Clinical trial results:
A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Prevention of Thrombotic Events with Ticagrelor Compared to Placebo on a Background of Acetyl Salicylic Acid (ASA) Therapy in Patients with History of Myocardial Infarction

Summary

EudraCT number	2009-017242-30
Trial protocol	NL GB DE HU RO CZ SK PL BE ES SE IT NO BG
Global end of trial date	03 December 2014

Results information

Result version number	v1 (current)
This version publication date	04 May 2016
First version publication date	04 May 2016

Trial information

Trial identification

Sponsor protocol code	D5132C00001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	PEGASUS-TIMI 54: NOT APPLICABLE

Notes:

Sponsors

Sponsor organisation name	AstraZeneca AB
Sponsor organisation address	Pepparedsleden 1, Mölndal, Sweden, 431 83
Public contact	Anders Himmelmann, AstraZeneca AB, +46 (0)31 776 10 00, ClinicalTrialTransparency@astrazeneca.com
Scientific contact	Anders Himmelmann, AstraZeneca AB, +46 (0)31 776 10 00, ClinicalTrialTransparency@astrazeneca.com
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Notes:

Paediatric regulatory details

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

1901/2006 apply to this trial?	

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	22 January 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 December 2014
Global end of trial reached?	Yes
Global end of trial date	03 December 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to compare the effect of long-term treatment with ticagrelor vs. placebo on a background of ASA on the event rate of the composite of cardiovascular death, non-fatal MI, or non-fatal stroke in patients with history of MI and high risk of developing atherothrombotic events. The primary efficacy variable is time to first occurrence of any event after randomization from the composite of cardiovascular death, non-fatal MI, or non-fatal stroke.

Protection of trial subjects:

The Independent Data Monitoring Committee was an external, independent group with relevant expertise in cardiology, clinical trials, and biostatistics. The Committee met on a regular basis during the study to among other things make recommendations regarding the continuing safety of current participants and those yet to be recruited.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 October 2010
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: 499
Country: Number of subjects enrolled	Australia: 327
Country: Number of subjects enrolled	Belgium: 431
Country: Number of subjects enrolled	Brazil: 864
Country: Number of subjects enrolled	Bulgaria: 447
Country: Number of subjects enrolled	Canada: 1306
Country: Number of subjects enrolled	Chile: 322
Country: Number of subjects enrolled	China: 383
Country: Number of subjects enrolled	Colombia: 528
Country: Number of subjects enrolled	Czech Republic: 870
Country: Number of subjects enrolled	France: 333
Country: Number of subjects enrolled	Germany: 924
Country: Number of subjects enrolled	Hungary: 831
Country: Number of subjects enrolled	Italy: 392

Country: Number of subjects enrolled	Japan: 903
Country: Number of subjects enrolled	Netherlands: 1560
Country: Number of subjects enrolled	Norway: 336
Country: Number of subjects enrolled	Peru: 245
Country: Number of subjects enrolled	Philippines: 250
Country: Number of subjects enrolled	Poland: 1399
Country: Number of subjects enrolled	Korea, Republic of: 506
Country: Number of subjects enrolled	Romania: 404
Country: Number of subjects enrolled	Russian Federation: 1061
Country: Number of subjects enrolled	Slovakia: 475
Country: Number of subjects enrolled	South Africa: 473
Country: Number of subjects enrolled	Spain: 535
Country: Number of subjects enrolled	Sweden: 507
Country: Number of subjects enrolled	Turkey: 180
Country: Number of subjects enrolled	Ukraine: 623
Country: Number of subjects enrolled	United Kingdom: 647
Country: Number of subjects enrolled	United States: 2601
Worldwide total number of subjects	21162
EEA total number of subjects	10091

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)	9627
From 65 to 84 years	11319
85 years and over	216

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

21326 patients were enrolled. 164 enrolled patients were not randomzed (148 due to incorrect enrollment; 16 due to patient decision)

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Ticagrelor 90 mg

Arm description:

Ticagrelor 90 mg twice daily (BD)

Arm type	Experimental
Investigational medicinal product name	Ticagrelor 90 mg bd
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ticagrelor 90 mg twice daily

Arm title	Ticagrelor 60 mg

Arm description:

Ticagrelor 60 mg twice daily (BD)

Arm type	Experimental
Investigational medicinal product name	Ticagrelor 60 mg bd
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Ticagrelor 60 mg twice daily

Arm title	Placebo

Arm description:

Matching placebo

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Chewable/dispersible tablet
Routes of administration	Oral use

Dosage and administration details:
Placebo twice daily

Number of subjects in period 1	Ticagrelor 90 mg	Ticagrelor 60 mg	Placebo
Started	7050	7045	7067
Completed	6995	6989	7014
Not completed	55	56	53
Consent withdrawn by subject	52	50	52
Lost to follow-up	3	6	1

Baseline characteristics

Reporting groups	
Reporting group title	Ticagrelor 90 mg
Reporting group description: Ticagrelor 90 mg twice daily (BD)	
Reporting group title	Ticagrelor 60 mg
Reporting group description: Ticagrelor 60 mg twice daily (BD)	
Reporting group title	Placebo
Reporting group description: Matching placebo	

Reporting group values	Ticagrelor 90 mg	Ticagrelor 60 mg	Placebo
Number of subjects	7050	7045	7067
Age categorical Units: Subjects			
Adults (18-64 years)	3190	3283	3154
From 65-84 years	3782	3690	3847
85 years and over	78	72	66
Age Continuous | Units: years			
arithmetic mean	65.4	65.2	65.4
standard deviation	± 8.4	± 8.4	± 8.3
Gender, Male/Female Units: Participants			
Female	1682	1661	1717
Male	5368	5384	5350

Reporting group values	Total		
Number of subjects	21162		
Age categorical Units: Subjects			
Adults (18-64 years)	9627		
From 65-84 years	11319		
85 years and over	216		
Age Continuous | Units: years arithmetic mean standard deviation	- -		
Gender, Male/Female Units: Participants			
Female	5060		
Male	16102		

End points

End points reporting groups

Reporting group title	Ticagrelor 90 mg
Reporting group description: Ticagrelor 90 mg twice daily (BD)	
Reporting group title	Ticagrelor 60 mg
Reporting group description: Ticagrelor 60 mg twice daily (BD)	
Reporting group title	Placebo
Reporting group description: Matching placebo	

Primary: Kaplan-Meier Estimate of the Percentage of Patients Who Experienced Cardiovascular Death (CV Death), Myocardial Infarction (MI) or Stroke Within 3 years from Randomization

End point title	Kaplan-Meier Estimate of the Percentage of Patients Who Experienced Cardiovascular Death (CV Death), Myocardial Infarction (MI) or Stroke Within 3 years from Randomization

End point description:

Participants with CV death, MI or Stroke. If no event, censoring occurs at the earliest of the efficacy cut-off date 14 Sep 2014, withdrawal of consent, non-CV death or at the last time point of complete clinical event assessment. Events were adjudicated by a blinded endpoint committee. The Kaplan-Meier estimate reports the percentage of patients who experienced CV Death, MI or stroke within 3 years from randomization

End point type	Primary

End point timeframe:

Randomization up to 47 months

End point values	Ticagrelor 90 mg	Ticagrelor 60 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7050	7045	7067	
Units: Percentage of Patients				
number (not applicable)	7.8	7.8	9	

Statistical analyses

Statistical analysis title	Primary efficacy endpoint 90mg vs placebo
Comparison groups	Ticagrelor 90 mg v Placebo

Number of subjects included in analysis	14117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008
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

Statistical analysis title	Primary efficacy endpoint 60mg vs placebo
Comparison groups	Ticagrelor 60 mg v Placebo
Number of subjects included in analysis	14112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0043
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	0.95

Primary: Kaplan-Meier Estimate of the Percentage of Patients Who Experienced a TIMI Major Bleeding Within 3 years from first dose of study drug Units: Percentage of Patients

End point title	Kaplan-Meier Estimate of the Percentage of Patients Who Experienced a TIMI Major Bleeding Within 3 years from first dose of study drug Units: Percentage of Patients

End point description:

A Thrombolysis in Myocardial Infarction (TIMI) study group major bleeding is defined as any fatal bleeding (leading directly to death within 7 days), any intrcranial bleeding or any clinically overt signs of haemorrhage associated with a drop in Haemoglobin of >= 5g/dL. Events were adjudicated by a clinical events committee. Censoring ocurrs at 7 days following last dose of study drug. The Kaplan-Meier estimate reports the percentage of patients who experienced a TIMI Major bleeding within 3 years from first dose of study drug.

End point type	Primary

End point timeframe:

First dosing up to 48 months

End point values	Ticagrelor 90 mg	Ticagrelor 60 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6988	6958	6996	
Units: Percentage of Patients				
number (not applicable)	2.6	2.3	1.1	

Statistical analyses

Statistical analysis title	TIMI Major bleeding ticagrelor 90mg vs placebo
Comparison groups	Ticagrelor 90 mg v Placebo
Number of subjects included in analysis	13984
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	2.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.96
upper limit	3.7

Statistical analysis title	TIMI Major bleeding ticagrelor 60mg vs placebo
Comparison groups	Ticagrelor 60 mg v Placebo
Number of subjects included in analysis	13954
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	2.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.68
upper limit	3.21

Secondary: Kaplan-Meier Estimate of the Percentage of Patients Who Experienced Cardiovascular Death (CV Death) Within 3 years from Randomization

End point title	Kaplan-Meier Estimate of the Percentage of Patients Who Experienced Cardiovascular Death (CV Death) Within 3 years from Randomization

End point description:

Participants with CV death. If no event, censoring occurs at the earliest of the efficacy cut-off date 14 Sep 2014, withdrawal of consent, non-CV death or at the last time point of complete clinical event assessment. Events were adjudicated by a blinded endpoint committee. The Kaplan-Meier estimate reports the percentage of patients who experienced CV Death within 3 years from randomization

End point type	Secondary

End point timeframe:

Randomization up to 47 months

End point values	Ticagrelor 90 mg	Ticagrelor 60 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7050	7045	7067	
Units: Percentage of Patients				
number (not applicable)	2.9	2.9	3.4	

Statistical analyses

Statistical analysis title	CV Death: ticagrelor 90 mg vs placebo
Comparison groups	Ticagrelor 90 mg v Placebo
Number of subjects included in analysis	14117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1547
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.06

Statistical analysis title	CV Death: ticagrelor 60 mg vs placebo
Comparison groups	Ticagrelor 60 mg v Placebo
Number of subjects included in analysis	14112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0676
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.01

Secondary: Kaplan-Meier Estimate of the Percentage of Patients Who Died from Any Cause Within 3 years from Randomization

End point title	Kaplan-Meier Estimate of the Percentage of Patients Who Died from Any Cause Within 3 years from Randomization

End point description:

Participants with death from any cause. If no event, censoring occurs at the earliest of the efficacy cut-off date 14 Sep 2014, withdrawal of consent or the last time point the particapant was known to be alive. Events were adjudicated by a blinded endpoint committee. The Kaplan-Meier estimate reports the percentage of patients who died from any cause within 3 years from randomization

End point type	Secondary

End point timeframe:

Randomization up to 47 months

End point values	Ticagrelor 90 mg	Ticagrelor 60 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7050	7045	7067	
Units: Percentage of Patients				
number (not applicable)	5.1	4.7	5.2	

Statistical analyses

Statistical analysis title	All-cause mortality: ticagrelor 90 mg vs placebo
Comparison groups	Ticagrelor 90 mg v Placebo
Number of subjects included in analysis	14117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9851
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.16

Statistical analysis title	All-cause mortality ticagrelor 60 mg vs placebo
Comparison groups	Ticagrelor 60 mg v Placebo
Number of subjects included in analysis	14112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.135
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.04

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From first dose of study drug until last study visit	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17

Reporting groups	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Ticagrelor 90mg bd
Reporting group description: -	
Reporting group title	Ticagrelor 60mg bd
Reporting group description: -	

Serious adverse events	Placebo	Ticagrelor 90mg bd	Ticagrelor 60mg bd
Total subjects affected by serious adverse events			
subjects affected / exposed	1757 / 6996 (25.11%)	1918 / 6988 (27.45%)	1853 / 6958 (26.63%)
number of deaths (all causes)	329	333	290
number of deaths resulting from adverse events	11	5	14
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acinic cell carcinoma of salivary gland			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 myeloid leukaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Adenocarcinoma			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Adenocarcinoma gastric			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	3 / 6988 (0.04%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	7 / 6988 (0.10%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 7	1 / 7	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Adenolymphoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal adenoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Ameloblastoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Anaplastic large cell lymphoma T- and null-cell types			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Anogenital warts			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Astrocytoma malignant			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical fibroxanthoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
B-cell lymphoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	6 / 6996 (0.09%)	9 / 6988 (0.13%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 12	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of bladder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of thyroid gland			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of ureter			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Benign ovarian tumour			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign pancreatic neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Benign renal neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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

Benign salivary gland neoplasm alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 soft tissue neoplasm alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Bile duct adenocarcinoma alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bile duct cancer alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 neoplasm alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Bladder cancer alternative dictionary used: MedDRA 17			
subjects affected / exposed	11 / 6996 (0.16%)	5 / 6988 (0.07%)	15 / 6958 (0.22%)
occurrences causally related to treatment / all	0 / 12	0 / 5	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer recurrent alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	4 / 6988 (0.06%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder papilloma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	3 / 6988 (0.04%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Bladder transitional cell carcinoma recurrent			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Bone cancer			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bone cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bone sarcoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Bowen's disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Brain neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Brain neoplasm malignant			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Breast cancer female			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	7 / 6988 (0.10%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer male			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Breast cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	4 / 6988 (0.06%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Breast cancer recurrent			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brenner tumour			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Bronchial carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchioloalveolar carcinoma			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Cervix cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Cervix carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Cervix carcinoma stage 0			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cholesteatoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Choroid melanoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 lymphocytic leukaemia alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic myeloid leukaemia alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon adenoma alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	7 / 6988 (0.10%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	14 / 6988 (0.20%)	14 / 6958 (0.20%)
occurrences causally related to treatment / all	1 / 7	0 / 14	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Colon cancer metastatic alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 6996 (0.11%)	7 / 6988 (0.10%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 5	0 / 5
Colon neoplasm alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenocarcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Diffuse large B-cell lymphoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Endometrial adenocarcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer stage I			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Epithelioid mesothelioma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Essential thrombocythaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fallopian tube cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Fibroma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Follicle centre lymphoma, follicular grade I, II, III stage IV			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Gallbladder adenocarcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder cancer			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gallbladder cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastric adenoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Gastric cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 6996 (0.11%)	8 / 6988 (0.11%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 9	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Gastrointestinal cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Gastrointestinal stromal cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 stromal tumour alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal tract adenoma alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal cancer alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Glioblastoma alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Glioblastoma multiforme alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Haemangioma alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 cancer alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Hepatic cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Hepatic neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Hepatocellular carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hodgkin's disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypergammaglobulinaemia benign monoclonal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Inflammatory pseudotumour			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 adenocarcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	0 / 6958 (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
Invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Large intestine benign neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	0 / 6958 (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
Laryngeal neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Laryngeal squamous cell carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Leiomyoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyosarcoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Lentigo maligna			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	0 / 6958 (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
Leukaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Lip and/or oral cavity cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Lip neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	4 / 6988 (0.06%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lung adenocarcinoma metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
Lung cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 6996 (0.14%)	14 / 6988 (0.20%)	11 / 6958 (0.16%)
occurrences causally related to treatment / all	0 / 10	0 / 14	0 / 11
deaths causally related to treatment / all	0 / 8	0 / 9	0 / 3
Lung carcinoma cell type unspecified recurrent			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 carcinoma cell type unspecified stage I			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 carcinoma cell type unspecified stage IV			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Lung neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 6996 (0.14%)	17 / 6988 (0.24%)	10 / 6958 (0.14%)
occurrences causally related to treatment / all	0 / 10	0 / 17	0 / 10
deaths causally related to treatment / all	0 / 4	0 / 9	0 / 5
Lymphoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	4 / 6988 (0.06%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Lymphoma cutis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Lymphoplasmacytoid lymphoma/immunocytoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Malignant anorectal neoplasm			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Malignant fibrous histiocytoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 6996 (0.14%)	5 / 6988 (0.07%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 12	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Malignant neoplasm of ampulla of Vater			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Malignant neoplasm of unknown primary site			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Malignant peritoneal neoplasm			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 pleural effusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Mediastinum neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melanocytic naevus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma benign			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metastases to central nervous system			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 liver			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Metastases to lymph nodes			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 pancreas			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Metastases to peritoneum			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Metastatic bronchial carcinoma			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Metastatic carcinoma of the bladder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Metastatic gastric cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 4	0 / 2	0 / 1
Metastatic malignant melanoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	4 / 6988 (0.06%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Metastatic neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Metastatic pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Metastatic salivary gland cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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

Metastatic squamous cell carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Monoclonal gammopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelofibrosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myeloproliferative disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
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 neoplasm benign			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Neoplasm malignant			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Neoplasm prostate			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm skin			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Neuroendocrine carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Neuroendocrine carcinoma metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	0 / 6958 (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
Neuroendocrine tumour			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Non-Hodgkin's lymphoma recurrent			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma stage I			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Non-Hodgkin's lymphoma stage II			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma unspecified histology aggressive			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Non-small cell lung cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	3 / 6988 (0.04%)	0 / 6958 (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
Non-small cell lung cancer metastatic			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Oesophageal adenocarcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Oesophageal adenocarcinoma metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Oesophageal cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Oesophageal carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	5 / 6988 (0.07%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 2	1 / 6	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 0
Oncocytoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral cavity cancer metastatic			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Oropharyngeal cancer recurrent			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Ovarian cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Ovarian cancer stage III			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Pancoast's tumour			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	6 / 6988 (0.09%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 4	0 / 1
Pancreatic carcinoma metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	5 / 6988 (0.07%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	1 / 7	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 3	0 / 4
Pancreatic neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Paranasal sinus neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parathyroid tumour benign			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Pelvic neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penile squamous cell carcinoma			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penis carcinoma metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Pharyngeal cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Pharyngeal cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Pituitary tumour benign			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	0 / 6958 (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

Pleomorphic adenoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 mesothelioma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pleural mesothelioma malignant			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Polycythaemia vera			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	37 / 6996 (0.53%)	38 / 6988 (0.54%)	29 / 6958 (0.42%)
occurrences causally related to treatment / all	0 / 37	0 / 38	0 / 29
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Prostate cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	8 / 6988 (0.11%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 3
Prostate cancer recurrent			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage II			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Prostatic adenoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Rectal cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Rectal cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Rectosigmoid cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Renal cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	4 / 6988 (0.06%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Renal cell carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	5 / 6988 (0.07%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma recurrent			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	3 / 6988 (0.04%)	0 / 6958 (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
Renal oncocytoma			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Salivary gland adenoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland cancer recurrent			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Salivary gland neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Sarcomatoid mesothelioma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Small cell lung cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	4 / 6988 (0.06%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Small cell lung cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Small intestine carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 cord neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Splenic marginal zone lymphoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Squamous cell carcinoma of lung			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	4 / 6988 (0.06%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Squamous cell carcinoma of pharynx			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 skin			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid adenoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 cancer metastatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Tongue neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Tonsil cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Tonsillar neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Transitional cell carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	6 / 6988 (0.09%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 4	1 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma metastatic			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Tumour associated fever			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Tumour haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	1 / 2	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Undifferentiated nasopharyngeal carcinoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric cancer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral cancer			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 tract neoplasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Uterine leiomyoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 disorders			
Accelerated hypertension			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiodysplasia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Aortic aneurysm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	13 / 6996 (0.19%)	19 / 6988 (0.27%)	19 / 6958 (0.27%)
occurrences causally related to treatment / all	0 / 13	0 / 20	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm rupture			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	4 / 6988 (0.06%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Aortic dissection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Aortic dissection rupture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aortic rupture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aortic stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 6996 (0.11%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Aortic thrombosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Aorto-duodenal fistula			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 rupture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Arteriosclerosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Arteriovenous fistula			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Circulatory collapse			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Deep vein thrombosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 6996 (0.14%)	10 / 6988 (0.14%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 10	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic vascular disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Essential hypertension			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Extremity necrosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Femoral artery aneurysm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Femoral artery embolism			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery occlusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Hot flush			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	18 / 6996 (0.26%)	8 / 6988 (0.11%)	15 / 6958 (0.22%)
occurrences causally related to treatment / all	1 / 18	0 / 8	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hypertensive crisis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	12 / 6996 (0.17%)	10 / 6988 (0.14%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	0 / 14	0 / 11	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 6996 (0.14%)	10 / 6988 (0.14%)	9 / 6958 (0.13%)
occurrences causally related to treatment / all	0 / 10	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothenar hammer syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Hypovolaemic shock			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iliac artery occlusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent claudication			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	5 / 6996 (0.07%)	4 / 6988 (0.06%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leriche syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Lymphoedema			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant hypertension			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 hypotension			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	5 / 6988 (0.07%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penetrating atherosclerotic ulcer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	15 / 6996 (0.21%)	17 / 6988 (0.24%)	10 / 6958 (0.14%)
occurrences causally related to treatment / all	0 / 18	0 / 17	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Peripheral artery aneurysm alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis alternative dictionary used: MedDRA 17			
subjects affected / exposed	17 / 6996 (0.24%)	5 / 6988 (0.07%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 22	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	4 / 6988 (0.06%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral circulatory failure alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Peripheral embolism alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia alternative dictionary used: MedDRA 17			
subjects affected / exposed	9 / 6996 (0.13%)	5 / 6988 (0.07%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 13	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder alternative dictionary used: MedDRA 17			

subjects affected / exposed	8 / 6996 (0.11%)	4 / 6988 (0.06%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poor peripheral circulation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Shock			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Shock haemorrhagic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Steal syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian artery occlusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Subclavian artery stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Superior vena cava syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Temporal arteritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Varicose vein			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vena cava thrombosis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Venous insufficiency			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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			
Asthenia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac death			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Catheter site haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 2	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	6 / 6988 (0.09%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	42 / 6996 (0.60%)	42 / 6988 (0.60%)	34 / 6958 (0.49%)
occurrences causally related to treatment / all	0 / 42	2 / 42	3 / 34
deaths causally related to treatment / all	0 / 42	2 / 42	3 / 34
Device battery issue			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
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 breakage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Device defective			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Device dislocation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	0 / 6958 (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

Device lead damage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Device lead issue			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Device malfunction			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Device material issue			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 occlusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Drowning			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Drug withdrawal syndrome			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Euthanasia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Fatigue			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Gait disturbance			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hernia obstructive			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Hypothermia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 healing			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Injection site bruising			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device complication			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ failure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Non-cardiac chest pain			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	109 / 6996 (1.56%)	115 / 6988 (1.65%)	113 / 6958 (1.62%)
occurrences causally related to treatment / all	0 / 118	3 / 122	1 / 124
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	3 / 6988 (0.04%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stent-graft endoleak			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	33 / 6996 (0.47%)	27 / 6988 (0.39%)	27 / 6958 (0.39%)
occurrences causally related to treatment / all	0 / 33	0 / 27	0 / 27
deaths causally related to treatment / all	0 / 33	0 / 27	0 / 27
Sudden death			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	9 / 6996 (0.13%)	6 / 6988 (0.09%)	11 / 6958 (0.16%)
occurrences causally related to treatment / all	1 / 9	0 / 6	0 / 11
deaths causally related to treatment / all	1 / 9	0 / 6	0 / 11

Systemic inflammatory response syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Vessel puncture site haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergy to arthropod sting			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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 reaction			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	0 / 6958 (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
Anaphylactic shock			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Anti-neutrophil cytoplasmic antibody positive vasculitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contrast media allergy			
alternative dictionary used:			

MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reaction to food additive			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Sarcoidosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Reproductive system and breast disorders			
Acquired hydrocele			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	2 / 6988 (0.03%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acquired phimosis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign prostatic hyperplasia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	26 / 6996 (0.37%)	20 / 6988 (0.29%)	25 / 6958 (0.36%)
occurrences causally related to treatment / all	0 / 26	0 / 20	2 / 26
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast fibrosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 prostatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Cervical cyst			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Cervical dysplasia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystocele			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Endometrial hyperplasia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gynaecomastia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Menorrhagia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Metrorrhagia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian necrosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Prostatic mass			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatism			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Prostatitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	5 / 6988 (0.07%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 7	1 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatomegaly			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	0 / 6958 (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
Uterine cyst			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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

Uterine polyp			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Uterine prolapse			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterovaginal prolapse			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Vaginal prolapse			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Varicocele			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	2 / 6988 (0.03%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Acute respiratory distress syndrome			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Acute respiratory failure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	6 / 6988 (0.09%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	1 / 7	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 0
Aspiration			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Asthma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	9 / 6988 (0.13%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 12	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Atelectasis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Bronchial haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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

Bronchial obstruction			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis chronic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Bronchospasm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Choking			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 obstructive pulmonary disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	45 / 6996 (0.64%)	54 / 6988 (0.77%)	39 / 6958 (0.56%)
occurrences causally related to treatment / all	0 / 65	1 / 74	1 / 62
deaths causally related to treatment / all	0 / 3	0 / 5	0 / 2
Chronic respiratory failure			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Cough			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Diaphragmatic paralysis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Diffuse panbronchiolitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Dyspnoea			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	12 / 6996 (0.17%)	29 / 6988 (0.41%)	23 / 6958 (0.33%)
occurrences causally related to treatment / all	1 / 12	11 / 30	8 / 24
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Dyspnoea exertional			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Epiglottic cyst			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiglottic oedema			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Epistaxis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	20 / 6988 (0.29%)	15 / 6958 (0.22%)
occurrences causally related to treatment / all	1 / 2	16 / 21	12 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	5 / 6988 (0.07%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	1 / 1	5 / 6	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Hydrothorax			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 pulmonary fibrosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Interstitial lung disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	5 / 6988 (0.07%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	1 / 4	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Laryngeal oedema			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung consolidation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal polyps			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nasal septum deviation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Nocturnal dyspnoea			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Obstructive airways disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Organising pneumonia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal oedema			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Pleural adhesion			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 effusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	16 / 6996 (0.23%)	2 / 6988 (0.03%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 18	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pleurisy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	5 / 6988 (0.07%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumothorax			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	5 / 6988 (0.07%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax spontaneous			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary arterial hypertension alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 congestion alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 embolism alternative dictionary used: MedDRA 17			
subjects affected / exposed	17 / 6996 (0.24%)	21 / 6988 (0.30%)	17 / 6958 (0.24%)
occurrences causally related to treatment / all	0 / 17	0 / 23	0 / 17
deaths causally related to treatment / all	0 / 2	0 / 5	0 / 1
Pulmonary fibrosis alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary haemorrhage alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Pulmonary hypertension alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	0 / 6958 (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 oedema			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	5 / 6988 (0.07%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 2
Respiratory arrest			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Respiratory distress			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Respiratory failure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	6 / 6988 (0.09%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	1 / 3	0 / 6	0 / 7
deaths causally related to treatment / all	1 / 3	0 / 2	0 / 3
Respiratory tract haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract inflammation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sleep apnoea syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	3 / 6988 (0.04%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Vocal cord leukoplakia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Psychiatric disorders			
Affective disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol abuse			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	3 / 6988 (0.04%)	0 / 6958 (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
Alcoholism			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Anxiety			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar I disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 2	1 / 3	0 / 0
Confusional state			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Conversion disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Delirium			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Depressed mood			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 6996 (0.11%)	11 / 6988 (0.16%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	0 / 11	0 / 13	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insomnia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panic attack			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	0 / 6958 (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
Panic disorder			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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-traumatic stress disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Psychiatric decompensation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric symptom			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic behaviour			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somatoform disorder cardiovascular			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Suicide attempt			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood electrolytes decreased			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Blood glucose decreased			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Blood urine present			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 stress test abnormal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Clostridium test positive			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Ejection fraction decreased			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Electrocardiogram abnormal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glycosylated haemoglobin increased			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematocrit decreased			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Liver function test abnormal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Lymph node palpable			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Occult blood positive			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scan myocardial perfusion abnormal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 increased			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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, poisoning and procedural complications			
Abdominal wound dehiscence			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental overdose			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Alcohol poisoning			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia postoperative			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaesthetic complication			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Anastomotic complication			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic ulcer haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	5 / 6988 (0.07%)	11 / 6958 (0.16%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arterial injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Arterial restenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Arthropod sting			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Back injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 fissure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Brain herniation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Burns second degree			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Burns third degree			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Carbon monoxide poisoning			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery restenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Cervical vertebral fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Chemical peritonitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	0 / 6958 (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
Concussion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cystitis radiation			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural haematoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Face injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	4 / 6988 (0.06%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	4 / 6988 (0.06%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 6996 (0.14%)	11 / 6988 (0.16%)	11 / 6958 (0.16%)
occurrences causally related to treatment / all	0 / 11	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fibula fracture alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured ischium alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Gas poisoning alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 injury alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Gun shot wound			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria traumatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Heat exhaustion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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

Heat stroke alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Hip fracture alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	5 / 6988 (0.07%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	5 / 6988 (0.07%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	4 / 6988 (0.06%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia, obstructive alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Inflammation of wound alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 anastomosis complication alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint capsule rupture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Joint dislocation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	5 / 6988 (0.07%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	4 / 6988 (0.06%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Ligament rupture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ligament sprain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
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 crushing injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Limb injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb traumatic amputation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Lip injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	5 / 6988 (0.07%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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

Osteoradionecrosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pancreatic leak			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Patella fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Peripheral arterial reocclusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery restenosis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Periprosthetic fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax traumatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poisoning			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 gastric surgery syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fistula			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Post procedural haematoma alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	4 / 6988 (0.06%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 4	3 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematuria alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	3 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 6996 (0.14%)	11 / 6988 (0.16%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	0 / 11	4 / 12	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural persistent drain fluid alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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-traumatic pain alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Postoperative ileus alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	0 / 6958 (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
Postoperative respiratory failure alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	0 / 6958 (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
Postoperative thoracic procedure complication			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Postoperative wound complication			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpericardiotomy syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Procedural haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	6 / 6988 (0.09%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 4	2 / 7	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Procedural hypotension			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	0 / 6958 (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
Pubis fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
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 contusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Radial nerve injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 dysphagia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Radius fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	5 / 6988 (0.07%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Remnant gastritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 haematoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 6996 (0.11%)	8 / 6988 (0.11%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Scapula fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Soft tissue injury			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 compression fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 6996 (0.14%)	4 / 6988 (0.06%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 10	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord injury cervical			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	0 / 6958 (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
Splenic rupture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	0 / 6958 (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
Subdural haematoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	5 / 6988 (0.07%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	3 / 5	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Subdural haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Suture related complication			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	4 / 6988 (0.06%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Thoracic vertebral fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	6 / 6988 (0.09%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	0 / 6958 (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
Traumatic haematoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	13 / 6988 (0.19%)	10 / 6958 (0.14%)
occurrences causally related to treatment / all	0 / 4	5 / 14	2 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	0 / 6988 (0.00%)	0 / 6958 (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
Traumatic intracranial haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	11 / 6996 (0.16%)	18 / 6988 (0.26%)	17 / 6958 (0.24%)
occurrences causally related to treatment / all	0 / 13	2 / 20	4 / 19
deaths causally related to treatment / all	0 / 1	0 / 4	0 / 1
Traumatic spinal cord compression			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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

Ulna fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention postoperative			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
VIIIth nerve injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 occlusion			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 graft thrombosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 procedure complication			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 pseudoaneurysm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Venous injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	0 / 6958 (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

Wound dehiscence			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Wrist fracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Atrial septal defect			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Cardiac disorders			
Acute coronary syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Acute left ventricular failure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	3 / 6988 (0.04%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 0
Acute myocardial infarction			

alternative dictionary used: MedDRA 17			
subjects affected / exposed	28 / 6996 (0.40%)	19 / 6988 (0.27%)	20 / 6958 (0.29%)
occurrences causally related to treatment / all	0 / 28	1 / 19	1 / 20
deaths causally related to treatment / all	0 / 26	1 / 17	1 / 17
Adams-Stokes syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	51 / 6996 (0.73%)	51 / 6988 (0.73%)	45 / 6958 (0.65%)
occurrences causally related to treatment / all	1 / 53	0 / 55	0 / 47
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	4 / 6988 (0.06%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Aortic valve disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 valve stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 2
Arrhythmia supraventricular			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Atrial fibrillation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	67 / 6996 (0.96%)	74 / 6988 (1.06%)	94 / 6958 (1.35%)
occurrences causally related to treatment / all	0 / 73	0 / 88	0 / 104
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	16 / 6996 (0.23%)	13 / 6988 (0.19%)	14 / 6958 (0.20%)
occurrences causally related to treatment / all	0 / 20	0 / 13	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial tachycardia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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

Atrioventricular block			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Atrioventricular block complete			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	13 / 6996 (0.19%)	3 / 6988 (0.04%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	2 / 14	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	4 / 6988 (0.06%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	1 / 5	2 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bifascicular block			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Bradyarrhythmia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	7 / 6988 (0.10%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bundle branch block left			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Bundle branch block right			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 arrest			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	7 / 6988 (0.10%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	1 / 6	0 / 8	0 / 8
deaths causally related to treatment / all	1 / 4	0 / 5	0 / 5
Cardiac asthma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 failure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	58 / 6996 (0.83%)	54 / 6988 (0.77%)	53 / 6958 (0.76%)
occurrences causally related to treatment / all	0 / 73	1 / 69	0 / 70
deaths causally related to treatment / all	0 / 13	0 / 4	0 / 7
Cardiac failure acute			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	4 / 6988 (0.06%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 6	0 / 1	0 / 3
Cardiac failure chronic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	14 / 6996 (0.20%)	19 / 6988 (0.27%)	11 / 6958 (0.16%)
occurrences causally related to treatment / all	0 / 16	0 / 25	0 / 19
deaths causally related to treatment / all	0 / 2	0 / 5	0 / 1

Cardiac failure congestive			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	51 / 6996 (0.73%)	70 / 6988 (1.00%)	53 / 6958 (0.76%)
occurrences causally related to treatment / all	0 / 60	0 / 97	0 / 79
deaths causally related to treatment / all	0 / 2	0 / 14	0 / 5
Cardiac hypertrophy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Cardiac perforation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Cardiac tamponade			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 valve disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 ventricular thrombosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	7 / 6996 (0.10%)	6 / 6988 (0.09%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 6	0 / 5	0 / 6
Cardiogenic shock			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 6996 (0.14%)	4 / 6988 (0.06%)	9 / 6958 (0.13%)
occurrences causally related to treatment / all	0 / 10	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 6	0 / 2	0 / 8
Cardiomyopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiopulmonary failure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardiovascular insufficiency			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0
Conduction disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Cor pulmonale chronic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Coronary artery disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	6 / 6988 (0.09%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Coronary artery stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	6 / 6988 (0.09%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery thrombosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dressler's syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Gastrocardiac syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Heart valve incompetence			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracardiac thrombus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 cardiomyopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	8 / 6988 (0.11%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Left ventricular dysfunction			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	4 / 6988 (0.06%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Low cardiac output syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Mitral valve calcification			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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

Mitral valve incompetence			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	0 / 6988 (0.00%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve prolapse			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial fibrosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Myocardial infarction			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	11 / 6996 (0.16%)	10 / 6988 (0.14%)	9 / 6958 (0.13%)
occurrences causally related to treatment / all	0 / 11	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 11	0 / 10	0 / 9
Myocardial ischaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	3 / 6988 (0.04%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Myocardial oedema			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Myocardial rupture			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Myocarditis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Nodal arrhythmia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nodal rhythm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Palpitations			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulseless electrical activity			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Sick sinus syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	8 / 6988 (0.11%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	1 / 8	0 / 9	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinoatrial block			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Sinus arrest			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus arrhythmia			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Sinus bradycardia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	12 / 6988 (0.17%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 7	4 / 12	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subendocardial ischaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Supraventricular extrasystoles			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	4 / 6988 (0.06%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 5	1 / 4	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systolic dysfunction			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	3 / 6988 (0.04%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tachyarrhythmia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	0 / 6988 (0.00%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia paroxysmal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Ventricular arrhythmia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ventricular dysfunction			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Ventricular extrasystoles			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	3 / 6988 (0.04%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	9 / 6996 (0.13%)	4 / 6988 (0.06%)	11 / 6958 (0.16%)
occurrences causally related to treatment / all	0 / 9	0 / 4	0 / 11
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 5
Ventricular tachycardia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	12 / 6996 (0.17%)	17 / 6988 (0.24%)	17 / 6958 (0.24%)
occurrences causally related to treatment / all	1 / 12	0 / 20	1 / 20
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Nervous system disorders			
Amyotrophic lateral sclerosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Brain injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Brain oedema			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 stem infarction			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Brain stem syndrome			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid arteriosclerosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery aneurysm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Carotid artery disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	15 / 6988 (0.21%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 17	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid sinus syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Carpal tunnel syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cauda equina syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system lesion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Cerebellar ataxia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral arteriosclerosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cerebral cyst			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	2 / 6988 (0.03%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	1 / 5	0 / 2	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 1
Cerebral infarction			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Cerebral ischaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Cerebral microangiopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
Cerebrovascular disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical cord compression			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cervical myelopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical radiculopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Cervicobrachial syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cluster headache			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Cognitive disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complex regional pain syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Convulsion			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dementia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	0 / 6988 (0.00%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dementia Alzheimer's type			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Demyelinating polyneuropathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	9 / 6988 (0.13%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 2	1 / 10	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Epilepsy alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	5 / 6988 (0.07%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extrapyramidal disorder alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Grand mal convulsion alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Guillain-Barre syndrome alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	0 / 6958 (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
Haemorrhage intracranial alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Haemorrhagic stroke alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 6996 (0.14%)	5 / 6988 (0.07%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	6 / 10	1 / 5	2 / 3
deaths causally related to treatment / all	3 / 6	0 / 3	1 / 1
Haemorrhagic transformation stroke alternative dictionary used: MedDRA 17			

subjects affected / exposed	4 / 6996 (0.06%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Headache			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	4 / 6988 (0.06%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercapnic coma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Hypertensive encephalopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Hypoxic-ischaemic encephalopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
IIIrd nerve paralysis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intraventricular haemorrhage alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cerebral infarction alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ischaemic stroke alternative dictionary used: MedDRA 17			
subjects affected / exposed	18 / 6996 (0.26%)	11 / 6988 (0.16%)	11 / 6958 (0.16%)
occurrences causally related to treatment / all	0 / 19	1 / 11	1 / 11
deaths causally related to treatment / all	0 / 12	0 / 8	1 / 9
Leukoencephalopathy alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Loss of consciousness alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	0 / 6958 (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
Mononeuritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Monoparesis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 sclerosis relapse			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Muscle contractions involuntary			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myoclonus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Nerve root compression			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Neuritis cranial			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Neuropathy peripheral			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normal pressure hydrocephalus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Occipital neuralgia			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Parkinson's disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Parkinsonism			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Peripheral nerve paresis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Polyneuropathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Presyncope			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	3 / 6988 (0.04%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	0 / 6	1 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychomotor hyperactivity			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Quadriparesis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Radiculopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured cerebral aneurysm			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Sciatica			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	3 / 6988 (0.04%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Senile dementia			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serotonin syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 claudication			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Spinal cord compression			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Subarachnoid haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1

Syncope			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	28 / 6996 (0.40%)	37 / 6988 (0.53%)	31 / 6958 (0.45%)
occurrences causally related to treatment / all	0 / 30	3 / 39	1 / 33
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal lobe epilepsy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Tension headache			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient global amnesia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Trigeminal neuralgia			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Uraemic encephalopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
VIIth nerve paralysis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paresis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vagus nerve disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 encephalopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular parkinsonism			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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

Vertebral artery stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Vertebrobasilar insufficiency			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Blood and lymphatic system disorders			
Anaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	9 / 6996 (0.13%)	12 / 6988 (0.17%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 9	5 / 12	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia macrocytic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Anaemia megaloblastic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Anaemia of chronic disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Anaemia of malignant disease			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia vitamin B12 deficiency			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Aplastic anaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulation factor deficiency			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 anaemia alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	4 / 6988 (0.06%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	1 / 2	2 / 4	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercoagulation alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Hypochromic anaemia alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Immune thrombocytopenic purpura alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Increased tendency to bruise alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia alternative dictionary used: MedDRA 17			

subjects affected / exposed	3 / 6996 (0.04%)	24 / 6988 (0.34%)	11 / 6958 (0.16%)
occurrences causally related to treatment / all	2 / 3	10 / 25	3 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Leukopenia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Microcytic anaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	4 / 6988 (0.06%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4	4 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrogenic anaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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

Normochromic normocytic anaemia alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	3 / 6988 (0.04%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pernicious anaemia alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic haemorrhage alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenomegaly alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Spontaneous haematoma alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	1 / 3	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spontaneous haemorrhage alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	8 / 6988 (0.11%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 6	5 / 8	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Acute vestibular syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Auricular perichondritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Deafness unilateral			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inner ear disorder			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Meniere's disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Middle ear effusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presbyacusis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 hearing loss			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tympanic membrane perforation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Vertigo			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	4 / 6988 (0.06%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 8	1 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vertigo labyrinthine			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 positional			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	6 / 6988 (0.09%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Age-related macular degeneration			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angle closure glaucoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Cataract			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	14 / 6996 (0.20%)	10 / 6988 (0.14%)	16 / 6958 (0.23%)
occurrences causally related to treatment / all	0 / 17	0 / 11	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract nuclear			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctival haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic retinopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Endocrine ophthalmopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Extraocular muscle paresis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Eye haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Eyelid ptosis alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Glaucoma alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular degeneration alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 fibrosis alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open angle glaucoma alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Opsoclonus myoclonus alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic ischaemic neuropathy alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pterygium			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Retinal artery embolism			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Retinal artery occlusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 degeneration			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Retinal detachment			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	3 / 6988 (0.04%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Retinal vein occlusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Tolosa-Hunt syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	2 / 2	1 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	0 / 6958 (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
Abdominal discomfort			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	5 / 6988 (0.07%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia obstructive			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	7 / 6988 (0.10%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	1 / 4	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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 pain upper			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 abdomen			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1

Anal fissure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
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 fistula			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Anal polyp			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Appendiceal mucocoele			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Ascites			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Barrett's oesophagus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	2 / 6988 (0.03%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	9 / 6988 (0.13%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dental caries			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic hernia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	7 / 6988 (0.10%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dieulafoy's vascular malformation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	3 / 6988 (0.04%)	0 / 6958 (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
Diverticulitis intestinal haemorrhagic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	3 / 5	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	8 / 6988 (0.11%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	2 / 9	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	11 / 6988 (0.16%)	12 / 6958 (0.17%)
occurrences causally related to treatment / all	1 / 2	8 / 12	12 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	5 / 6988 (0.07%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 1	3 / 5	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	7 / 6988 (0.10%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	3 / 4	5 / 7	5 / 7
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Duodenitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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

Dyspepsia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Enterocolitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Enterocolitis haemorrhagic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Erosive duodenitis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive oesophagitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Faecalith			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 hernia, obstructive			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Food poisoning			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 polyps			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	13 / 6988 (0.19%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	2 / 4	6 / 14	4 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	18 / 6988 (0.26%)	14 / 6958 (0.20%)
occurrences causally related to treatment / all	4 / 7	13 / 18	9 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Gastritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 6996 (0.14%)	17 / 6988 (0.24%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	1 / 11	3 / 18	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis atrophic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Gastritis erosive			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	4 / 6988 (0.06%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	2 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis hypertrophic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroduodenitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Gastroduodenitis haemorrhagic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal angiodysplasia haemorrhagic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal erosion			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 6996 (0.11%)	26 / 6988 (0.37%)	15 / 6958 (0.22%)
occurrences causally related to treatment / all	7 / 9	13 / 27	12 / 15
deaths causally related to treatment / all	1 / 2	0 / 4	1 / 1
Gastrointestinal mucosal disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 necrosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Gastrointestinal pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal perforation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal polyp haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	1 / 3	1 / 2	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal ulcer haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	5 / 6988 (0.07%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal vascular malformation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	3 / 6988 (0.04%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	10 / 6996 (0.14%)	11 / 6988 (0.16%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 11	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival bleeding			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic erosive gastritis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	3 / 6996 (0.04%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	1 / 3	3 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	4 / 6988 (0.06%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	2 / 3	2 / 4	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	4 / 6988 (0.06%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ileus paralytic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	0 / 6958 (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
Impaired gastric emptying			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Inguinal hernia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	21 / 6996 (0.30%)	25 / 6988 (0.36%)	26 / 6958 (0.37%)
occurrences causally related to treatment / all	0 / 22	0 / 25	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia strangulated			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal infarction			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Intestinal ischaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Intestinal obstruction			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	3 / 6996 (0.04%)	5 / 6988 (0.07%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 3	1 / 5	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Intestinal perforation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intussusception			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Irritable bowel syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Large intestinal ulcer haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Large intestine perforation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 6996 (0.11%)	12 / 6988 (0.17%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 12	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	1 / 2	2 / 3	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	4 / 6988 (0.06%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	2 / 4	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Melaena			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	4 / 6988 (0.06%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	1 / 2	3 / 4	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Oesophageal achalasia			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	3 / 6996 (0.04%)	0 / 6988 (0.00%)	0 / 6958 (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
Oesophageal haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal obstruction			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal ulcer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Oesophageal ulcer haemorrhage alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Oesophagitis alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	3 / 6988 (0.04%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis haemorrhagic alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Pancreatic duct obstruction alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Pancreatic fistula alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Pancreatic mass alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	7 / 6988 (0.10%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 8	1 / 7
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pancreatitis acute			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	8 / 6988 (0.11%)	10 / 6958 (0.14%)
occurrences causally related to treatment / all	1 / 7	1 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Pancreatitis haemorrhagic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Papilla of Vater stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Parotid gland inflammation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Peptic ulcer haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	4 / 6988 (0.06%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	1 / 1	2 / 4	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Proctitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis haemorrhagic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	5 / 6988 (0.07%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	2 / 5	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polyp			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Reflux gastritis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 intestinal haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	1 / 6988 (0.01%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Thrombosis mesenteric vessel			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Tongue blistering			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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

Toothache			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Umbilical hernia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	3 / 6988 (0.04%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia, obstructive			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	3 / 6988 (0.04%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	7 / 6988 (0.10%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	1 / 1	0 / 7	5 / 7
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Volvulus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Volvulus of small bowel			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Vomiting			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Acute hepatic failure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Bile duct stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	0 / 6958 (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
Bile duct stone			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 6996 (0.11%)	1 / 6988 (0.01%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	1 / 10	0 / 1	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 dyskinesia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biloma			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cholangitis sclerosing			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Cholecystitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	10 / 6988 (0.14%)	17 / 6958 (0.24%)
occurrences causally related to treatment / all	0 / 5	0 / 10	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	11 / 6996 (0.16%)	7 / 6988 (0.10%)	11 / 6958 (0.16%)
occurrences causally related to treatment / all	0 / 11	0 / 7	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cholecystitis chronic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cholelithiasis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	31 / 6996 (0.44%)	15 / 6988 (0.21%)	18 / 6958 (0.26%)
occurrences causally related to treatment / all	0 / 31	0 / 15	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Chronic hepatitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cirrhosis alcoholic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 cirrhosis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	0 / 6958 (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
Hepatic vein thrombosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Hepatomegaly			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocholecystis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Hyperplastic cholecystopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Jaundice			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Non-alcoholic steatohepatitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Portal vein thrombosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 and subcutaneous tissue disorders			
Actinic keratosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	2 / 3	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cutaneous sarcoidosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Decubitus ulcer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	0 / 6958 (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
Dermal cyst			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Dermatitis allergic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 foot			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	4 / 6988 (0.06%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug eruption			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dry gangrene			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Ecchymosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Hyperhidrosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Hyperkeratosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Hypersensitivity vasculitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panniculitis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma gangrenosum			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Rash			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash generalised			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	0 / 6958 (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

Stevens-Johnson syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 and urinary disorders			
Acute prerenal failure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder diverticulum			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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 neck sclerosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Bladder prolapse			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Bladder tamponade			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus bladder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	5 / 6988 (0.07%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urethral			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	4 / 6988 (0.06%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Cystitis noninfective			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 nephropathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Glomerulonephritis membranoproliferative			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Glomerulonephritis membranous			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	9 / 6988 (0.13%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	2 / 3	3 / 9	9 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage urinary tract			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	4 / 6988 (0.06%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive nephropathy			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 6996 (0.11%)	21 / 6988 (0.30%)	10 / 6958 (0.14%)
occurrences causally related to treatment / all	0 / 12	2 / 22	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bladder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 uropathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Pelvi-ureteric obstruction			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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

Renal colic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	4 / 6988 (0.06%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst ruptured			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Renal failure			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	15 / 6996 (0.21%)	6 / 6988 (0.09%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	0 / 18	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 4	0 / 2	0 / 2
Renal failure acute			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	28 / 6996 (0.40%)	32 / 6988 (0.46%)	32 / 6958 (0.46%)
occurrences causally related to treatment / all	0 / 34	0 / 34	1 / 32
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 1
Renal failure chronic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	5 / 6988 (0.07%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 6	1 / 8
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Renal haemorrhage			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Renal impairment			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	1 / 6988 (0.01%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular acidosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 urinary incontinence			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric rupture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ureteric stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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

Urethral stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	1 / 6988 (0.01%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Urinoma			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
Autoimmune thyroiditis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	0 / 6958 (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
Hyperthyroidism			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Toxic nodular goitre			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 and connective tissue disorders			
Ankylosing spondylitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Arthralgia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	9 / 6996 (0.13%)	10 / 6988 (0.14%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Back pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	8 / 6988 (0.11%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical spinal stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondrocalcinosis pyrophosphate			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondropathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Dupuytren's contracture			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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

Facet joint syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	0 / 6958 (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
Fracture malunion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Fracture nonunion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gouty arthritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Hand deformity			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Intervertebral disc compression			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Intervertebral disc degeneration			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	14 / 6996 (0.20%)	8 / 6988 (0.11%)	10 / 6958 (0.14%)
occurrences causally related to treatment / all	0 / 15	0 / 11	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Jaw cyst			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Joint ankylosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Joint effusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	5 / 6988 (0.07%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscal degeneration			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Mobility decreased			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Monarthritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Muscle haemorrhage			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 hypertrophy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Muscular weakness			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Musculoskeletal chest pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	20 / 6996 (0.29%)	16 / 6988 (0.23%)	22 / 6958 (0.32%)
occurrences causally related to treatment / all	1 / 20	0 / 17	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia intercostal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Myopathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Myositis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Osteoarthritis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	59 / 6996 (0.84%)	54 / 6988 (0.77%)	54 / 6958 (0.78%)
occurrences causally related to treatment / all	0 / 62	0 / 57	0 / 59
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Pain in extremity			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in jaw			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Periarthritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Polyarthritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Polymyalgia rheumatica			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyositis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Psoriatic arthropathy			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Resorption bone increased			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Rhabdomyolysis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	7 / 6996 (0.10%)	12 / 6988 (0.17%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 12	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacroiliitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Spinal column stenosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	9 / 6958 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Spinal osteoarthritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	7 / 6988 (0.10%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	1 / 6988 (0.01%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Spondylolysis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sympathetic posterior cervical syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic lupus erythematosus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Tendon calcification			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon disorder			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Trigger finger			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Abdominal sepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Abdominal wall abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Abdominal wall infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	4 / 6988 (0.06%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Acquired immunodeficiency syndrome			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Acute sinusitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebiasis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Anal abscess			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	9 / 6996 (0.13%)	7 / 6988 (0.10%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	0 / 9	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Avian influenza			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bacterial infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	3 / 6988 (0.04%)	0 / 6958 (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
Bacterial prostatitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Bacterial pyelonephritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Bartholin's abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 sepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Breast abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	19 / 6996 (0.27%)	22 / 6988 (0.31%)	10 / 6958 (0.14%)
occurrences causally related to treatment / all	1 / 20	1 / 27	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 6996 (0.11%)	12 / 6988 (0.17%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 12	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 1
Bronchopulmonary aspergillosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 infective			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Campylobacter gastroenteritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	14 / 6996 (0.20%)	12 / 6988 (0.17%)	17 / 6958 (0.24%)
occurrences causally related to treatment / all	0 / 15	0 / 13	1 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis laryngeal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral toxoplasmosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Chest wall abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 suppurative			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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 sinusitis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Clostridium colitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Clostridium difficile infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile sepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Congo-Crimean haemorrhagic fever			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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

Cystitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 related infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	2 / 6988 (0.03%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic gangrene			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Diverticulitis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	12 / 6996 (0.17%)	11 / 6988 (0.16%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	1 / 12	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Ear infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Emphysematous cholecystitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Encephalitis brain stem			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Endocarditis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Endocarditis bacterial			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Enteritis infectious			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Enterococcal sepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Enterocolitis infectious			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Epididymitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	4 / 6988 (0.06%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiglottitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	7 / 6996 (0.10%)	4 / 6988 (0.06%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia pyelonephritis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Escherichia sepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Escherichia urinary tract infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Extradural abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Eye infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Furuncle			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 6996 (0.11%)	5 / 6988 (0.07%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0

Gastritis viral			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	18 / 6996 (0.26%)	18 / 6988 (0.26%)	15 / 6958 (0.22%)
occurrences causally related to treatment / all	0 / 18	0 / 18	1 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis bacterial			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Gastroenteritis norovirus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	0 / 6958 (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
Gastroenteritis rotavirus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Gastroenteritis salmonella			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Gastroenteritis viral			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	4 / 6996 (0.06%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Gingivitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
H1N1 influenza			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Helicobacter gastritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Helicobacter infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Hepatitis A			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 viral			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex meningoencephalitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site infection			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected dermal cyst			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected fistula			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Infected skin ulcer			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	4 / 6988 (0.06%)	0 / 6958 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Infectious colitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Infectious pleural effusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	0 / 6958 (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

Infective exacerbation of chronic obstructive airways disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	2 / 6988 (0.03%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	2 / 6988 (0.03%)	0 / 6958 (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
Intervertebral discitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Laryngitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Leishmaniasis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Listeria sepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	0 / 6958 (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
Lobar pneumonia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Localised infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lower respiratory tract infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	4 / 6988 (0.06%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Lower respiratory tract infection bacterial			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lyme disease			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Malaria			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Meningitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Meningitis bacterial			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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

Muscle abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Myringitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
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 abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Nasopharyngitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Necrotising fasciitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Ophthalmic herpes zoster			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Orchitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	5 / 6988 (0.07%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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

Paraspinal abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Periodontitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	2 / 6988 (0.03%)	0 / 6958 (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
Perirectal abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	6 / 6988 (0.09%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 0
Peritonsillar abscess			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Pilonidal cyst			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Pneumococcal sepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pneumocystis jirovecii pneumonia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	76 / 6996 (1.09%)	77 / 6988 (1.10%)	69 / 6958 (0.99%)
occurrences causally related to treatment / all	1 / 83	0 / 86	1 / 72
deaths causally related to treatment / all	0 / 4	0 / 7	1 / 10
Pneumonia bacterial			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	11 / 6996 (0.16%)	6 / 6988 (0.09%)	15 / 6958 (0.22%)
occurrences causally related to treatment / all	0 / 12	0 / 6	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 3

Pneumonia cytomegaloviral			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 haemophilus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 legionella			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia necrotising			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 pseudomonal			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia streptococcal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 viral			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural pneumonia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Postoperative wound infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	8 / 6958 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis infectious			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pseudomembranous colitis alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonas infection alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	0 / 6958 (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 tuberculosis alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	4 / 6988 (0.06%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyopneumothorax			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	1 / 6988 (0.01%)	0 / 6958 (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
Respiratory tract infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	4 / 6996 (0.06%)	4 / 6988 (0.06%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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

Salmonellosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Scrotal abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	15 / 6996 (0.21%)	17 / 6988 (0.24%)	20 / 6958 (0.29%)
occurrences causally related to treatment / all	0 / 16	0 / 18	0 / 20
deaths causally related to treatment / all	0 / 3	0 / 8	0 / 5
Septic necrosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 shock			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	6 / 6996 (0.09%)	12 / 6988 (0.17%)	7 / 6958 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 12	0 / 7
deaths causally related to treatment / all	0 / 5	0 / 8	0 / 3
Sialoadenitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Sinusitis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	4 / 6988 (0.06%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
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 infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Streptococcal abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	2 / 6988 (0.03%)	0 / 6958 (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
Subacute endocarditis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Subcutaneous abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Toxoplasmosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Tracheobronchitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethritis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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 abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Urinary tract infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	15 / 6996 (0.21%)	28 / 6988 (0.40%)	27 / 6958 (0.39%)
occurrences causally related to treatment / all	0 / 15	0 / 30	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection pseudomonal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	19 / 6988 (0.27%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 19	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Vestibular neuronitis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Viral diarrhoea			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Viral infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound abscess			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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
Wound infection			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	3 / 6996 (0.04%)	6 / 6988 (0.09%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection bacterial			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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 infection staphylococcal			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Yersinia infection			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Metabolism and nutrition disorders			
Abnormal loss of weight			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Dehydration			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	8 / 6996 (0.11%)	11 / 6988 (0.16%)	9 / 6958 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 13	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	13 / 6996 (0.19%)	15 / 6988 (0.21%)	15 / 6958 (0.22%)
occurrences causally related to treatment / all	0 / 15	0 / 17	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	13 / 6996 (0.19%)	11 / 6988 (0.16%)	12 / 6958 (0.17%)
occurrences causally related to treatment / all	0 / 13	0 / 14	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic complication			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Diabetic ketoacidosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Failure to thrive			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Gout			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Hyperglycaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	5 / 6988 (0.07%)	4 / 6958 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hyperkalaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	3 / 6988 (0.04%)	5 / 6958 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypocalcaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	5 / 6988 (0.07%)	6 / 6958 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Hyponatraemia			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	3 / 6988 (0.04%)	2 / 6958 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
alternative dictionary used: MedDRA 17			

subjects affected / exposed	1 / 6996 (0.01%)	1 / 6988 (0.01%)	0 / 6958 (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
Lactic acidosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactose intolerance			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	0 / 6988 (0.00%)	1 / 6958 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	0 / 6988 (0.00%)	0 / 6958 (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
Metabolic acidosis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	2 / 6996 (0.03%)	2 / 6988 (0.03%)	0 / 6958 (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
Obesity			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	1 / 6996 (0.01%)	0 / 6988 (0.00%)	0 / 6958 (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
Type 1 diabetes mellitus			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	0 / 6996 (0.00%)	1 / 6988 (0.01%)	0 / 6958 (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			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	5 / 6996 (0.07%)	6 / 6988 (0.09%)	3 / 6958 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 6	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo	Ticagrelor 90mg bd	Ticagrelor 60mg bd
Total subjects affected by non-serious adverse events			
subjects affected / exposed	945 / 6996 (13.51%)	2245 / 6988 (32.13%)	1992 / 6958 (28.63%)
Injury, poisoning and procedural complications			
Contusion			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	111 / 6996 (1.59%)	385 / 6988 (5.51%)	353 / 6958 (5.07%)
occurrences (all)	122	473	471
Blood and lymphatic system disorders			
Increased tendency to bruise			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	65 / 6996 (0.93%)	464 / 6988 (6.64%)	419 / 6958 (6.02%)
occurrences (all)	70	575	520
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	329 / 6996 (4.70%)	1091 / 6988 (15.61%)	876 / 6958 (12.59%)
occurrences (all)	362	1340	1036
Epistaxis			
alternative dictionary used: MedDRA 17			
subjects affected / exposed	165 / 6996 (2.36%)	505 / 6988 (7.23%)	420 / 6958 (6.04%)
occurrences (all)	221	668	623
Infections and infestations			
Nasopharyngitis			
alternative dictionary used: MedDRA 17			

subjects affected / exposed occurrences (all)	377 / 6996 (5.39%) 469	368 / 6988 (5.27%) 490	364 / 6958 (5.23%) 486

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 March 2011	The primary reason for the global amendment was to stop patients with history of prior ischaemic stroke from receiving study drug as there was, at the time of the amendment, growing data from studies of other antiplatelet drugs (none of them ticagrelor) suggesting that more intensive antiplatelet therapy might pose high risk of intracranial haemorrhage (ICH) in patients with a history of ischaemic stroke (Morrow et al 2013, Wiviott et al 2007). While there are no data that ticagrelor predisposes patients with prior ischaemic stroke to intracranial haemorrhage, it was considered prudent going forward to exclude patients with prior stroke from the study so as not to potentially complicate the interpretation of the results. Previously randomised stroke patients continued to be followed up off treatment. This study was neither intended nor powered to answer specific safety questions relating to small subgroups such as those patients with prior ischaemic stroke. This action, to exclude patients with prior stroke from this study, should not be interpreted to restrict any future investigation of ticagrelor in patients with prior stroke for this or for other potential indications. Indeed, AstraZeneca is conducting a trial of ticagrelor in acute stroke patients (IND115, 807, D5134C00001). In addition to excluding patients with history of stroke, the amendment also broadened the prior exclusion to also exclude patients with a history of a central nervous system tumour on intracranial vascular abnormality (eg, aneurysm, arteriovenous malformation) at any time, or intracranial or spinal cord surgery within 5 years, because these are conditions that are associated with an increased risk of intracranial/intraspinal haemorrhage.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported