

**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
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**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

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 randomized (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
<b>Arm title</b>	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

<b>Arm title</b>	Ticagrelor 60 mg
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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

<b>Arm title</b>	Placebo
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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

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**Dosage and administration details:**

Placebo twice daily

<b>Number of subjects in period 1</b>	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

<b>Statistical analysis title</b>	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 intracranial bleeding or any clinically overt signs of haemorrhage associated with a drop in Haemoglobin of $\geq 5$ g/dL. Events were adjudicated by a clinical events committee. Censoring occurs 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	



<b>End point values</b>	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

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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
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**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
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**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**

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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
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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 participant 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
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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

<b>Statistical analysis title</b>	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
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	17
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### Reporting groups

Reporting group title	Placebo
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Reporting group description: -

Reporting group title	Ticagrelor 90mg bd
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Reporting group description: -

Reporting group title	Ticagrelor 60mg bd
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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

<p>Skin cancer</p> <p>alternative dictionary used: MedDRA 17</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>2 / 6996 (0.03%)</p> <p>0 / 5</p> <p>0 / 0</p>	<p>0 / 6988 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>1 / 6958 (0.01%)</p> <p>0 / 1</p> <p>0 / 1</p>
<p>Small cell lung cancer</p> <p>alternative dictionary used: MedDRA 17</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>2 / 6996 (0.03%)</p> <p>0 / 2</p> <p>0 / 0</p>	<p>4 / 6988 (0.06%)</p> <p>0 / 4</p> <p>0 / 1</p>	<p>2 / 6958 (0.03%)</p> <p>0 / 2</p> <p>0 / 0</p>
<p>Small cell lung cancer metastatic</p> <p>alternative dictionary used: MedDRA 17</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 6996 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>2 / 6988 (0.03%)</p> <p>0 / 2</p> <p>0 / 2</p>	<p>0 / 6958 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>
<p>Small intestine carcinoma</p> <p>alternative dictionary used: MedDRA 17</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>1 / 6996 (0.01%)</p> <p>0 / 1</p> <p>0 / 0</p>	<p>0 / 6988 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>1 / 6958 (0.01%)</p> <p>0 / 1</p> <p>0 / 0</p>
<p>Spinal cord neoplasm</p> <p>alternative dictionary used: MedDRA 17</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 6996 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>1 / 6988 (0.01%)</p> <p>0 / 1</p> <p>0 / 1</p>	<p>0 / 6958 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>
<p>Splenic marginal zone lymphoma</p> <p>alternative dictionary used: MedDRA 17</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 6996 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 6988 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>1 / 6958 (0.01%)</p> <p>0 / 1</p> <p>0 / 0</p>
<p>Squamous cell carcinoma</p> <p>alternative dictionary used: MedDRA 17</p>			

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
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
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 occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6996 (0.00%) 0 / 0 0 / 0	1 / 6988 (0.01%) 0 / 1 0 / 0	3 / 6958 (0.04%) 0 / 3 0 / 0
Wound haemorrhage alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6996 (0.00%) 0 / 0 0 / 0	1 / 6988 (0.01%) 0 / 1 0 / 0	0 / 6958 (0.00%) 0 / 0 0 / 0
Wrist fracture alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6996 (0.00%) 0 / 0 0 / 0	0 / 6988 (0.00%) 0 / 0 0 / 0	4 / 6958 (0.06%) 0 / 4 0 / 0
Congenital, familial and genetic disorders Atrial septal defect alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6996 (0.00%) 0 / 0 0 / 0	1 / 6988 (0.01%) 0 / 1 0 / 0	0 / 6958 (0.00%) 0 / 0 0 / 0
Cardiac disorders Acute coronary syndrome alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	3 / 6996 (0.04%) 0 / 3 0 / 1	0 / 6988 (0.00%) 0 / 0 0 / 0	1 / 6958 (0.01%) 0 / 1 0 / 0
Acute left ventricular failure alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	5 / 6996 (0.07%) 0 / 6 0 / 3	3 / 6988 (0.04%) 0 / 3 0 / 1	1 / 6958 (0.01%) 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
Quadripareisis 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
VIth 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
Presbycusis 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
Gastroesophageal 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 occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6996 (0.00%) 0 / 0 0 / 0	1 / 6988 (0.01%) 0 / 1 0 / 0	0 / 6958 (0.00%) 0 / 0 0 / 0
Umbilical hernia alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	3 / 6996 (0.04%) 0 / 3 0 / 0	3 / 6988 (0.04%) 0 / 3 0 / 0	8 / 6958 (0.11%) 0 / 8 0 / 0
Umbilical hernia, obstructive alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6996 (0.00%) 0 / 0 0 / 0	3 / 6988 (0.04%) 0 / 3 0 / 0	1 / 6958 (0.01%) 0 / 1 0 / 0
Upper gastrointestinal haemorrhage alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6996 (0.01%) 1 / 1 1 / 1	7 / 6988 (0.10%) 0 / 7 0 / 0	7 / 6958 (0.10%) 5 / 7 0 / 0
Volvulus alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6996 (0.00%) 0 / 0 0 / 0	1 / 6988 (0.01%) 0 / 1 0 / 0	0 / 6958 (0.00%) 0 / 0 0 / 0
Volvulus of small bowel alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6996 (0.00%) 0 / 0 0 / 0	1 / 6988 (0.01%) 0 / 1 0 / 0	0 / 6958 (0.00%) 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
Hydrocholecystitis 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 occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6996 (0.00%) 0 / 0 0 / 0	1 / 6988 (0.01%) 0 / 1 0 / 0	1 / 6958 (0.01%) 0 / 1 0 / 0
Jaundice cholestatic alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6996 (0.01%) 0 / 1 0 / 0	0 / 6988 (0.00%) 0 / 0 0 / 0	1 / 6958 (0.01%) 0 / 1 0 / 0
Liver disorder alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6996 (0.00%) 0 / 0 0 / 0	1 / 6988 (0.01%) 0 / 1 0 / 0	0 / 6958 (0.00%) 0 / 0 0 / 0
Non-alcoholic steatohepatitis alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6996 (0.00%) 0 / 0 0 / 0	0 / 6988 (0.00%) 0 / 0 0 / 0	2 / 6958 (0.03%) 0 / 2 0 / 1
Portal vein thrombosis alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6996 (0.01%) 0 / 1 0 / 0	0 / 6988 (0.00%) 0 / 0 0 / 0	0 / 6958 (0.00%) 0 / 0 0 / 0
Skin and subcutaneous tissue disorders Actinic keratosis alternative dictionary used: MedDRA 17 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6996 (0.01%) 0 / 1 0 / 0	0 / 6988 (0.00%) 0 / 0 0 / 0	1 / 6958 (0.01%) 0 / 1 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
Monarthrititis			
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

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

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 %

<b>Non-serious adverse events</b>	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	377 / 6996 (5.39%)	368 / 6988 (5.27%)	364 / 6958 (5.23%)
occurrences (all)	469	490	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 or 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:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported