (current)
This version publication date	01 January 2020
First version publication date	01 January 2020

Trial information

Trial identification

Sponsor protocol code	CACZ885M2301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01327846
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma, AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharama, AG, 41 613241111, Novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma, AG, 41 613241111, Novartis.email@novartis.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	14 April 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 April 2019
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Core phase: The primary objective of this study was to demonstrate the superiority of at least one dose of canakinumab compared to placebo in reducing the risk of recurrent major cardiovascular events (cardiovascular death, non-fatal MI and non-fatal stroke) in a population of clinically stable patients with prior MI with elevated hsCRP receiving standard of care. Extension phase: The purpose of the Extension phase was to obtain further follow-up information on long-term safety on continued exposure to canakinumab in trial participants.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 April 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 375
Country: Number of subjects enrolled	Australia: 86
Country: Number of subjects enrolled	Austria: 58
Country: Number of subjects enrolled	Belgium: 94
Country: Number of subjects enrolled	Brazil: 719
Country: Number of subjects enrolled	Bulgaria: 209
Country: Number of subjects enrolled	Canada: 398
Country: Number of subjects enrolled	China: 126
Country: Number of subjects enrolled	Colombia: 183
Country: Number of subjects enrolled	Croatia: 36
Country: Number of subjects enrolled	Czech Republic: 382
Country: Number of subjects enrolled	Estonia: 70
Country: Number of subjects enrolled	Germany: 643
Country: Number of subjects enrolled	Greece: 64
Country: Number of subjects enrolled	Guatemala: 81
Country: Number of subjects enrolled	Hungary: 328
Country: Number of subjects enrolled	Iceland: 119

Country: Number of subjects enrolled	India: 592
Country: Number of subjects enrolled	Italy: 231
Country: Number of subjects enrolled	Japan: 235
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 62
Country: Number of subjects enrolled	Latvia: 43
Country: Number of subjects enrolled	Lithuania: 121
Country: Number of subjects enrolled	Mexico: 61
Country: Number of subjects enrolled	Netherlands: 623
Country: Number of subjects enrolled	Norway: 133
Country: Number of subjects enrolled	Peru: 11
Country: Number of subjects enrolled	Poland: 142
Country: Number of subjects enrolled	Romania: 293
Country: Number of subjects enrolled	Russian Federation: 315
Country: Number of subjects enrolled	Serbia: 45
Country: Number of subjects enrolled	Slovakia: 401
Country: Number of subjects enrolled	Slovenia: 78
Country: Number of subjects enrolled	South Africa: 63
Country: Number of subjects enrolled	Sweden: 202
Country: Number of subjects enrolled	Taiwan: 106
Country: Number of subjects enrolled	Turkey: 26
Country: Number of subjects enrolled	United Kingdom: 290
Country: Number of subjects enrolled	United States: 2017
Worldwide total number of subjects	10061
EEA total number of subjects	4560

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	6291
From 65 to 84 years	3717
85 years and over	53

Subject disposition

Recruitment

Recruitment details:

10066 patients enrolled in Core phase (4 randomized groups); 5 patients enrolled in safety set were not included in efficacy set. 5777 patients continued in Extension phase (539 only washout period, 5238 in treatment period(s)). The Core phase completed as planned; the Extension phase was terminated. Sub-studies terminated prior to data collection.

Pre-assignment

Screening details:

A total of 17482 patients were screened, and 10102 patients completed the screening phase. A total of 6430 patients did not complete the screening phase due to screen failure.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group I

Arm description:

Core phase: Blinded Canakinumab 300 mg quarterly subcutaneous + standard of care (SoC) therapy
Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy

Arm type	Experimental
Investigational medicinal product name	Canakinumab
Investigational medicinal product code	ACZ885
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg quarterly sc (2x canakinumab 150 mg in 1mL solution)

Arm title	Group II

Arm description:

Core phase: Blinded Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy
Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy

Arm type	Experimental
Investigational medicinal product name	Canakinumab
Investigational medicinal product code	ACZ855
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

150 mg in 1 mL solution quarterly sc

Arm title	Group III

Arm description:

Core phase: Blinded Canakinumab 50 mg quarterly subcutaneous + standard of care (SoC) therapy
Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy

Arm type	Experimental
Investigational medicinal product name	Canakinumab
Investigational medicinal product code	ACZ855
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

50 mg in 0.5 mL solution quarterly sc

Arm title	Group IV

Arm description:

Core phase: Blinded matching placebo quarterly subcutaneous + standard of care (SoC) therapy
Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy

Arm type	Placebo
Investigational medicinal product name	Canakinumab matching placebo
Investigational medicinal product code	Canakinumab matching placebo
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

50 mg matching placebo quarterly sc and/or 150 mg quarterly sc matching placebo

Number of subjects in period 1	Group I	Group II	Group III
Started	2263	2284	2170
Completed	2235	2252	2144
Not completed	28	32	26
Subject decision (vital status: missing)	1	2	2
Subject decision (vital stat: alive)	23	24	13
Subject decision (vital stat: unkn)	-	-	3
Lost to follow-up	3	3	4
Subject decision (vital stat: dead)	1	3	4

Number of subjects in period 1	Group IV
Started	3344
Completed	3311
Not completed	33
Subject decision (vital status: missing)	1
Subject decision (vital stat: alive)	20
Subject decision (vital stat: unkn)	3
Lost to follow-up	5
Subject decision (vital stat: dead)	4

Period 2

Period 2 title	Extension Phase
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Group I

Arm description:

Core phase: Blinded Canakinumab 300 mg quarterly subcutaneous + standard of care (SoC) therapy
Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy

Arm type	Experimental
Investigational medicinal product name	Canakinumab
Investigational medicinal product code	ACZ885
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

150 mg in 1 mL solution quarterly sc

Arm title	Group II

Arm description:

Core phase: Blinded Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy
Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy

Arm type	Experimental
Investigational medicinal product name	Canakinumab
Investigational medicinal product code	ACZ855
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

150 mg in 1 mL solution quarterly sc

Arm title	Group III

Arm description:

Core phase: Blinded Canakinumab 50 mg quarterly subcutaneous + standard of care (SoC) therapy
Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy

Arm type	Experimental
Investigational medicinal product name	Canakinumab
Investigational medicinal product code	ACZ855
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

150 mg in 1 mL solution quarterly sc

Arm title	Group IV

Arm description:

Core phase: Blinded matching placebo quarterly subcutaneous + standard of care (SoC) therapy
Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy

Arm type	Experimental
Investigational medicinal product name	Canakinumab
Investigational medicinal product code	ACZ855
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

150 mg in 1 mL solution quarterly sc

Number of subjects in period 2[1]	Group I	Group II	Group III
Started	1267	1287	1279
Stopped/discontinued study at washout	127 [2]	97 [3]	137 [4]
Completed treatment period	41 [5]	45 [6]	49 [7]
Details missing	0 [8]	1 [9]	1 [10]
Completed	168	143	187
Not completed	1099	1144	1092
Consent withdrawn by subject	20	13	19
Technical Problems	2	4	2
Study terminated by sponsor	1073	1124	1067
Lost to follow-up	4	3	4

Number of subjects in period 2[1]	Group IV
Started	1944
Stopped/discontinued study at washout	178 [11]
Completed treatment period	60 [12]
Details missing	0 [13]
Completed	238
Not completed	1706
Consent withdrawn by subject	37
Technical Problems	2
Study terminated by sponsor	1660
Lost to follow-up	7

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

[10] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

[11] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

[12] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

[13] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: This study was conducted in 2 phases: A Core phase and an extension phase.

Baseline characteristics

Reporting groups	
Reporting group title	Group I
Reporting group description:	
Core phase: Blinded Canakinumab 300 mg quarterly subcutaneous + standard of care (SoC) therapy Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy	
Reporting group title	Group II
Reporting group description:	
Core phase: Blinded Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy	
Reporting group title	Group III
Reporting group description:	
Core phase: Blinded Canakinumab 50 mg quarterly subcutaneous + standard of care (SoC) therapy Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy	
Reporting group title	Group IV
Reporting group description:	
Core phase: Blinded matching placebo quarterly subcutaneous + standard of care (SoC) therapy Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy	

Reporting group values	Group I	Group II	Group III
Number of subjects	2263	2284	2170
Age, Customized Units: Subjects			
< 65	1424	1428	1350
65 < 85	828	838	807
>85	11	18	13
Sex: Female, Male Units: Subjects			
Female	606	575	541
Male	1657	1709	1629
Race/Ethnicity, Customized Units: Subjects			
Caucasian	1804	1808	1772
Black	84	67	61
Asian	265	278	232
Native American	47	49	41
Pacific Islander	0	0	1
Unknown	3	3	1
Other	60	79	62

Reporting group values	Group IV	Total	
Number of subjects	3344	10061	
Age, Customized Units: Subjects			
< 65	2089	6291	
65 < 85	1244	3717	

>85	11	53	

Sex: Female, Male Units: Subjects			
Female	865	2587	
Male	2479	7474	
Race/Ethnicity, Customized Units: Subjects			
Caucasian	2652	8036	
Black	106	318	
Asian	388	1163	
Native American	82	219	
Pacific Islander	1	2	
Unknown	3	10	
Other	112	313	

End points reporting groups

Reporting group title	Group I
Reporting group description:	
Core phase: Blinded Canakinumab 300 mg quarterly subcutaneous + standard of care (SoC) therapy Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy	
Reporting group title	Group II
Reporting group description:	
Core phase: Blinded Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy	
Reporting group title	Group III
Reporting group description:	
Core phase: Blinded Canakinumab 50 mg quarterly subcutaneous + standard of care (SoC) therapy Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy	
Reporting group title	Group IV
Reporting group description:	
Core phase: Blinded matching placebo quarterly subcutaneous + standard of care (SoC) therapy Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy	
Reporting group title	Group I
Reporting group description:	
Core phase: Blinded Canakinumab 300 mg quarterly subcutaneous + standard of care (SoC) therapy Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy	
Reporting group title	Group II
Reporting group description:	
Core phase: Blinded Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy	
Reporting group title	Group III
Reporting group description:	
Core phase: Blinded Canakinumab 50 mg quarterly subcutaneous + standard of care (SoC) therapy Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy	
Reporting group title	Group IV
Reporting group description:	
Core phase: Blinded matching placebo quarterly subcutaneous + standard of care (SoC) therapy Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy	

Primary: Analysis of Core phase First CEC Confirmed Major Adverse Cardiovascular Events (MACE) and its components

End point title	Analysis of Core phase First CEC Confirmed Major Adverse Cardiovascular Events (MACE) and its components
End point description:	
Time to occurrence of CEC (Cardiovascular clinical events adjudication committee) confirmed MACE, which was a composite endpoint consisting of CEC confirmed CV death, CEC confirmed non-fatal MI,or CEC confirmed non-fatal stroke. Patients with the CEC adjudicated reason for death of “Unknown” were counted as CV (cardiovascular) death.	
End point type	Primary

End point timeframe:

From randomization to end of treatment plus 30 days, up to approximately 6 years

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2263	2284	2170	3344
Units: Participants				
MACE	322	320	313	535
CV death	151	144	137	235
MI (fatal and non-fatal)	174	159	169	292
MI (non-fatal)	171	158	168	291
Stroke (fatal and non-fatal)	51	63	58	92
Stroke (non-fatal)	51	63	58	91

Statistical analyses

Statistical analysis title	Primary Analysis [MACE]

Statistical analysis description:

H11: The hazard rate of first adjudication committee confirmed MACE in the canakinumab 300 mg dose group is greater than or equal to the hazard rate of the placebo group

Comparison groups	Group I v Group IV
Number of subjects included in analysis	5607
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0648 [1]
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	0.99

Notes:

[1] - 1-sided adjusted for multiplicity using weighted Dunnett test. [significance level 0.0245]

Statistical analysis title	Primary Analysis [MACE]

Statistical analysis description:

H21: The hazard rate of first adjudication committee confirmed MACE in the canakinumab 150 mg dose group is greater than or equal to the hazard rate of the placebo group

Comparison groups	Group II v Group IV

Number of subjects included in analysis	5628
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0241 [2]
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.98

Notes:

[2] - 1-sided adjusted for multiplicity using weighted Dunnett test. [significance level 0.0245]

Statistical analysis title	Primary Analysis [MACE]

Statistical analysis description:

H31: The hazard rate of first adjudication committee confirmed MACE in the canakinumab 50 mg dose group is greater than or equal to the hazard rate of the placebo group.

Comparison groups	Group III v Group IV
Number of subjects included in analysis	5514
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1895 [3]
Method	Logrank
Parameter estimate	Cox proportional hazard
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.07

Notes:

[3] - 1-sided adjusted for multiplicity using weighted Dunnett test. [significance level 0.0245]

Statistical analysis title	Primary Analysis [CV Death]
Comparison groups	Group I v Group IV
Number of subjects included in analysis	5607
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.572 [4]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.16

Notes:
[4] - 2-sided unadjusted p-value

Statistical analysis title	Primary Analysis [CV Death]
Comparison groups	Group II v Group IV
Number of subjects included in analysis	5628
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.296 [5]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.1

Notes:
[5] - 2-sided unadjusted p-value

Statistical analysis title	Primary Analysis [CV Death]
Comparison groups	Group III v Group IV
Number of subjects included in analysis	5514
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.369 [6]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.12

Notes:
[6] - 2-sided unadjusted p-value

Statistical analysis title	Primary Analysis [MI (Fatal and Non-Fatal)]
Comparison groups	Group I v Group IV
Number of subjects included in analysis	5607
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.067 [7]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.84

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.01

Notes:

[7] - 2-sided unadjusted p-value

Statistical analysis title	Primary Analysis [MI (Fatal and Non-Fatal)]
Comparison groups	Group II v Group IV
Number of subjects included in analysis	5628
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.006 [8]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.92

Notes:

[8] - 2-sided unadjusted p-value

Statistical analysis title	Primary Analysis [MI (Fatal and Non-Fatal)]
Comparison groups	Group III v Group IV
Number of subjects included in analysis	5514
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.542 [9]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.14

Notes:

[9] - 2-sided unadjusted p-value

Statistical analysis title	Primary Analysis [MI (Non-Fatal)]
Comparison groups	Group I v Group IV

Number of subjects included in analysis	5607
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1

Statistical analysis title	Primary Analysis [MI (Non-Fatal)]
Comparison groups	Group II v Group IV
Number of subjects included in analysis	5628
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Hazard ratio (HR)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	0.92

Statistical analysis title	Primary Analysis [MI (Non-Fatal)]
Comparison groups	Group III v Group IV
Number of subjects included in analysis	5514
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Hazard ratio (HR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.14

Statistical analysis title	Primary Analysis [Stroke (Fatal and Non-Fatal)]
Comparison groups	Group I v Group IV

Number of subjects included in analysis	5607
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.19 [10]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.12

Notes:

[10] - 2-sided unadjusted p-value

Statistical analysis title	Primary Analysis [Stroke (Fatal and Non-Fatal)]
Comparison groups	Group II v Group IV
Number of subjects included in analysis	5628
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.912 [11]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.35

Notes:

[11] - 2-sided unadjusted p-value

Statistical analysis title	Primary Analysis [Stroke (Fatal and Non-Fatal)]
Comparison groups	Group III v Group IV
Number of subjects included in analysis	5514
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.871 [12]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.43

Notes:

[12] - 2-sided unadjusted p-value

Statistical analysis title	Primary Analysis [Stroke (Non-Fatal)]

Comparison groups	Group I v Group IV
Number of subjects included in analysis	5607
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	1.13

Statistical analysis title	Primary Analysis [Stroke (Non-Fatal)]
Comparison groups	Group II v Group IV
Number of subjects included in analysis	5628
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Hazard ratio (HR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.37

Statistical analysis title	Primary Analysis [Stroke (Non-Fatal)]
Comparison groups	Group III v Group IV
Number of subjects included in analysis	5514
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Hazard ratio (HR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.45

Primary: Substudy 1 (Core phase): Change from baseline in carotid plaque burden in the bifurcation region of the index carotid artery

End point title	Substudy 1 (Core phase): Change from baseline in carotid plaque burden in the bifurcation region of the index carotid artery[13]

End point description:

End point type	Primary

End point timeframe:

24 months

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Substudy 1 was cancelled; no statistical analyses was performed.

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[14]	0[15]	0[16]	0[17]
Units: carotid plaque burden				

Notes:

[14] - Analysis not performed

[15] - Analysis not performed

[16] - Analysis not performed

[17] - Analysis not performed

Statistical analyses

No statistical analyses for this end point

Primary: Substudy 2 (Core phase): Change from baseline of the insulin secretion rate (ISR) relative to glucose 0-30 min defined as Φ30 = AUCISR 0-30 / AUCGluc 0-30 averaged across the year 3, 4, 5 visits

End point title	Substudy 2 (Core phase): Change from baseline of the insulin secretion rate (ISR) relative to glucose 0-30 min defined as Φ30 = AUCISR 0-30 / AUCGluc 0-30 averaged across the year 3, 4, 5 visits[18]

End point description:

End point type	Primary

End point timeframe:

From randomization up to approximately 6 years

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Substudy 2 was cancelled; no statistical analyses was performed.

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[19]	0[20]	0[21]	0[22]
Units: change in ISR to glucose				

Notes:

[19] - Analysis not performed

[20] - Analysis not performed

[21] - Analysis not performed

[22] - Analysis not performed

Statistical analyses

No statistical analyses for this end point

Secondary: Patients with Core phase CEC confirmed CV death, non-fatal MI, non-fatal stroke, or hospitalization for unstable angina requiring unplanned revascularization

End point title	Patients with Core phase CEC confirmed CV death, non-fatal MI, non-fatal stroke, or hospitalization for unstable angina requiring unplanned revascularization

End point description:

Occurrence of the composite cardiovascular endpoint consisting of cardiovascular death, non-fatal MI, non-fatal stroke or hospitalization for unstable angina requiring unplanned revascularization MACE includes CV death, non-fatal MI and non-fatal stroke. CEC = Clinical Endpoints Committee

End point type	Secondary

End point timeframe:

From randomization, to end of treatment pus 30 days, up to approximately 6 years

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2263	2284	2170	3344
Units: Participants				
MACE or unstable angina	348	352	344	601
Unstable angina	34	38	38	85

Statistical analyses

Statistical analysis title	Analysis [MACE or Unstable Angina]
Comparison groups	Group I v Group IV
Number of subjects included in analysis	5607
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0648 [23]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	0.94

Notes:

[23] - 1-sided adjusted for multiplicity using weighted Dunnett test. [significance level 0.0245]

Statistical analysis title	Analysis [MACE or Unstable Angina]
Comparison groups	Group II v Group IV

Number of subjects included in analysis	5628
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0241 [24]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	0.95

Notes:

[24] - 1-sided adjusted for multiplicity using weighted Dunnett test. [significance level 0.0245]

Statistical analysis title	Analysis [MACE or Unstable Angina]
Comparison groups	Group III v Group IV
Number of subjects included in analysis	5514
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1895 [25]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.03

Notes:

[25] - 1-sided adjusted for multiplicity using weighted Dunnett test. [significance level 0.0245]

Statistical analysis title	Analysis [Unstable Angina]
Comparison groups	Group I v Group IV
Number of subjects included in analysis	5607
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.007 [26]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	0.86

Notes:

[26] - 2-sided unadjusted p-value

Statistical analysis title	Analysis [Unstable Angina]

Comparison groups	Group II v Group IV
Number of subjects included in analysis	5628
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.022 [27]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.44
upper limit	0.94

Notes:

[27] - 2-sided unadjusted p-value

Statistical analysis title	Analysis [Unstable Angina]
Comparison groups	Group III v Group IV
Number of subjects included in analysis	5514
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.086 [28]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	1.05

Notes:

[28] - 2-sided unadjusted p-value

Secondary: Patients with Core phase new onset type 2 diabetes among patients with pre-diabetes at randomization

End point title	Patients with Core phase new onset type 2 diabetes among patients with pre-diabetes at randomization

End point description:

Time to CEC confirmed new onset of type 2 diabetes among those with pre-diabetes at randomization (i.e. excluding those that are normoglycemic at baseline)

End point type	Secondary

End point timeframe:

From randomization up to approximately 6 years

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1132	1094	1089	1645
Units: Participants	169	171	161	246

Statistical analyses

Statistical analysis title	Analysis
Comparison groups	Group I v Group IV
Number of subjects included in analysis	2777
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8456 [29]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.23

Notes:

[29] - 1-sided adjusted for multiplicity using weighted Dunnett test. [significance level 0.0245]

Statistical analysis title	Analysis
Comparison groups	Group II v Group IV
Number of subjects included in analysis	2739
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8456 [30]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.29

Notes:

[30] - 1-sided adjusted for multiplicity using weighted Dunnett test. [significance level 0.0245]

Statistical analysis title	Analysis
Comparison groups	Group III v Group IV

Number of subjects included in analysis	2734
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6541 [31]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.2

Notes:

[31] - 1-sided adjusted for multiplicity using weighted Dunnett test. [significance level 0.0245]

Secondary: Core phase all-cause mortality, non-fatal MI, or non-fatal stroke	
End point title	Core phase all-cause mortality, non-fatal MI, or non-fatal stroke
End point description:	
Occurrence of the composite endpoint consisting of all-cause mortality, non-fatal IM, or non-fatal stroke	
End point type	Secondary
End point timeframe:	
From randomization, to end of treatment plus 30 days, up to approximately 6 years	

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2263	2284	2170	3344
Units: Participants	403	395	394	661

Statistical analyses

Statistical analysis title	Analysis
Comparison groups	Group I v Group IV
Number of subjects included in analysis	5607
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.028 [32]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	0.99

Notes:
[32] - 2-sided unadjusted p-value

Statistical analysis title	Analysis
Comparison groups	Group II v Group IV
Number of subjects included in analysis	5628
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.011 [33]
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	0.96

Notes:
[33] - 2-sided unadjusted p-value

Statistical analysis title	Analysis
Comparison groups	Group III v Group IV
Number of subjects included in analysis	5514
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.377 [34]
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	1.07

Notes:
[34] - 2-sided unadjusted p-value

Secondary: Core phase all-cause mortality	
End point title	Core phase all-cause mortality
End point description:	
Number of participant deaths	
End point type	Secondary
End point timeframe:	
From randomization, to end of treatment plus 30 days, up to approximately 6 years	

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2263	2284	2170	3344
Units: Participants	239	238	228	375

Statistical analyses

Statistical analysis title	Analysis
Comparison groups	Group I v Group IV
Number of subjects included in analysis	5607
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.406 [35]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.1

Notes:

[35] - 2-sided unadjusted p-value

Statistical analysis title	Analysis
Comparison groups	Group II v Group IV
Number of subjects included in analysis	5628
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.329 [36]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.09

Notes:

[36] - 2-sided unadjusted p-value

Statistical analysis title	Analysis
Comparison groups	Group III v Group IV

Number of subjects included in analysis	5514
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.597 [37]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.13

Notes:

[37] - 2-sided unadjusted p-value

Secondary: Substudy 1 (Core phase): Change from baseline of the total vessel wall area at month 3 in the bifurcation region of the Index Carotid Artery

End point title	Substudy 1 (Core phase): Change from baseline of the total vessel wall area at month 3 in the bifurcation region of the Index Carotid Artery

End point description:

End point type	Secondary

End point timeframe:

3 months

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[38]	0[39]	0[40]	0[41]
Units: area				

Notes:

[38] - Analysis not performed

[39] - Analysis not performed

[40] - Analysis not performed

[41] - Analysis not performed

Statistical analyses

No statistical analyses for this end point

Secondary: Substudy 1 (Core phase): Mean total vessel wall area across the left and right carotid artery at Month 3 and Month 24

End point title	Substudy 1 (Core phase): Mean total vessel wall area across the left and right carotid artery at Month 3 and Month 24

End point description:

End point type	Secondary

End point timeframe:

24 months

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[42]	0[43]	0[44]	0[45]
Units: Mean area				

Notes:

[42] - Analysis not performed

[43] - Analysis not performed

[44] - Analysis not performed

[45] - Analysis not performed

Statistical analyses

No statistical analyses for this end point

Secondary: Substudy 1 (Core phase): Change from baseline in corresponding total vessel wall area in the left and right carotid arteries

End point title	Substudy 1 (Core phase): Change from baseline in corresponding total vessel wall area in the left and right carotid arteries

End point description:

End point type	Secondary

End point timeframe:

24 months

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[46]	0[47]	0[48]	0[49]
Units: area				

Notes:

[46] - Analysis not performed

[47] - Analysis not performed

[48] - Analysis not performed

[49] - Analysis not performed

Statistical analyses

No statistical analyses for this end point

Secondary: Substudy 1 (Core phase): The existence of a baseline total vessel wall area by treatment interaction as well as the consistency of the treatment effect across subgroups

End point title	Substudy 1 (Core phase): The existence of a baseline total vessel wall area by treatment interaction as well as the consistency of the treatment effect across subgroups

End point description:

End point type	Secondary

End point timeframe:

24 months

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[50]	0[51]	0[52]	0[53]
Units: area				

Notes:

[50] - Analysis not performed

[51] - Analysis not performed

[52] - Analysis not performed

[53] - Analysis not performed

Statistical analyses

No statistical analyses for this end point

Secondary: Substudy 2: (Core phase) Change from baseline in insulin sensitivity index

End point title	Substudy 2: (Core phase) Change from baseline in insulin sensitivity index

End point description:

End point type	Secondary

End point timeframe:

From randomization up to approximately 6 years

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[54]	0[55]	0[56]	0[57]
Units: Insulin sensitivity index				

Notes:

[54] - Analysis not performed

[55] - Analysis not performed

[56] - Analysis not performed

[57] - Analysis not performed

Statistical analyses

No statistical analyses for this end point

Secondary: Substudy 2: (Core phase) Change from baseline in OGTT stimulated area under curve (AUC) 0-120 min of glucose concentration, insulin concentration, pro-insulin concentration, and Insulin Concentration/glucose Concentration Ratio

End point title	Substudy 2: (Core phase) Change from baseline in OGTT stimulated area under curve (AUC) 0-120 min of glucose concentration, insulin concentration, pro-insulin concentration, and Insulin Concentration/glucose Concentration Ratio

End point description:

End point type	Secondary

End point timeframe:

From randomization up to approximately 6 years

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[58]	0[59]	0[60]	0[61]
Units: AUC				

Notes:

[58] - Analysis not performed

[59] - Analysis not performed

[60] - Analysis not performed

[61] - Analysis not performed

Statistical analyses

No statistical analyses for this end point

Secondary: Substudy 2: (Core phase) Change from Baseline in Fasting Pro-Insulin Concentration/Insulin Concentration Ratio

End point title	Substudy 2: (Core phase) Change from Baseline in Fasting Pro-Insulin Concentration/Insulin Concentration Ratio

End point description:

End point type	Secondary

End point timeframe:

From randomization up to approximately 6 years

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[62]	0[63]	0[64]	0[65]
Units: Ratio				

Notes:

[62] - Analysis not performed

[63] - Analysis not performed

[64] - Analysis not performed

[65] - Analysis not performed

Statistical analyses

No statistical analyses for this end point

Secondary: Substudy 2: (Core phase) Change from baseline in OGTT stimulated area under the curve (AUC) 0-120 min of C-peptide Concentration

End point title	Substudy 2: (Core phase) Change from baseline in OGTT stimulated area under the curve (AUC) 0-120 min of C-peptide Concentration

End point description:

End point type	Secondary

End point timeframe:

From randomization up to approximately 6 years

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[66]	0[67]	0[68]	0[69]
Units: AUC				

Notes:

[66] - Analysis not performed

[67] - Analysis not performed

[68] - Analysis not performed

[69] - Analysis not performed

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of Adverse Events (Core Phase)

End point title	Summary of Adverse Events (Core Phase)

End point description:

Summary of Adverse Events (AEs) and Serious Adverse Events (SAEs) occurring during the double-blind Core phase of the study. AEs/SAEs are any signs or symptoms that occur during the study treatment.

End point type	Secondary

End point timeframe:

From randomization, to end of treatment plus 30 days, up to approximately 6 years

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2263	2284[70]	2170	3344[71]
Units: Participants				
Patients with at least one AE	1987	1970	1872	2915
AEs suspected to be related to study drug	355	350	267	474
Patients with at least one SAE	836	812	741	1204
Discontinued due to SAEs	135	130	117	198
Discontinued due to non-serious AEs	40	34	26	47

AEs leading to study treatment interruption	268	270	228	399

Notes:

[70] - The number of subjects started was 2284; number of subjects analyzed was 2285

[71] - The number of subjects started was 3344; the number of subjects analyzed was 3348.

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of Adverse Events (Extension Phase)

End point title	Summary of Adverse Events (Extension Phase)

End point description:

Summary of Adverse Events (AEs) and Serious Adverse Events (SAEs) occurring during the Extension phase of the study. AEs/SAEs are any signs or symptoms that occur during the study treatment.

End point type	Secondary

End point timeframe:

From start of Extension phase, to end of treatment plus 30 days, up to approximately 2 years

End point values	Group I	Group II	Group III	Group IV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1267	1287	1279	1944
Units: Participants				
Patients with at least one AE	788	845	793	1250
AEs suspected to be related to study drug	40	34	43	65
Patients with at least one SAE	310	326	322	465
Discontinued due to SAEs	67	71	71	98
Discontinued due to non-serious AEs	8	6	12	8
AEs leading to study treatment interruption	59	72	62	100

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Core Phase: From randomization, to end of treatment plus 30 days, up to approximately 6 years.
Extension Phase: From start of Extension phase, to end of treatment plus 30 days, up to approximately 2 years

Adverse event reporting additional description:

AEs/SAEs are any signs or symptoms that occur during the study treatment. During the Core phase, CV events being study endpoints were exempt from AE/SAE reporting; in contrast, during the Extension phase, all CV events were reported as AEs/SAEs. Groups I to IV show AE/SAEs during the Core phase; Group V shows AE/SAEs during the Extension phase.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	Group I

Reporting group description:

Core phase: Blinded Canakinumab 300 mg quarterly subcutaneous + standard of care (SoC) therapy
Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy

Reporting group title	Group II

Reporting group description:

Core phase: Blinded Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy.
Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy

Reporting group title	Group III

Reporting group description:

Core phase: Blinded Canakinumab 50 mg quarterly subcutaneous + standard of care (SoC) therapy
Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy

Reporting group title	Group IV

Reporting group description:

Core phase: Blinded matching placebo quarterly subcutaneous + standard of care (SoC) therapy
Extension phase: Switched to open-label Canakinumab 150 mg
quarterly subcutaneous + standard of care (SoC) therapy

Reporting group title	Group V

Reporting group description:

Extension phase: Switched to open-label Canakinumab 150 mg quarterly subcutaneous + standard of care (SoC) therapy

Serious adverse events	Group I	Group II	Group III
Total subjects affected by serious adverse events			
subjects affected / exposed	759 / 2263 (33.54%)	743 / 2285 (32.52%)	686 / 2170 (31.61%)
number of deaths (all causes)	239	240	228
number of deaths resulting from adverse events	9	9	11

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute leukaemia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Adenocarcinoma gastric			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	1 / 3	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	2 / 2
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoma benign			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Adenosquamous cell lung cancer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal adenoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal neoplasm			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiolipoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiosarcoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell lymphoma			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	14 / 2263 (0.62%)	18 / 2285 (0.79%)	18 / 2170 (0.83%)
occurrences causally related to treatment / all	3 / 15	0 / 22	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign cardiac neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Benign gastric neoplasm			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign lung neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of bladder			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of scrotum			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of skin			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign salivary gland neoplasm			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign small intestinal neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign urinary tract neoplasm			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct cancer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	5 / 2263 (0.22%)	5 / 2285 (0.22%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	1 / 6	1 / 5	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder papilloma			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	3 / 2263 (0.13%)	2 / 2285 (0.09%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bone cancer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone cancer metastatic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			

subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm malignant			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Breast cancer			
subjects affected / exposed	4 / 2263 (0.18%)	0 / 2285 (0.00%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	1 / 4	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Breast cancer female			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer metastatic			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Brenner tumour			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoid tumour of the gastrointestinal tract			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 2	0 / 0
Chronic lymphocytic leukaemia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon adenoma			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	3 / 2263 (0.13%)	4 / 2285 (0.18%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	2 / 3	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Colon neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenocarcinoma			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma stage IV			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer stage III			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extranodal marginal zone B-cell lymphoma (MALT type)			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrous histiocytoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder adenocarcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric adenoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	5 / 2263 (0.22%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 5	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 1
Gastrointestinal carcinoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Hepatic cancer metastatic			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Hepatic cancer stage IV			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hodgkin's disease			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory pseudotumour			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal adenocarcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive breast carcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratoacanthoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine benign neoplasm			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal cancer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal squamous cell carcinoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo maligna			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip and/or oral cavity cancer			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Lip squamous cell carcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liposarcoma			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	3 / 2285 (0.13%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 2
Lung adenocarcinoma stage III			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma stage IV			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung cancer metastatic			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Lung carcinoma cell type unspecified recurrent			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage III			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			

subjects affected / exposed	4 / 2263 (0.18%)	9 / 2285 (0.39%)	9 / 2170 (0.41%)
occurrences causally related to treatment / all	1 / 5	0 / 10	1 / 10
deaths causally related to treatment / all	0 / 3	0 / 4	1 / 8
Lung squamous cell carcinoma metastatic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lymphoproliferative disorder			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Malignant fibrous histiocytoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant mediastinal neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	2 / 2263 (0.09%)	5 / 2285 (0.22%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 5	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma in situ			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of pleura			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of unknown primary site			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Malignant pleural effusion			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Mantle cell lymphoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medullary thyroid cancer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma benign			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to adrenals			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to central nervous system			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to kidney			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to liver			
subjects affected / exposed	2 / 2263 (0.09%)	5 / 2285 (0.22%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	1 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 1
Metastases to lung			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 4
Metastases to lymph nodes			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Metastases to pelvis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to pleura			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metastases to rectum			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Metastatic bronchial carcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic malignant melanoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoclonal gammopathy			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucinous adenocarcinoma of appendix			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycosis fungoides			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Myelofibrosis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal cavity cancer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm skin			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine breast tumour			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma refractory			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Non-small cell lung cancer			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Non-small cell lung cancer metastatic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer stage IV			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Oesophageal adenocarcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oesophageal adenocarcinoma stage II			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal cancer metastatic			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Oesophageal carcinoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Oesophageal neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal squamous cell carcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oligodendroglioma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal squamous cell carcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian adenoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian neoplasm			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	1 / 2263 (0.04%)	4 / 2285 (0.18%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 1	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	1 / 4	0 / 3
Pancreatic carcinoma metastatic			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 2	0 / 1	0 / 0
Papillary cystadenoma lymphomatosum			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary renal cell carcinoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parathyroid tumour benign			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penile cancer			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phaeochromocytoma			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal cancer			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pituitary tumour benign			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleomorphic adenoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycythaemia vera			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	12 / 2263 (0.53%)	10 / 2285 (0.44%)	10 / 2170 (0.46%)
occurrences causally related to treatment / all	2 / 12	0 / 10	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer metastatic			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Prostate cancer recurrent			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic adenoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	4 / 2263 (0.18%)	2 / 2285 (0.09%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	1 / 4	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Rectal cancer metastatic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectosigmoid cancer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 2
Renal cancer metastatic			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 3
Renal neoplasm			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal oncocytoma			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rosai-Dorfman syndrome			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland adenoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland neoplasm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seborrhoeic keratosis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin cancer			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Small cell lung cancer metastatic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestine adenocarcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestine carcinoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestine carcinoma metastatic			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	12 / 2263 (0.53%)	5 / 2285 (0.22%)	6 / 2170 (0.28%)
occurrences causally related to treatment / all	2 / 12	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Squamous cell carcinoma of lung			
subjects affected / exposed	2 / 2263 (0.09%)	5 / 2285 (0.22%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 0
Squamous cell carcinoma of skin			

subjects affected / exposed	3 / 2263 (0.13%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the hypopharynx			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superficial spreading melanoma stage II			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testis cancer			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Throat cancer			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Thyroid cancer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer metastatic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid neoplasm			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Tonsil cancer metastatic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma urethra			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour perforation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine cancer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Accelerated hypertension			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aneurysm ruptured			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiodysplasia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm			
subjects affected / exposed	8 / 2263 (0.35%)	4 / 2285 (0.18%)	6 / 2170 (0.28%)
occurrences causally related to treatment / all	0 / 8	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aortic aneurysm rupture			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Aortic dissection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic stenosis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortitis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Arterial haemorrhage			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial insufficiency			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteritis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brachiocephalic artery stenosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Embolism arterial			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism venous			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential hypertension			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Femoral artery aneurysm			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery embolism			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	2 / 2263 (0.09%)	3 / 2285 (0.13%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemodynamic instability			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	10 / 2263 (0.44%)	8 / 2285 (0.35%)	8 / 2170 (0.37%)
occurrences causally related to treatment / all	0 / 10	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	7 / 2263 (0.31%)	5 / 2285 (0.22%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	8 / 2263 (0.35%)	5 / 2285 (0.22%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intermittent claudication			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal haemorrhage			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic limb pain			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphatic fistula			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphorrhoea			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant hypertension			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypertension			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	1 / 2263 (0.04%)	3 / 2285 (0.13%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pallor			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			

subjects affected / exposed	3 / 2263 (0.13%)	4 / 2285 (0.18%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			
subjects affected / exposed	0 / 2263 (0.00%)	3 / 2285 (0.13%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Peripheral embolism			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			
subjects affected / exposed	0 / 2263 (0.00%)	3 / 2285 (0.13%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Peripheral venous disease			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Shock haemorrhagic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal arteritis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose ulceration			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular insufficiency			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	4 / 2263 (0.18%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac death			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	3 / 2263 (0.13%)	12 / 2285 (0.53%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	1 / 14	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			

subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complication associated with device			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	1 / 1
Drowning			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug intolerance			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exercise tolerance decreased			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial pain			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			

subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heteroplasia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperplasia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site irritation			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated hernia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Inflammation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site reaction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic ulcer			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Local swelling			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Malaise			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mass			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	3 / 2263 (0.13%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 0
Necrosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	44 / 2263 (1.94%)	48 / 2285 (2.10%)	39 / 2170 (1.80%)
occurrences causally related to treatment / all	0 / 57	0 / 53	0 / 41
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pacemaker syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyp			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudocyst			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	4 / 2263 (0.18%)	4 / 2285 (0.18%)	6 / 2170 (0.28%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stent-graft endoleak			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Sudden death			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical failure			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stent restenosis			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stent stenosis			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stent thrombosis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vessel puncture site haemorrhage			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contrast media allergy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Homicide			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign prostatic hyperplasia			
subjects affected / exposed	5 / 2263 (0.22%)	6 / 2285 (0.26%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 5	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystocele			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysmenorrhoea			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial hyperplasia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymal cyst			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Erectile dysfunction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Female genital tract fistula			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital atrophy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital prolapse			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menorrhagia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic pain			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postmenopausal haemorrhage			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic haemorrhage			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic mass			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatism			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatomegaly			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spermatocele			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine cervix stenosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicocele			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose veins pelvic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 2263 (0.00%)	3 / 2285 (0.13%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	10 / 2263 (0.44%)	7 / 2285 (0.31%)	11 / 2170 (0.51%)
occurrences causally related to treatment / all	1 / 11	0 / 7	1 / 12
deaths causally related to treatment / all	1 / 4	0 / 2	0 / 0
Alveolitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alveolitis allergic			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asphyxia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	7 / 2263 (0.31%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	2 / 8	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	3 / 2263 (0.13%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis chronic			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cheyne-Stokes respiration			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	28 / 2263 (1.24%)	21 / 2285 (0.92%)	16 / 2170 (0.74%)
occurrences causally related to treatment / all	2 / 48	2 / 23	1 / 21
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 2
Cough			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	14 / 2263 (0.62%)	8 / 2285 (0.35%)	10 / 2170 (0.46%)
occurrences causally related to treatment / all	0 / 14	0 / 9	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Dyspnoea exertional			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			

subjects affected / exposed	3 / 2263 (0.13%)	2 / 2285 (0.09%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemothorax			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiccups			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypopnoea			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic interstitial pneumonia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic pneumonia syndrome			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Interstitial lung disease			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Laryngeal oedema			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngospasm			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung consolidation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung hernia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nasal obstruction			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal polyps			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal turbinate hypertrophy			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pickwickian syndrome			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural adhesion			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	8 / 2263 (0.35%)	5 / 2285 (0.22%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 10	1 / 5	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	1 / 2263 (0.04%)	3 / 2285 (0.13%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	1 / 2263 (0.04%)	4 / 2285 (0.18%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	5 / 2263 (0.22%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax spontaneous			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary haematoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	2 / 2263 (0.09%)	3 / 2285 (0.13%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			

subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary microemboli			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	4 / 2263 (0.18%)	4 / 2285 (0.18%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary sarcoidosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory alkalosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory distress			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	12 / 2263 (0.53%)	11 / 2285 (0.48%)	9 / 2170 (0.41%)
occurrences causally related to treatment / all	0 / 14	1 / 11	0 / 9
deaths causally related to treatment / all	0 / 5	0 / 6	0 / 3
Respiratory tract inflammation			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract irritation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis allergic			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus congestion			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus polyp			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status asthmaticus			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord leukoplakia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Acute stress disorder			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Affective disorder			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholic psychosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholism			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety disorder			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety disorder due to a general medical condition			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bipolar I disorder			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burnout syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conversion disorder			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium tremens			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	7 / 2263 (0.31%)	4 / 2285 (0.18%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dissociative amnesia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug use disorder			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised anxiety disorder			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination, visual			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head banging			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Homicidal ideation			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insomnia			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional self-injury			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	4 / 2263 (0.18%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panic attack			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Personality change			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder due to a general medical condition			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restlessness			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizophrenia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnambulism			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device battery issue			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device end of service			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device failure			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device inappropriate shock delivery			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device issue			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device lead damage			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device lead issue			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device loosening			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device occlusion			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device signal detection issue			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lead dislodgement			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholic liver disease			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune hepatitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	4 / 2263 (0.18%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary cirrhosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary dilatation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary fistula			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 2	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cholecystitis			
subjects affected / exposed	11 / 2263 (0.49%)	4 / 2285 (0.18%)	8 / 2170 (0.37%)
occurrences causally related to treatment / all	1 / 11	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cholecystitis acute			
subjects affected / exposed	5 / 2263 (0.22%)	7 / 2285 (0.31%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 5	1 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	8 / 2263 (0.35%)	8 / 2285 (0.35%)	8 / 2170 (0.37%)
occurrences causally related to treatment / all	0 / 8	0 / 9	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder polyp			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic hepatic cyst			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic congestion			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hepatic function abnormal			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic steatosis			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic vein thrombosis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis toxic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatomegaly			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatorenal failure			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatosplenomegaly			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hydrocholecystis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic hepatitis			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-alcoholic fatty liver			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Steatohepatitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anticoagulation drug level above therapeutic			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase MB increased			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose increased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood magnesium decreased			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood pressure increased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood urine present			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body mass index decreased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central venous pressure increased			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest X-ray abnormal			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium test positive			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human metapneumovirus test positive			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Imaging procedure abnormal			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio decreased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio increased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Oxygen saturation decreased			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quality of life decreased			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scan myocardial perfusion abnormal			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin T increased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volume blood decreased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight increased			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accident			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Accidental overdose			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia postoperative			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic leak			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	5 / 2263 (0.22%)	0 / 2285 (0.00%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial injury			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropod sting			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asbestosis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone contusion			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac function disturbance postoperative			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central cord syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Closed globe injury			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Comminuted fracture			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			

subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery restenosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dural tear			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epicondylitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face injury			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			

subjects affected / exposed	3 / 2263 (0.13%)	5 / 2285 (0.22%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 2263 (0.04%)	3 / 2285 (0.13%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture displacement			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder injury			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma necrosis			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site haemorrhage			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Incision site pain			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			

subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia, obstructive			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional overdose			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional product misuse			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	4 / 2263 (0.18%)	0 / 2285 (0.00%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			

subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament injury			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ligament rupture			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb traumatic amputation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			

subjects affected / exposed	0 / 2263 (0.00%)	3 / 2285 (0.13%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle contusion			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal foreign body			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve injury			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			

subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Patella fracture			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery restenosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirenal haematoma			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumoconiosis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax traumatic			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural discharge			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fever			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative hernia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound complication			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Procedural complication			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural intestinal perforation			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis fracture			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation mucositis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	4 / 2263 (0.18%)	3 / 2285 (0.13%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	4 / 2263 (0.18%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Scapula fracture			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scratch			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skeletal injury			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column injury			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord injury			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord injury cervical			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress fracture			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	2 / 2263 (0.09%)	4 / 2285 (0.18%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			

subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	4 / 2263 (0.18%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth fracture			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Tracheal haemorrhage			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Traumatic amputation			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic arthritis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haematoma			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention postoperative			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft complication			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm ruptured			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound secretion			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Branchial cyst			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular arteriovenous malformation			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic arteriovenous malformation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hereditary haemochromatosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nonketotic hyperglycinaemia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyloric stenosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheo-oesophageal fistula			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	6 / 2263 (0.27%)	1 / 2285 (0.04%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Acute left ventricular failure			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Adams-Stokes syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	42 / 2263 (1.86%)	41 / 2285 (1.79%)	37 / 2170 (1.71%)
occurrences causally related to treatment / all	0 / 51	0 / 52	0 / 43
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	39 / 2263 (1.72%)	34 / 2285 (1.49%)	37 / 2170 (1.71%)
occurrences causally related to treatment / all	0 / 50	0 / 45	0 / 37
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve incompetence			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Aortic valve stenosis			

subjects affected / exposed	3 / 2263 (0.13%)	2 / 2285 (0.09%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	4 / 2263 (0.18%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Arrhythmia supraventricular			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriospasm coronary			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	3 / 2263 (0.13%)	6 / 2285 (0.26%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Atrial flutter			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial tachycardia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block first degree			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	1 / 2263 (0.04%)	4 / 2285 (0.18%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradyarrhythmia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	4 / 2263 (0.18%)	2 / 2285 (0.09%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 4	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac aneurysm			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			

subjects affected / exposed	2 / 2263 (0.09%)	7 / 2285 (0.31%)	7 / 2170 (0.32%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 5	0 / 4
Cardiac discomfort			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	5 / 2263 (0.22%)	4 / 2285 (0.18%)	7 / 2170 (0.32%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 4	0 / 1	0 / 0
Cardiac failure acute			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0
Cardiac failure chronic			
subjects affected / exposed	5 / 2263 (0.22%)	2 / 2285 (0.09%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	4 / 2263 (0.18%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cardiac fibrillation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac pseudoaneurysm			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			

subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Cardiogenic shock			
subjects affected / exposed	1 / 2263 (0.04%)	3 / 2285 (0.13%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 3
Cardiomegaly			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Conduction disorder			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive cardiomyopathy			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cor pulmonale			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	9 / 2263 (0.40%)	10 / 2285 (0.44%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	1 / 10	0 / 13	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Coronary artery insufficiency			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intracardiac thrombus			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			

subjects affected / exposed	3 / 2263 (0.13%)	5 / 2285 (0.22%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microvascular coronary artery disease			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			
subjects affected / exposed	5 / 2263 (0.22%)	3 / 2285 (0.13%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 5	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	4 / 2263 (0.18%)	2 / 2285 (0.09%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 5
Myocardial ischaemia			
subjects affected / exposed	6 / 2263 (0.27%)	3 / 2285 (0.13%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Nodal arrhythmia			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	3 / 2263 (0.13%)	2 / 2285 (0.09%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prinzmetal angina			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulseless electrical activity			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular dysfunction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Silent myocardial infarction			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus arrest			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	3 / 2263 (0.13%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	4 / 2263 (0.18%)	2 / 2285 (0.09%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachyarrhythmia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			

subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Torsade de pointes			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve incompetence			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trifascicular block			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	4 / 2263 (0.18%)	9 / 2285 (0.39%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	1 / 4	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ventricular tachyarrhythmia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			

subjects affected / exposed	10 / 2263 (0.44%)	5 / 2285 (0.22%)	9 / 2170 (0.41%)
occurrences causally related to treatment / all	0 / 13	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Amnesia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Aphasia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apraxia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Balance disorder			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain injury			
subjects affected / exposed	0 / 2263 (0.00%)	3 / 2285 (0.13%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Brain oedema			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Carotid arteriosclerosis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery aneurysm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery disease			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery occlusion			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	3 / 2263 (0.13%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cauda equina syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar stroke			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cervical myelopathy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical radiculopathy			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dementia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia with Lewy bodies			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic coma			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic neuropathy			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplegia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	6 / 2263 (0.27%)	2 / 2285 (0.09%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysaesthesia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dystonia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal dyscognitive seizures			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic transformation stroke			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	4 / 2263 (0.18%)	3 / 2285 (0.13%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersomnia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive encephalopathy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic coma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic encephalopathy			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IIIrd nerve paresis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar stroke			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			

subjects affected / exposed	1 / 2263 (0.04%)	3 / 2285 (0.13%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbosacral radiculopathy			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental impairment			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mixed dementia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve compression			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normal pressure hydrocephalus			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuritis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic intolerance			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralysis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paresis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral nerve lesion			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post herpetic neuralgia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post stroke seizure			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restless legs syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	3 / 2263 (0.13%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sensory disturbance			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal claudication			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord infarction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylitic myelopathy			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stupor			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural hygroma			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	15 / 2263 (0.66%)	17 / 2285 (0.74%)	16 / 2170 (0.74%)
occurrences causally related to treatment / all	0 / 16	1 / 19	2 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tension headache			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamic infarction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic cerebral infarction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonic convulsion			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient global amnesia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal neuralgia			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper motor neurone lesion			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paralysis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular dementia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Vascular encephalopathy			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Abnormal clotting factor			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			

subjects affected / exposed	15 / 2263 (0.66%)	10 / 2285 (0.44%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	1 / 15	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Bone marrow oedema			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic anaemia			
subjects affected / exposed	4 / 2263 (0.18%)	2 / 2285 (0.09%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hilar lymphadenopathy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Histiocytosis haematophagic			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypochromic anaemia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Leukopenia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy mediastinal			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoclonal B-cell lymphocytosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normocytic anaemia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	1 / 1	0 / 0
Polycythaemia			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infarction			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenomegaly			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	5 / 2263 (0.22%)	0 / 2285 (0.00%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	1 / 5	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Thrombocytopenic purpura			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear pain			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoacusis			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniere's disease			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otosclerosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presbyacusis			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden hearing loss			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tympanic membrane perforation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	3 / 2263 (0.13%)	5 / 2285 (0.22%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angle closure glaucoma			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness transient			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	4 / 2263 (0.18%)	8 / 2285 (0.35%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 4	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract cortical			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract diabetic			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract nuclear			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corneal degeneration			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corneal infiltrates			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dacryostenosis acquired			

subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic retinopathy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye haemorrhage			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid ptosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iridocyclitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lens dislocation			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular degeneration			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular fibrosis			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular hole			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular oedema			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neovascular age-related macular degeneration			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular ischaemic syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloedema			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal artery thrombosis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal haemorrhage			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vein occlusion			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vein thrombosis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous haemorrhage			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal discomfort			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			

subjects affected / exposed	7 / 2263 (0.31%)	4 / 2285 (0.18%)	10 / 2170 (0.46%)
occurrences causally related to treatment / all	0 / 7	0 / 4	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	6 / 2263 (0.27%)	2 / 2285 (0.09%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute abdomen			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholic pancreatitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal skin tags			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal ulcer			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal ulcer haemorrhage			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal disorder			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal mucocoele			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendix disorder			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Change of bowel habit			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastritis			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			

subjects affected / exposed	3 / 2263 (0.13%)	3 / 2285 (0.13%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Colitis microscopic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic fistula			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	4 / 2263 (0.18%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	1 / 2263 (0.04%)	3 / 2285 (0.13%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dental caries			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic gastroenteropathy			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	3 / 2263 (0.13%)	5 / 2285 (0.22%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 3	0 / 5	1 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dieulafoy's vascular malformation			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			

subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer perforation			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epigastric discomfort			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive duodenitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive oesophagitis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faeces discoloured			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flatulence			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallstone ileus			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	7 / 2263 (0.31%)	6 / 2285 (0.26%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric volvulus			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	4 / 2263 (0.18%)	1 / 2285 (0.04%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroduodenitis			

subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal angiodysplasia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal erosion			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	13 / 2263 (0.57%)	16 / 2285 (0.70%)	14 / 2170 (0.65%)
occurrences causally related to treatment / all	0 / 13	1 / 23	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 3
Gastrointestinal necrosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal pain			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal perforation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal ulcer			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal vascular malformation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 2263 (0.04%)	5 / 2285 (0.22%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	1 / 2263 (0.04%)	3 / 2285 (0.13%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic necrotic pancreatitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	2 / 2263 (0.09%)	3 / 2285 (0.13%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids thrombosed			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal ulcer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated inguinal hernia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory bowel disease			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	8 / 2263 (0.35%)	5 / 2285 (0.22%)	7 / 2170 (0.32%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia strangulated			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal fistula			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal infarction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal mass			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			

subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intestinal perforation			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intestinal ulcer			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic enteritis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal stenosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Large intestine polyp			

subjects affected / exposed	3 / 2263 (0.13%)	4 / 2285 (0.18%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 2263 (0.04%)	4 / 2285 (0.18%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric artery stenosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric artery thrombosis			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Mesenteric vascular insufficiency			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Mouth cyst			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth ulceration			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcotic bowel syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	4 / 2263 (0.18%)	3 / 2285 (0.13%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal obstruction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal perforation			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal rupture			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal ulcer			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic cyst			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pancreatic disorder			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic duct dilatation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic mass			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic pseudocyst			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	6 / 2263 (0.27%)	6 / 2285 (0.26%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pancreatitis acute			
subjects affected / exposed	3 / 2263 (0.13%)	6 / 2285 (0.26%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Pancreatitis chronic			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis necrotising			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer haemorrhage			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haemorrhage			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumatosis intestinalis			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumoperitoneum			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ranula			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 2263 (0.04%)	6 / 2285 (0.26%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal lesion			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal perforation			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polyp			

subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haemorrhage			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Salivary gland calculus			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestine ulcer			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			

subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis mesenteric vessel			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	1 / 2263 (0.04%)	4 / 2285 (0.18%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	3 / 2263 (0.13%)	8 / 2285 (0.35%)	8 / 2170 (0.37%)
occurrences causally related to treatment / all	0 / 4	0 / 8	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	5 / 2263 (0.22%)	4 / 2285 (0.18%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Actinic keratosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blister			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brow ptosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dermatitis allergic			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	1 / 2263 (0.04%)	6 / 2285 (0.26%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Eczema			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperhidrosis			

subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkeratosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity vasculitis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurodermatitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prurigo			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus allergic			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinophyma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			

subjects affected / exposed	0 / 2263 (0.00%)	5 / 2285 (0.22%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 0	1 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stasis dermatitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson syndrome			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous emphysema			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	20 / 2263 (0.88%)	30 / 2285 (1.31%)	16 / 2170 (0.74%)
occurrences causally related to treatment / all	1 / 21	0 / 31	0 / 20
deaths causally related to treatment / all	0 / 4	0 / 3	0 / 2
Acute prerenal failure			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anuria			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Azotaemia			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Calculus bladder			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urethral			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	4 / 2263 (0.18%)	5 / 2285 (0.22%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	1 / 5	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Diabetic nephropathy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Focal segmental glomerulosclerosis			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis membranous			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	5 / 2263 (0.22%)	6 / 2285 (0.26%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hydronephrosis			
subjects affected / exposed	2 / 2263 (0.09%)	3 / 2285 (0.13%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive nephropathy			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower urinary tract symptoms			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	3 / 2263 (0.13%)	2 / 2285 (0.09%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Obstructive uropathy			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pollakiuria			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyuria			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prerenal failure			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery thrombosis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Renal colic			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	7 / 2263 (0.31%)	10 / 2285 (0.44%)	11 / 2170 (0.51%)
occurrences causally related to treatment / all	0 / 8	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 4	0 / 2
Renal haematoma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	1 / 2263 (0.04%)	4 / 2285 (0.18%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal injury			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal mass			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Renal tubular necrosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress urinary incontinence			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric stenosis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral obstruction			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder polyp			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	4 / 2263 (0.18%)	4 / 2285 (0.18%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Urinary tract obstruction			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vesicocutaneous fistula			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Goitre			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism primary			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypopituitarism			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Primary hyperaldosteronism			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic goitre			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 2263 (0.09%)	5 / 2285 (0.22%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis reactive			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	4 / 2263 (0.18%)	8 / 2285 (0.35%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 4	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical spinal stenosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondromalacia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondropathy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Compartment syndrome			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dactylitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dupuytren's contracture			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			

subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fasciitis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Finger deformity			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture malunion			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gouty arthritis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gouty tophus			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immunoglobulin G4 related disease			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Intervertebral disc calcification			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc compression			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc degeneration			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc displacement			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			

subjects affected / exposed	4 / 2263 (0.18%)	2 / 2285 (0.09%)	6 / 2170 (0.28%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw cyst			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint instability			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint swelling			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	1 / 2263 (0.04%)	4 / 2285 (0.18%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscal degeneration			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metatarsalgia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle atrophy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle haemorrhage			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle spasms			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle swelling			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	3 / 2263 (0.13%)	3 / 2285 (0.13%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myofascial pain syndrome			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathic arthropathy			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	19 / 2263 (0.84%)	21 / 2285 (0.92%)	18 / 2170 (0.83%)
occurrences causally related to treatment / all	0 / 22	0 / 24	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteolysis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporotic fracture			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	5 / 2263 (0.22%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in jaw			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			

subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shoulder deformity			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue mass			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	6 / 2263 (0.27%)	2 / 2285 (0.09%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal deformity			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	3 / 2263 (0.13%)	2 / 2285 (0.09%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendonitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigger finger			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral foraminal stenosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral wedging			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			

subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal sepsis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess intestinal			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess jaw			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	4 / 2263 (0.18%)	1 / 2285 (0.04%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 4	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess oral			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess soft tissue			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute hepatitis B			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	3 / 2263 (0.13%)	4 / 2285 (0.18%)	6 / 2170 (0.28%)
occurrences causally related to treatment / all	0 / 3	1 / 4	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Atypical pneumonia			

subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 3	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 2	1 / 1	0 / 0
Bacterial disease carrier			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial pyelonephritis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bacteroides infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bartholin's abscess			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone abscess			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	10 / 2263 (0.44%)	9 / 2285 (0.39%)	6 / 2170 (0.28%)
occurrences causally related to treatment / all	0 / 11	1 / 9	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis infective			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis infective staphylococcal			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbuncle			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	29 / 2263 (1.28%)	32 / 2285 (1.40%)	19 / 2170 (0.88%)
occurrences causally related to treatment / all	6 / 35	9 / 37	2 / 21
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cellulitis gangrenous			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis of male external genital organ			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system infection			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chikungunya virus infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis infective			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chorioretinitis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic tonsillitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridial infection			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	1 / 3	0 / 1	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	1 / 2	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic abscess			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Creutzfeldt-Jakob disease			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Diabetic gangrene			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	8 / 2263 (0.35%)	9 / 2285 (0.39%)	8 / 2170 (0.37%)
occurrences causally related to treatment / all	0 / 9	1 / 9	4 / 8
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Ear infection			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis bacterial			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiglottitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	6 / 2263 (0.27%)	12 / 2285 (0.53%)	6 / 2170 (0.28%)
occurrences causally related to treatment / all	1 / 8	2 / 13	1 / 6
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
External ear cellulitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal skin infection			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Furuncle			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder abscess			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder empyema			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastritis viral			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	6 / 2263 (0.27%)	5 / 2285 (0.22%)	6 / 2170 (0.28%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastroenteritis clostridial			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	2 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal bacterial infection			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma infection			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus sepsis			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic pneumonia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Helicobacter infection			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic amoebiasis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatitis viral			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes ophthalmic			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human ehrlichiosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypopyon			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site abscess			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site infection			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Incision site cellulitis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected bite			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected cyst			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Infection			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious colitis			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	5 / 2263 (0.22%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	1 / 9	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective spondylitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	4 / 2263 (0.18%)	6 / 2285 (0.26%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint abscess			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leptospirosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	1 / 3	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	3 / 2263 (0.13%)	2 / 2285 (0.09%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 3	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lyme disease			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangitis			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device site infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningococcal sepsis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric abscess			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle abscess			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycobacterial infection			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycobacterium avium complex infection			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising fasciitis			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	4 / 2263 (0.18%)	3 / 2285 (0.13%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 4	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis bacterial			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis blastomyces			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pancreatic abscess			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parametritis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perichondritis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal abscess			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periodontitis			

subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal abscess			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal abscess			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	67 / 2263 (2.96%)	60 / 2285 (2.63%)	53 / 2170 (2.44%)
occurrences causally related to treatment / all	13 / 72	15 / 69	9 / 58
deaths causally related to treatment / all	1 / 13	2 / 12	2 / 9
Pneumonia bacterial			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia escherichia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia necrotising			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural cellulitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural sepsis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Postoperative abscess			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			

subjects affected / exposed	2 / 2263 (0.09%)	2 / 2285 (0.09%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Proctitis infectious			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Propionibacterium infection			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas bronchitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoas abscess			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			

subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelitis			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 3	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 2263 (0.04%)	5 / 2285 (0.22%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyoderma			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyuria			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal abscess			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			

subjects affected / exposed	2 / 2263 (0.09%)	7 / 2285 (0.31%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	2 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rubella			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrub typhus			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	19 / 2263 (0.84%)	25 / 2285 (1.09%)	15 / 2170 (0.69%)
occurrences causally related to treatment / all	5 / 19	9 / 25	3 / 15
deaths causally related to treatment / all	3 / 7	2 / 12	0 / 6
Sepsis syndrome			

subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic embolus			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic necrosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	6 / 2263 (0.27%)	8 / 2285 (0.35%)	6 / 2170 (0.28%)
occurrences causally related to treatment / all	0 / 6	0 / 8	2 / 6
deaths causally related to treatment / all	0 / 5	0 / 6	1 / 5
Sialoadenitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	3 / 2263 (0.13%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis fungal			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal abscess			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			

subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal mediastinitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	4 / 2263 (0.18%)	3 / 2285 (0.13%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	2 / 4	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdiaphragmatic abscess			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural empyema			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Testicular abscess			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tetanus			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	13 / 2263 (0.57%)	11 / 2285 (0.48%)	10 / 2170 (0.46%)
occurrences causally related to treatment / all	3 / 13	5 / 12	0 / 10
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	3 / 2263 (0.13%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection fungal			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection pseudomonal			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	4 / 2263 (0.18%)	4 / 2285 (0.18%)	5 / 2170 (0.23%)
occurrences causally related to treatment / all	0 / 4	0 / 4	1 / 5
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Vestibular neuronitis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral cardiomyopathy			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral diarrhoea			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval abscess			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 2263 (0.00%)	3 / 2285 (0.13%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection bacterial			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection staphylococcal			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound sepsis			
subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Acidosis			

subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cachexia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	5 / 2263 (0.22%)	6 / 2285 (0.26%)	6 / 2170 (0.28%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Diabetes mellitus			
subjects affected / exposed	3 / 2263 (0.13%)	10 / 2285 (0.44%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 10	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	2 / 2263 (0.09%)	1 / 2285 (0.04%)	7 / 2170 (0.32%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes with hyperosmolarity			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic complication			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Diabetic metabolic decompensation			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid overload			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperammonaemia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperchloraemia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	3 / 2263 (0.13%)	4 / 2285 (0.18%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome			

subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	3 / 2263 (0.13%)	4 / 2285 (0.18%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypermagnesaemia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	4 / 2263 (0.18%)	4 / 2285 (0.18%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	1 / 4	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	3 / 2170 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			

subjects affected / exposed	2 / 2263 (0.09%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 2263 (0.00%)	2 / 2285 (0.09%)	4 / 2170 (0.18%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Insulin resistant diabetes			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insulin-requiring type 2 diabetes mellitus			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ketoacidosis			
subjects affected / exposed	0 / 2263 (0.00%)	0 / 2285 (0.00%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	1 / 2263 (0.04%)	0 / 2285 (0.00%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	1 / 2263 (0.04%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metabolic acidosis			

subjects affected / exposed	1 / 2263 (0.04%)	2 / 2285 (0.09%)	2 / 2170 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 1
Obesity			
subjects affected / exposed	5 / 2263 (0.22%)	1 / 2285 (0.04%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 2263 (0.00%)	1 / 2285 (0.04%)	0 / 2170 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	3 / 2263 (0.13%)	2 / 2285 (0.09%)	1 / 2170 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0

Serious adverse events	Group IV	Group V	
Total subjects affected by serious adverse events			
subjects affected / exposed	1099 / 3348 (32.83%)	1216 / 5777 (21.05%)	
number of deaths (all causes)	378	211	
number of deaths resulting from adverse events	8	7	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute leukaemia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Adenocarcinoma			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Adenocarcinoma gastric			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	5 / 3348 (0.15%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	1 / 5	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Adenoma benign			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenosquamous cell lung cancer			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal adenoma			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal neoplasm			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiolipoma			

subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Angiosarcoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
B-cell lymphoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	21 / 3348 (0.63%)	30 / 5777 (0.52%)	
occurrences causally related to treatment / all	0 / 32	3 / 33	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign cardiac neoplasm			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign gastric neoplasm			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign lung neoplasm			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of bladder			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of scrotum			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of skin			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign salivary gland neoplasm			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign small intestinal neoplasm			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign urinary tract neoplasm			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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 / 3348 (0.03%)	0 / 5777 (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	5 / 3348 (0.15%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	3 / 6	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 0	
Bladder neoplasm			

subjects affected / exposed	2 / 3348 (0.06%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder papilloma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone cancer			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bone cancer metastatic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bowen's disease			
subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm malignant			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			

subjects affected / exposed	2 / 3348 (0.06%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer female			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brenner tumour			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial carcinoma			
subjects affected / exposed	3 / 3348 (0.09%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 3	0 / 2	
Carcinoid tumour of the gastrointestinal tract			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix carcinoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic lymphocytic leukaemia			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon adenoma			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	6 / 3348 (0.18%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 6	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colon neoplasm			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenocarcinoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma stage IV			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer stage III			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extranodal marginal zone B-cell lymphoma (MALT type)			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibroma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibrous histiocytoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder adenocarcinoma			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric adenoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			
subjects affected / exposed	5 / 3348 (0.15%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	1 / 6	1 / 5	
deaths causally related to treatment / all	0 / 1	0 / 2	
Gastrointestinal carcinoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal tract adenoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Glioma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemangioma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatic cancer metastatic			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	1 / 2	0 / 0	
Hepatic cancer stage IV			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic neoplasm			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatocellular carcinoma			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hodgkin's disease			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory pseudotumour			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal adenocarcinoma			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive breast carcinoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratoacanthoma			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine benign neoplasm			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal squamous cell carcinoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lentigo maligna			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukaemia			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip and/or oral cavity cancer			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip squamous cell carcinoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liposarcoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	7 / 3348 (0.21%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 4	0 / 0	
Lung adenocarcinoma stage III			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma stage IV			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung carcinoma cell type unspecified recurrent			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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 III			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Lung neoplasm malignant			
subjects affected / exposed	25 / 3348 (0.75%)	14 / 5777 (0.24%)	
occurrences causally related to treatment / all	3 / 25	1 / 14	
deaths causally related to treatment / all	0 / 16	1 / 7	
Lung squamous cell carcinoma metastatic			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lymphoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoproliferative disorder			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant fibrous histiocytoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant mediastinal neoplasm			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant melanoma			
subjects affected / exposed	2 / 3348 (0.06%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma in situ			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of pleura			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant neoplasm of unknown primary site			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant pleural effusion			

subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mantle cell lymphoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medullary thyroid cancer			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma benign			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to adrenals			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Metastases to kidney			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to liver			
subjects affected / exposed	4 / 3348 (0.12%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	1 / 4	1 / 2	
deaths causally related to treatment / all	1 / 4	1 / 1	
Metastases to lung			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Metastases to lymph nodes			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to pelvis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to pleura			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to rectum			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to spine			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic bronchial carcinoma			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic malignant melanoma			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoclonal gammopathy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucinous adenocarcinoma of appendix			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycosis fungoides			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelofibrosis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal cavity cancer			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Neoplasm skin			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine breast tumour			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma refractory			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			

subjects affected / exposed	1 / 3348 (0.03%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Non-small cell lung cancer metastatic			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal adenocarcinoma			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Oesophageal adenocarcinoma stage II			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal cancer metastatic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Oesophageal neoplasm			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal squamous cell carcinoma			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oligodendroglioma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal squamous cell carcinoma			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian adenoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian neoplasm			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	5 / 3348 (0.15%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	1 / 6	0 / 3	
deaths causally related to treatment / all	1 / 3	0 / 2	
Pancreatic carcinoma metastatic			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	1 / 2	0 / 0	
Papillary cystadenoma lymphomatosum			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary renal cell carcinoma			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid tumour benign			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile cancer			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Phaeochromocytoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal cancer			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary tumour benign			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			

subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleomorphic adenoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia vera			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	13 / 3348 (0.39%)	15 / 5777 (0.26%)	
occurrences causally related to treatment / all	1 / 13	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer metastatic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer recurrent			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic adenoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenoma			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			
subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Rectal cancer metastatic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid cancer			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Renal cancer metastatic			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	1 / 3348 (0.03%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Renal neoplasm			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal oncocytoma			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rosai-Dorfman syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland adenoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seborrhoeic keratosis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin cancer			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer			
subjects affected / exposed	5 / 3348 (0.15%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
Small cell lung cancer metastatic			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestine adenocarcinoma			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 1		
Small intestine carcinoma				
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Small intestine carcinoma metastatic				
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Squamous cell carcinoma				
subjects affected / exposed	10 / 3348 (0.30%)	9 / 5777 (0.16%)		
occurrences causally related to treatment / all	2 / 11	1 / 9		
deaths causally related to treatment / all	0 / 1	0 / 0		
Squamous cell carcinoma of lung				
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)		
occurrences causally related to treatment / all	0 / 2	1 / 1		
deaths causally related to treatment / all	0 / 1	1 / 1		
Squamous cell carcinoma of skin				
subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)		
occurrences causally related to treatment / all	0 / 3	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Squamous cell carcinoma of the hypopharynx				
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Squamous cell carcinoma of the tongue				
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Superficial spreading melanoma stage II				

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testis cancer			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Throat cancer			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer metastatic			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid neoplasm			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer metastatic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			

subjects affected / exposed	0 / 3348 (0.00%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma urethra			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tumour perforation			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm ruptured			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Angiodysplasia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			

subjects affected / exposed	6 / 3348 (0.18%)	12 / 5777 (0.21%)	
occurrences causally related to treatment / all	0 / 6	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	0 / 3348 (0.00%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Aortic dissection			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortic stenosis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aortitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial insufficiency			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	2 / 3348 (0.06%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 3	
Arteriovenous fistula			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteritis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brachiocephalic artery stenosis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	1 / 3348 (0.03%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism arterial			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism venous			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential hypertension			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery aneurysm			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery embolism			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	5 / 3348 (0.15%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemodynamic instability			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	15 / 3348 (0.45%)	17 / 5777 (0.29%)	
occurrences causally related to treatment / all	0 / 29	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 2	
Hypertensive crisis			

subjects affected / exposed	11 / 3348 (0.33%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 13	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	11 / 3348 (0.33%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intermittent claudication			
subjects affected / exposed	3 / 3348 (0.09%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Internal haemorrhage			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic limb pain			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphatic fistula			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphorrhoea			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant hypertension			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypertension			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pallor			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	4 / 3348 (0.12%)	11 / 5777 (0.19%)	
occurrences causally related to treatment / all	0 / 5	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery aneurysm			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	0 / 3348 (0.00%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			

subjects affected / exposed	1 / 3348 (0.03%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery thrombosis			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	0 / 3348 (0.00%)	11 / 5777 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peripheral vascular disorder			
subjects affected / exposed	1 / 3348 (0.03%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral venous disease			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Temporal arteritis			

subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose ulceration			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular insufficiency			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Adverse drug reaction			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	3 / 3348 (0.09%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac death			
subjects affected / exposed	0 / 3348 (0.00%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 4	
Chest discomfort			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	9 / 3348 (0.27%)	9 / 5777 (0.16%)	
occurrences causally related to treatment / all	1 / 10	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chills			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	4 / 3348 (0.12%)	12 / 5777 (0.21%)	
occurrences causally related to treatment / all	1 / 4	1 / 12	
deaths causally related to treatment / all	1 / 4	1 / 12	
Drowning			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug intolerance			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exercise tolerance decreased			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial pain			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Generalised oedema			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia			

subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heteroplasia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hyperplasia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired healing			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site irritation			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated hernia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Influenza like illness			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injection site reaction			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic ulcer			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Local swelling			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mass			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	3 / 3348 (0.09%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	1 / 3	0 / 6	
deaths causally related to treatment / all	1 / 3	0 / 5	
Necrosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			

subjects affected / exposed	75 / 3348 (2.24%)	35 / 5777 (0.61%)	
occurrences causally related to treatment / all	1 / 92	0 / 36	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pacemaker syndrome			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyp			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudocyst			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	5 / 3348 (0.15%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stent-graft endoleak			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			

subjects affected / exposed	0 / 3348 (0.00%)	11 / 5777 (0.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 11	
Sudden death			
subjects affected / exposed	1 / 3348 (0.03%)	7 / 5777 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 7	
Surgical failure			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vascular stent restenosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	0 / 3348 (0.00%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vessel puncture site haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Allergy to arthropod sting			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Contrast media allergy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Homicide			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Benign prostatic hyperplasia			
subjects affected / exposed	5 / 3348 (0.15%)	8 / 5777 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysmenorrhoea			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymal cyst			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erectile dysfunction			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female genital tract fistula			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital atrophy			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital prolapse			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Menorrhagia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic pain			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic haemorrhage			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic mass			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatism			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectocele			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spermatocele			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cervix stenosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicocele			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose veins pelvic			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	4 / 3348 (0.12%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Acute respiratory failure			
subjects affected / exposed	13 / 3348 (0.39%)	21 / 5777 (0.36%)	
occurrences causally related to treatment / all	0 / 13	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 4	
Alveolitis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alveolitis allergic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asphyxia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Asthma			
subjects affected / exposed	3 / 3348 (0.09%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			

subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial hyperreactivity			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial obstruction			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis chronic			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cheyne-Stokes respiration			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	40 / 3348 (1.19%)	33 / 5777 (0.57%)	
occurrences causally related to treatment / all	3 / 54	3 / 41	
deaths causally related to treatment / all	0 / 2	1 / 3	
Cough			

subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dyspnoea			
subjects affected / exposed	23 / 3348 (0.69%)	19 / 5777 (0.33%)	
occurrences causally related to treatment / all	0 / 25	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 2	
Dyspnoea exertional			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysema			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	6 / 3348 (0.18%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	4 / 3348 (0.12%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 7	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiccups			

subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrothorax			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypopnoea			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	3 / 3348 (0.09%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic interstitial pneumonia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic pneumonia syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Laryngeal oedema			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngospasm			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung consolidation			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung hernia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infiltration			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal obstruction			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal polyps			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal turbinate hypertrophy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive airways disorder			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organising pneumonia			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal pain			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pickwickian syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural adhesion			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	6 / 3348 (0.18%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	2 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumomediastinum			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	4 / 3348 (0.12%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Productive cough			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary alveolar haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			

subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	2 / 3348 (0.06%)	18 / 5777 (0.31%)	
occurrences causally related to treatment / all	0 / 2	0 / 19	
deaths causally related to treatment / all	0 / 1	0 / 2	
Pulmonary fibrosis			
subjects affected / exposed	4 / 3348 (0.12%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Pulmonary haematoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	0 / 3348 (0.00%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary microemboli			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	2 / 3348 (0.06%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Pulmonary sarcoidosis			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory alkalosis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory arrest			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 3348 (0.00%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory failure			
subjects affected / exposed	12 / 3348 (0.36%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 12	0 / 5	
deaths causally related to treatment / all	0 / 4	0 / 1	
Respiratory tract inflammation			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory tract irritation			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis allergic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus congestion			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus polyp			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	5 / 3348 (0.15%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status asthmaticus			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord leukoplakia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wheezing			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute stress disorder			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adjustment disorder			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Affective disorder			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic psychosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	3 / 3348 (0.09%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder due to a general medical condition			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar I disorder			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burnout syndrome			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Confusional state			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conversion disorder			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium tremens			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	4 / 3348 (0.12%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dissociative amnesia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug use disorder			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised anxiety disorder			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination, visual			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head banging			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Homicidal ideation			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insomnia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional self-injury			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Major depression			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			

subjects affected / exposed	6 / 3348 (0.18%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic attack			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Personality change			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder due to a general medical condition			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Restlessness			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Schizophrenia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnambulism			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device battery issue			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device end of service			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device inappropriate shock delivery			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device issue			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device lead damage			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device lead issue			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device signal detection issue			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lead dislodgement			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Alcoholic liver disease			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune hepatitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary cirrhosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Biliary colic			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dilatation			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary fistula			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	9 / 3348 (0.27%)	7 / 5777 (0.12%)	
occurrences causally related to treatment / all	1 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	7 / 3348 (0.21%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	18 / 3348 (0.54%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 20	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder polyp			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic hepatic cyst			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	1 / 3348 (0.03%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic congestion			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic function abnormal			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic steatosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic vein thrombosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis toxic			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatomegaly			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatorenal failure			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatosplenomegaly			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocholecystis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic hepatitis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			

subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-alcoholic fatty liver			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-alcoholic steatohepatitis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Steatohepatitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatine phosphokinase MB			

increased			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose increased			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood magnesium decreased			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure increased			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood urine present			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Body mass index decreased			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central venous pressure increased			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest X-ray abnormal			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Clostridium test positive			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	1 / 3348 (0.03%)	0 / 5777 (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 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Human metapneumovirus test positive			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Imaging procedure abnormal			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio decreased			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oxygen saturation decreased			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Quality of life decreased			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scan myocardial perfusion abnormal			

subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin T increased			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volume blood decreased			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight increased			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
White blood cell count increased			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accident			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic leak			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal bite			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	4 / 3348 (0.12%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial injury			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod sting			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asbestosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone contusion			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain contusion			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac function disturbance postoperative			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central cord syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Closed globe injury			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Comminuted fracture			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	5 / 3348 (0.15%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery restenosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dural tear			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epicondylitis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Face injury			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	3 / 3348 (0.09%)	9 / 5777 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	5 / 3348 (0.15%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	5 / 3348 (0.15%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture displacement			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder injury			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stoma necrosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gun shot wound			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hand fracture			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			

subjects affected / exposed	3 / 3348 (0.09%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	6 / 3348 (0.18%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	4 / 3348 (0.12%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site pain			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	3 / 3348 (0.09%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia, obstructive			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Intentional overdose			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional product misuse			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw fracture			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laceration			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament injury			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament rupture			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb traumatic amputation			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	3 / 3348 (0.09%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	8 / 3348 (0.24%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 9	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle contusion			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle rupture			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle strain			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal foreign body			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve injury			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery restenosis			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprosthetic fracture			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirenal haematoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumoconiosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax traumatic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural discharge			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural fever			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			

subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative hernia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound complication			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural complication			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural intestinal perforation			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	1 / 3348 (0.03%)	0 / 5777 (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 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation mucositis			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	7 / 3348 (0.21%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 7	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Road traffic accident			
subjects affected / exposed	3 / 3348 (0.09%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 2	
Scapula fracture			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scratch			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seroma			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skeletal injury			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fracture			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column injury			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	5 / 3348 (0.15%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord injury			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord injury cervical			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic rupture			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stab wound			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal fracture			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress fracture			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Subdural haematoma			
subjects affected / exposed	5 / 3348 (0.15%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tendon injury			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	3 / 3348 (0.09%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth fracture			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic amputation			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic arthritis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic intracranial haemorrhage			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ulna fracture			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	3 / 3348 (0.09%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention postoperative			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft complication			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm ruptured			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound secretion			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Branchial cyst			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular arteriovenous malformation			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic arteriovenous malformation			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hereditary haemochromatosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nonketotic hyperglycinaemia			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phimosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyloric stenosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheo-oesophageal fistula			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	4 / 3348 (0.12%)	14 / 5777 (0.24%)	
occurrences causally related to treatment / all	1 / 4	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 3	
Acute left ventricular failure			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			

subjects affected / exposed	7 / 3348 (0.21%)	71 / 5777 (1.23%)	
occurrences causally related to treatment / all	0 / 7	0 / 83	
deaths causally related to treatment / all	0 / 3	0 / 2	
Adams-Stokes syndrome			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	76 / 3348 (2.27%)	66 / 5777 (1.14%)	
occurrences causally related to treatment / all	3 / 84	0 / 72	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	63 / 3348 (1.88%)	56 / 5777 (0.97%)	
occurrences causally related to treatment / all	1 / 72	0 / 57	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	3 / 3348 (0.09%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arrhythmia supraventricular			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis coronary artery			

subjects affected / exposed	3 / 3348 (0.09%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriospasm coronary			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	4 / 3348 (0.12%)	49 / 5777 (0.85%)	
occurrences causally related to treatment / all	0 / 5	1 / 52	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	1 / 3348 (0.03%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial thrombosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	4 / 3348 (0.12%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Atrioventricular block first degree			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	4 / 3348 (0.12%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	10 / 3348 (0.30%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 0	
Cardiac aneurysm			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	15 / 3348 (0.45%)	9 / 5777 (0.16%)	
occurrences causally related to treatment / all	0 / 16	0 / 9	
deaths causally related to treatment / all	0 / 6	0 / 6	
Cardiac discomfort			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	4 / 3348 (0.12%)	43 / 5777 (0.74%)	
occurrences causally related to treatment / all	0 / 4	1 / 54	
deaths causally related to treatment / all	0 / 0	0 / 9	
Cardiac failure acute			

subjects affected / exposed	0 / 3348 (0.00%)	16 / 5777 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac failure chronic			
subjects affected / exposed	2 / 3348 (0.06%)	15 / 5777 (0.26%)	
occurrences causally related to treatment / all	0 / 2	1 / 19	
deaths causally related to treatment / all	0 / 0	0 / 2	
Cardiac failure congestive			
subjects affected / exposed	0 / 3348 (0.00%)	30 / 5777 (0.52%)	
occurrences causally related to treatment / all	0 / 0	0 / 37	
deaths causally related to treatment / all	0 / 0	0 / 3	
Cardiac fibrillation			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pseudoaneurysm			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	1 / 3348 (0.03%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 5	
Cardiogenic shock			

subjects affected / exposed	7 / 3348 (0.21%)	9 / 5777 (0.16%)	
occurrences causally related to treatment / all	0 / 8	1 / 9	
deaths causally related to treatment / all	0 / 4	1 / 5	
Cardiomegaly			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiomyopathy			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Conduction disorder			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive cardiomyopathy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	20 / 3348 (0.60%)	27 / 5777 (0.47%)	
occurrences causally related to treatment / all	0 / 29	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 2	
Coronary artery insufficiency			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	1 / 3348 (0.03%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coronary artery stenosis			
subjects affected / exposed	2 / 3348 (0.06%)	14 / 5777 (0.24%)	
occurrences causally related to treatment / all	0 / 2	1 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive heart disease			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracardiac thrombus			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	4 / 3348 (0.12%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	0 / 4	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 3	
Left ventricular dysfunction			
subjects affected / exposed	1 / 3348 (0.03%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular hypertrophy			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microvascular coronary artery disease			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	1 / 3348 (0.03%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	2 / 3348 (0.06%)	42 / 5777 (0.73%)	
occurrences causally related to treatment / all	0 / 2	1 / 42	
deaths causally related to treatment / all	0 / 2	0 / 10	
Myocardial ischaemia			
subjects affected / exposed	6 / 3348 (0.18%)	10 / 5777 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 2	
Nodal arrhythmia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			

subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prinzmetal angina			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulseless electrical activity			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular dysfunction			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Silent myocardial infarction			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus arrest			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			

subjects affected / exposed	4 / 3348 (0.12%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torsade de pointes			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trifascicular block			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ventricular extrasystoles			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	7 / 3348 (0.21%)	7 / 5777 (0.12%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 3	
Ventricular tachyarrhythmia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	16 / 3348 (0.48%)	18 / 5777 (0.31%)	
occurrences causally related to treatment / all	0 / 26	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Apraxia			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance disorder			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain oedema			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Carotid arteriosclerosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery aneurysm			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery disease			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	1 / 3348 (0.03%)	8 / 5777 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda equina syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar stroke			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral arteriosclerosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	0 / 3348 (0.00%)	9 / 5777 (0.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	0 / 3348 (0.00%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebrovascular accident			
subjects affected / exposed	4 / 3348 (0.12%)	22 / 5777 (0.38%)	
occurrences causally related to treatment / all	0 / 4	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical myelopathy			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical radiculopathy			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicobrachial syndrome			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coma			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dementia Alzheimer's type			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia with Lewy bodies			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressed level of consciousness			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic coma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplegia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			

subjects affected / exposed	7 / 3348 (0.21%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysaesthesia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dystonia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	1 / 3348 (0.03%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Epilepsy			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Facial paralysis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Focal dyscognitive seizures			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic transformation stroke			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Headache			
subjects affected / exposed	4 / 3348 (0.12%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hydrocephalus			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersomnia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive encephalopathy			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic coma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemic encephalopathy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
IIIrd nerve paresis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial pressure increased			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	1 / 3348 (0.03%)	16 / 5777 (0.28%)	
occurrences causally related to treatment / all	0 / 1	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lacunar infarction			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar stroke			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar radiculopathy			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbosacral radiculopathy			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental impairment			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mixed dementia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nerve compression			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normal pressure hydrocephalus			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic neuritis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic intolerance			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paralysis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Paresis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve lesion			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post herpetic neuralgia			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post stroke seizure			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	4 / 3348 (0.12%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Restless legs syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	4 / 3348 (0.12%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	4 / 3348 (0.12%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sensory disturbance			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal claudication			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord infarction			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Spondylitic myelopathy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stupor			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural hygroma			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	25 / 3348 (0.75%)	16 / 5777 (0.28%)	
occurrences causally related to treatment / all	0 / 27	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tension headache			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamic infarction			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic cerebral infarction			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonic convulsion			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic encephalopathy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 3348 (0.00%)	15 / 5777 (0.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigeminal neuralgia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper motor neurone lesion			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIth nerve paralysis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Abnormal clotting factor			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	14 / 3348 (0.42%)	10 / 5777 (0.17%)	
occurrences causally related to treatment / all	1 / 15	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 1	
Bone marrow oedema			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated intravascular coagulation			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic anaemia			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hilar lymphadenopathy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Histiocytosis haematophagic			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypochromic anaemia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			

subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy mediastinal			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic anaemia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoclonal B-cell lymphocytosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic normocytic anaemia			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normocytic anaemia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenomegaly			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Thrombocytopenic purpura			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Cerumen impaction			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear pain			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniere's disease			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otosclerosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presbyacusis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanic membrane perforation			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			

subjects affected / exposed	4 / 3348 (0.12%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angle closure glaucoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness transient			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	12 / 3348 (0.36%)	8 / 5777 (0.14%)	
occurrences causally related to treatment / all	0 / 14	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract cortical			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract diabetic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract nuclear			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal degeneration			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal infiltrates			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryostenosis acquired			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid ptosis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iridocyclitis			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lens dislocation			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular degeneration			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular fibrosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular hole			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular oedema			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neovascular age-related macular degeneration			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular ischaemic syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papilloedema			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery thrombosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein occlusion			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein thrombosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			

subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abdominal hernia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	10 / 3348 (0.30%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	1 / 11	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Abdominal pain lower			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	2 / 3348 (0.06%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute abdomen			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Alcoholic pancreatitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fissure			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal skin tags			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal ulcer			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal ulcer haemorrhage			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anorectal disorder			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendiceal mucocoele			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendix disorder			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Change of bowel habit			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	3 / 3348 (0.09%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 3	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis microscopic			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			

subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic fistula			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	4 / 3348 (0.12%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dental caries			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gastroenteropathy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	2 / 3348 (0.06%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dieulafoy's vascular malformation			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum			

subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal stenosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer perforation			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical fistula			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epigastric discomfort			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive duodenitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erosive oesophagitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecaloma			

subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faeces discoloured			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flatulence			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallstone ileus			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer perforation			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric volvulus			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	6 / 3348 (0.18%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	1 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroduodenitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorder			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal erosion			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	13 / 3348 (0.39%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 14	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal necrosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal pain			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal perforation			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal ulcer			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal vascular malformation			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	4 / 3348 (0.12%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			

subjects affected / exposed	2 / 3348 (0.06%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic necrotic pancreatitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileal ulcer			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			

subjects affected / exposed	3 / 3348 (0.09%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory bowel disease			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	7 / 3348 (0.21%)	8 / 5777 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia strangulated			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal fistula			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal infarction			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Intestinal mass			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Intestinal perforation			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ulcer			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic enteritis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal stenosis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	12 / 3348 (0.36%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	1 / 13	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			

subjects affected / exposed	2 / 3348 (0.06%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery stenosis			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery thrombosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth cyst			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth ulceration			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Narcotic bowel syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	4 / 3348 (0.12%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Odynophagia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal obstruction			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal perforation			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal rupture			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal stenosis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophagitis			

subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic cyst			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic disorder			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic duct dilatation			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic mass			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic pseudocyst			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	11 / 3348 (0.33%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	1 / 13	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pancreatitis acute			
subjects affected / exposed	3 / 3348 (0.09%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	0 / 3	2 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			

subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis necrotising			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer haemorrhage			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal haemorrhage			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumoperitoneum			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctalgia			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctitis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ranula			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	1 / 3348 (0.03%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal lesion			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal perforation			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haematoma			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland calculus			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 3348 (0.03%)	9 / 5777 (0.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
Small intestinal perforation			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestine ulcer			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis mesenteric vessel			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	4 / 3348 (0.12%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			

subjects affected / exposed	8 / 3348 (0.24%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
Vomiting			
subjects affected / exposed	4 / 3348 (0.12%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Actinic keratosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blister			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brow ptosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	0 / 3348 (0.00%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperhidrosis			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkeratosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurodermatitis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prurigo			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pruritus allergic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinophyma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stasis dermatitis			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stevens-Johnson syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous emphysema			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	27 / 3348 (0.81%)	22 / 5777 (0.38%)	
occurrences causally related to treatment / all	3 / 29	1 / 25	
deaths causally related to treatment / all	1 / 1	0 / 0	
Acute prerenal failure			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anuria			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Azotaemia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus bladder			
subjects affected / exposed	1 / 3348 (0.03%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urethral			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			

subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	4 / 3348 (0.12%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 2	
Diabetic nephropathy			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Focal segmental glomerulosclerosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis membranous			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	7 / 3348 (0.21%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			

subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive nephropathy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower urinary tract symptoms			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	7 / 3348 (0.21%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive uropathy			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pollakiuria			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyuria			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prerenal failure			

subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stenosis			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery thrombosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	13 / 3348 (0.39%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 14	0 / 5	
deaths causally related to treatment / all	0 / 4	0 / 0	
Renal haematoma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal impairment			
subjects affected / exposed	1 / 3348 (0.03%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal injury			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal mass			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular necrosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric obstruction			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	7 / 3348 (0.21%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral obstruction			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder polyp			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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	4 / 3348 (0.12%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vesicocutaneous fistula			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism primary			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypopituitarism			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary hyperaldosteronism			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic goitre			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 3348 (0.12%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			

subjects affected / exposed	3 / 3348 (0.09%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis reactive			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	7 / 3348 (0.21%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	4 / 3348 (0.12%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	1 / 3348 (0.03%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondromalacia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondropathy			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compartment syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (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	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dactylitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dupuytren's contracture			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fasciitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Finger deformity			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture malunion			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty tophus			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin pain			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immunoglobulin G4 related disease			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc calcification			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc compression			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc displacement			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	10 / 3348 (0.30%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw cyst			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint instability			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint swelling			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	5 / 3348 (0.15%)	5 / 5777 (0.09%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscal degeneration			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metatarsalgia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle atrophy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle haemorrhage			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle swelling			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			

subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	5 / 3348 (0.15%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	4 / 3348 (0.12%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myofascial pain syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic arthropathy			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			

subjects affected / exposed	51 / 3348 (1.52%)	26 / 5777 (0.45%)	
occurrences causally related to treatment / all	0 / 53	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteochondrosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteolysis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporotic fracture			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in jaw			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	3 / 3348 (0.09%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	1 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	5 / 3348 (0.15%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shoulder deformity			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue mass			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			

subjects affected / exposed	4 / 3348 (0.12%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal deformity			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	5 / 3348 (0.15%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigger finger			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral wedging			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal sepsis			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess intestinal			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess jaw			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Abscess oral			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess soft tissue			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatitis B			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			

subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	4 / 3348 (0.12%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atypical pneumonia			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial disease carrier			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial pyelonephritis			

subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteroides infection			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bartholin's abscess			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (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 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone abscess			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	14 / 3348 (0.42%)	10 / 5777 (0.17%)	
occurrences causally related to treatment / all	1 / 14	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bronchitis bacterial			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bursitis infective			

subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis infective staphylococcal			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter infection			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida infection			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Carbuncle			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	27 / 3348 (0.81%)	22 / 5777 (0.38%)	
occurrences causally related to treatment / all	4 / 29	2 / 22	
deaths causally related to treatment / all	0 / 0	0 / 2	
Cellulitis gangrenous			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis of male external genital organ			

subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis staphylococcal			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Central nervous system infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chikungunya virus infection			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis infective			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chorioretinitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic tonsillitis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridial infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic abscess			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corona virus infection			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Creutzfeldt-Jakob disease			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cystitis			

subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	4 / 3348 (0.12%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Device related sepsis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	13 / 3348 (0.39%)	6 / 5777 (0.10%)	
occurrences causally related to treatment / all	3 / 15	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear infection			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	2 / 3348 (0.06%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis bacterial			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis infectious			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottitis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	9 / 3348 (0.27%)	13 / 5777 (0.23%)	
occurrences causally related to treatment / all	2 / 9	2 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			

subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
External ear cellulitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Folliculitis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fungal skin infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Furuncle			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder abscess			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder empyema			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			

subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis viral			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	8 / 3348 (0.24%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 9	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis clostridial			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis salmonella			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal bacterial infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal viral infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin infection			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophilus infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophilus sepsis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic pneumonia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Helicobacter infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic amoebiasis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis viral			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes ophthalmic			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	4 / 3348 (0.12%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	2 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Human ehrlichiosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypopyon			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site abscess			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site infection			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site cellulitis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incision site infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected bite			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected cyst			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious colitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of chronic obstructive airways disease			

subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective spondylitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	3 / 3348 (0.09%)	9 / 5777 (0.16%)	
occurrences causally related to treatment / all	0 / 3	2 / 9	
deaths causally related to treatment / all	0 / 0	0 / 3	
Intervertebral discitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint abscess			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Labyrinthitis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leptospirosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Localised infection			

subjects affected / exposed	5 / 3348 (0.15%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	1 / 5	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	4 / 3348 (0.12%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 4	3 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lyme disease			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphangitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaria			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastoiditis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinitis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis bacterial			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Meningococcal sepsis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric abscess			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metapneumovirus infection			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle abscess			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycobacterial infection			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycobacterium avium complex infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising fasciitis			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal candidiasis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	4 / 3348 (0.12%)	10 / 5777 (0.17%)	
occurrences causally related to treatment / all	1 / 4	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis bacterial			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis blastomyces			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis externa			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media acute			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media chronic			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic abscess			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae virus infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parametritis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paronychia			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic abscess			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perichondritis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal abscess			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontitis			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital cellulitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perirectal abscess			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal abscess			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	2 / 3348 (0.06%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pharyngeal abscess			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis streptococcal			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pilonidal cyst			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal sepsis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	83 / 3348 (2.48%)	70 / 5777 (1.21%)	
occurrences causally related to treatment / all	17 / 95	10 / 73	
deaths causally related to treatment / all	1 / 5	1 / 5	
Pneumonia bacterial			

subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	1 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia escherichia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia haemophilus			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia klebsiella			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pneumonia legionella			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia necrotising			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia pseudomonal			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia staphylococcal			

subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural cellulitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	0 / 3348 (0.00%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 0	2 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural sepsis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative abscess			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	1 / 3348 (0.03%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctitis infectious			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Propionibacterium infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomembranous colitis			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonal bacteraemia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pseudomonas bronchitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonas infection			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoas abscess			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 2	
Pulmonary tuberculosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			

subjects affected / exposed	5 / 3348 (0.15%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyoderma			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyuria			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal abscess			
subjects affected / exposed	0 / 3348 (0.00%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	7 / 3348 (0.21%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	3 / 8	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection viral			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rubella			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salmonellosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal abscess			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrub typhus			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	19 / 3348 (0.57%)	22 / 5777 (0.38%)	
occurrences causally related to treatment / all	5 / 21	3 / 22	
deaths causally related to treatment / all	4 / 8	0 / 5	
Sepsis syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic embolus			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic necrosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			

subjects affected / exposed	11 / 3348 (0.33%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	1 / 11	0 / 3	
deaths causally related to treatment / all	0 / 7	0 / 2	
Sialoadenitis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	2 / 3348 (0.06%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis fungal			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal abscess			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 3348 (0.00%)	3 / 5777 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	1 / 3348 (0.03%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal mediastinitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			

subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Streptococcal bacteraemia			
subjects affected / exposed	2 / 3348 (0.06%)	0 / 5777 (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 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdiaphragmatic abscess			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural empyema			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular abscess			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tetanus			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tonsillitis			

subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tuberculosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	21 / 3348 (0.63%)	19 / 5777 (0.33%)	
occurrences causally related to treatment / all	3 / 24	4 / 20	
deaths causally related to treatment / all	0 / 2	1 / 1	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection fungal			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection pseudomonal			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	3 / 3348 (0.09%)	7 / 5777 (0.12%)	
occurrences causally related to treatment / all	1 / 3	1 / 7	
deaths causally related to treatment / all	0 / 1	0 / 1	
Vestibular neuronitis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral cardiomyopathy			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral diarrhoea			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	1 / 3348 (0.03%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval abscess			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection bacterial			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection staphylococcal			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	6 / 3348 (0.18%)	8 / 5777 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			

subjects affected / exposed	11 / 3348 (0.33%)	8 / 5777 (0.14%)	
occurrences causally related to treatment / all	0 / 12	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetes mellitus inadequate control			
subjects affected / exposed	3 / 3348 (0.09%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes with hyperosmolarity			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic complication			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 3348 (0.00%)	2 / 5777 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid overload			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gout			

subjects affected / exposed	3 / 3348 (0.09%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperammonaemia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperchloraemia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	6 / 3348 (0.18%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	3 / 3348 (0.09%)	7 / 5777 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypermagnesaemia			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperuricaemia			

subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoalbuminaemia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	9 / 3348 (0.27%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 12	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	9 / 3348 (0.27%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 11	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	2 / 3348 (0.06%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insulin resistant diabetes			

subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insulin-requiring type 2 diabetes mellitus			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketoacidosis			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malnutrition			
subjects affected / exposed	0 / 3348 (0.00%)	1 / 5777 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic acidosis			
subjects affected / exposed	1 / 3348 (0.03%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Obesity			
subjects affected / exposed	2 / 3348 (0.06%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 3348 (0.00%)	0 / 5777 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			

subjects affected / exposed	1 / 3348 (0.03%)	4 / 5777 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Group I	Group II	Group III
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1271 / 2263 (56.16%)	1324 / 2285 (57.94%)	1199 / 2170 (55.25%)
Vascular disorders			
Hypertension			
subjects affected / exposed	198 / 2263 (8.75%)	216 / 2285 (9.45%)	208 / 2170 (9.59%)
occurrences (all)	242	258	249
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	142 / 2263 (6.27%)	164 / 2285 (7.18%)	129 / 2170 (5.94%)
occurrences (all)	176	202	166
Nervous system disorders			
Dizziness			
subjects affected / exposed	114 / 2263 (5.04%)	126 / 2285 (5.51%)	132 / 2170 (6.08%)
occurrences (all)	132	148	157
Headache			
subjects affected / exposed	133 / 2263 (5.88%)	111 / 2285 (4.86%)	120 / 2170 (5.53%)
occurrences (all)	163	139	183
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	113 / 2263 (4.99%)	99 / 2285 (4.33%)	84 / 2170 (3.87%)
occurrences (all)	126	116	91
Non-cardiac chest pain			
subjects affected / exposed	142 / 2263 (6.27%)	143 / 2285 (6.26%)	111 / 2170 (5.12%)
occurrences (all)	172	169	137
Oedema peripheral			
subjects affected / exposed	136 / 2263 (6.01%)	142 / 2285 (6.21%)	134 / 2170 (6.18%)
occurrences (all)	156	161	153
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	138 / 2263 (6.10%)	146 / 2285 (6.39%)	137 / 2170 (6.31%)
occurrences (all)	178	194	201
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	151 / 2263 (6.67%)	152 / 2285 (6.65%)	121 / 2170 (5.58%)
occurrences (all)	187	171	135
Dyspnoea			
subjects affected / exposed	126 / 2263 (5.57%)	123 / 2285 (5.38%)	110 / 2170 (5.07%)
occurrences (all)	143	140	133
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	165 / 2263 (7.29%)	181 / 2285 (7.92%)	144 / 2170 (6.64%)
occurrences (all)	199	226	169
Back pain			
subjects affected / exposed	169 / 2263 (7.47%)	177 / 2285 (7.75%)	157 / 2170 (7.24%)
occurrences (all)	197	200	171
Pain in extremity			
subjects affected / exposed	145 / 2263 (6.41%)	145 / 2285 (6.35%)	98 / 2170 (4.52%)
occurrences (all)	171	166	114
Infections and infestations			
Bronchitis			
subjects affected / exposed	131 / 2263 (5.79%)	162 / 2285 (7.09%)	114 / 2170 (5.25%)
occurrences (all)	164	204	151
Influenza			
subjects affected / exposed	141 / 2263 (6.23%)	145 / 2285 (6.35%)	118 / 2170 (5.44%)
occurrences (all)	168	167	147
Upper respiratory tract infection			
subjects affected / exposed	153 / 2263 (6.76%)	156 / 2285 (6.83%)	134 / 2170 (6.18%)
occurrences (all)	214	214	189
Urinary tract infection			
subjects affected / exposed	126 / 2263 (5.57%)	129 / 2285 (5.65%)	93 / 2170 (4.29%)
occurrences (all)	175	194	130
Viral upper respiratory tract infection			
subjects affected / exposed	264 / 2263 (11.67%)	297 / 2285 (13.00%)	263 / 2170 (12.12%)
occurrences (all)	428	477	439

Non-serious adverse events	Group IV	Group V	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1905 / 3348 (56.90%)	1497 / 5777 (25.91%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	309 / 3348 (9.23%)	241 / 5777 (4.17%)	
occurrences (all)	386	261	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	228 / 3348 (6.81%)	115 / 5777 (1.99%)	
occurrences (all)	284	126	
Nervous system disorders			
Dizziness			
subjects affected / exposed	189 / 3348 (5.65%)	107 / 5777 (1.85%)	
occurrences (all)	223	122	
Headache			
subjects affected / exposed	178 / 3348 (5.32%)	72 / 5777 (1.25%)	
occurrences (all)	245	85	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	169 / 3348 (5.05%)	72 / 5777 (1.25%)	
occurrences (all)	191	76	
Non-cardiac chest pain			
subjects affected / exposed	228 / 3348 (6.81%)	68 / 5777 (1.18%)	
occurrences (all)	284	71	
Oedema peripheral			
subjects affected / exposed	173 / 3348 (5.17%)	110 / 5777 (1.90%)	
occurrences (all)	196	117	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	216 / 3348 (6.45%)	110 / 5777 (1.90%)	
occurrences (all)	277	127	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	233 / 3348 (6.96%)	103 / 5777 (1.78%)	
occurrences (all)	288	115	

Dyspnoea			
subjects affected / exposed	193 / 3348 (5.76%)	112 / 5777 (1.94%)	
occurrences (all)	219	121	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	252 / 3348 (7.53%)	184 / 5777 (3.19%)	
occurrences (all)	297	200	
Back pain			
subjects affected / exposed	277 / 3348 (8.27%)	163 / 5777 (2.82%)	
occurrences (all)	327	169	
Pain in extremity			
subjects affected / exposed	204 / 3348 (6.09%)	128 / 5777 (2.22%)	
occurrences (all)	242	139	
Infections and infestations			
Bronchitis			
subjects affected / exposed	234 / 3348 (6.99%)	160 / 5777 (2.77%)	
occurrences (all)	322	183	
Influenza			
subjects affected / exposed	194 / 3348 (5.79%)	154 / 5777 (2.67%)	
occurrences (all)	248	163	
Upper respiratory tract infection			
subjects affected / exposed	252 / 3348 (7.53%)	125 / 5777 (2.16%)	
occurrences (all)	343	158	
Urinary tract infection			
subjects affected / exposed	175 / 3348 (5.23%)	123 / 5777 (2.13%)	
occurrences (all)	247	145	
Viral upper respiratory tract infection			
subjects affected / exposed	388 / 3348 (11.59%)	16 / 5777 (0.28%)	
occurrences (all)	641	16	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 September 2016	Amendment #9 to add the Extension Phase

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Comparison across groups is no longer feasible in the Extension phase because all patients received canakinumab 150 mg. Beyond the primary endpoint, all p-values for the canakinumab 50 mg and 300 mg groups are to be considered nominal only.

Notes: