



## Clinical trial results:

### Assessment of Clinical Effects of Cholesteryl Ester Transfer Protein Inhibition With Evacetrapib in Patients at a High-Risk for Vascular Outcomes

#### Summary

EudraCT number	2012-000061-21
Trial protocol	GB SK EE DE BE SE HU AT ES LT DK IT CZ PL BG NL
Global end of trial date	19 July 2016

#### Results information

Result version number	v1
This version publication date	06 March 2018
First version publication date	06 March 2018

#### Trial information

##### Trial identification

Sponsor protocol code	I1V-MC-EIAN
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01687998
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 11949, Trial Alias: I1V-MC-EIAN

Notes:

#### Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-285-4559,

Notes:

#### Paediatric regulatory details

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

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 July 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 July 2016
Was the trial ended prematurely?	Yes

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study is to test the hypothesis that evacetrapib 130 mg daily, in comparison to placebo, reduces the incidence of the composite endpoint of cardiovascular (CV) death, myocardial infarction (MI), stroke, coronary revascularization, or hospitalization for unstable angina (UA) in high-risk vascular disease (HRVD) participants.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 September 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	3 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 340
Country: Number of subjects enrolled	Poland: 483
Country: Number of subjects enrolled	Slovakia: 233
Country: Number of subjects enrolled	Spain: 131
Country: Number of subjects enrolled	Sweden: 66
Country: Number of subjects enrolled	United Kingdom: 116
Country: Number of subjects enrolled	Austria: 68
Country: Number of subjects enrolled	Belgium: 84
Country: Number of subjects enrolled	Bulgaria: 231
Country: Number of subjects enrolled	Czech Republic: 372
Country: Number of subjects enrolled	Denmark: 195
Country: Number of subjects enrolled	Estonia: 59
Country: Number of subjects enrolled	France: 97
Country: Number of subjects enrolled	Germany: 400
Country: Number of subjects enrolled	Hungary: 233
Country: Number of subjects enrolled	Italy: 83
Country: Number of subjects enrolled	Lithuania: 28

Country: Number of subjects enrolled	Russian Federation: 167
Country: Number of subjects enrolled	Hong Kong: 52
Country: Number of subjects enrolled	United States: 4475
Country: Number of subjects enrolled	China: 445
Country: Number of subjects enrolled	Korea, Republic of: 181
Country: Number of subjects enrolled	Brazil: 110
Country: Number of subjects enrolled	Argentina: 180
Country: Number of subjects enrolled	Romania: 130
Country: Number of subjects enrolled	Japan: 407
Country: Number of subjects enrolled	Ukraine: 133
Country: Number of subjects enrolled	Switzerland: 29
Country: Number of subjects enrolled	New Zealand: 127
Country: Number of subjects enrolled	Canada: 1245
Country: Number of subjects enrolled	Turkey: 3
Country: Number of subjects enrolled	Taiwan: 105
Country: Number of subjects enrolled	Mexico: 466
Country: Number of subjects enrolled	South Africa: 153
Country: Number of subjects enrolled	Israel: 146
Country: Number of subjects enrolled	Australia: 319
Worldwide total number of subjects	12092
EEA total number of subjects	3349

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)	5713
From 65 to 84 years	6278
85 years and over	101

## Subject disposition

### Recruitment

Recruitment details:

No Text Entered

### Pre-assignment

Screening details:

No Text Entered

### 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, Carer, Assessor

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Evacetrapib

Arm description:

Evacetrapib 130 milligram (mg) tablet, administered orally once daily for up to 4 years. Participants will also receive standard of care for high-risk vascular disease (HRVD).

Arm type	Experimental
Investigational medicinal product name	Evacetrapib
Investigational medicinal product code	
Other name	LY2484595
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Evacetrapib 130 mg tablet, administered orally once daily for up to 4 years. Participants will also receive standard of care for high-risk vascular disease (HRVD).

<b>Arm title</b>	Placebo
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Arm description:

Placebo, tablet administered orally once daily for up to 4 years. Participants will also receive standard of care for HRVD.

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

Dosage and administration details:

Placebo, tablet administered orally once daily for up to 4 years. Participants received standard of care for HRVD.

<b>Number of subjects in period 1</b>	Evacetrapib	Placebo
Started	6038	6054
Received at Least One Dose of Study Drug	6036	6052
Completed	5926	5934
Not completed	112	120
Consent withdrawn by subject	49	51
Alive	54	62
Lost to follow-up	9	7

## Baseline characteristics

### Reporting groups

Reporting group title	Overall Study
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Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	12092	12092	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	5713	5713	
From 65-84 years	6278	6278	
85 years and over	101	101	
Gender categorical			
Units: Subjects			
Female	2784	2784	
Male	9308	9308	
Race			
Units: Subjects			
American Indian or Alaska Native	469	469	
Asian	1290	1290	
Native Hawaiian or Other Pacific Islander	11	11	
Black or African American	294	294	
White	9904	9904	
More than one race	61	61	
Unknown or Not Reported	63	63	
Ethnicity			
Units: Subjects			
Hispanic or Latino	1022	1022	
Not Hispanic or Latino	10780	10780	
Unknown or Not Reported	290	290	

## End points

### End points reporting groups

Reporting group title	Evacetrapib
Reporting group description: Evacetrapib 130 milligram (mg) tablet, administered orally once daily for up to 4 years. Participants will also receive standard of care for high-risk vascular disease (HRVD).	
Reporting group title	Placebo
Reporting group description: Placebo, tablet administered orally once daily for up to 4 years. Participants will also receive standard of care for HRVD.	

### Primary: Time to First Occurrence of the Composite Primary Endpoint of Cardiovascular (CV) Death, Myocardial Infarction (MI), Stroke, Coronary Revascularization, or Hospitalization for Unstable Angina (UA) [Time Frame: Baseline to Study Completion (Up to 4 years)]

End point title	Time to First Occurrence of the Composite Primary Endpoint of Cardiovascular (CV) Death, Myocardial Infarction (MI), Stroke, Coronary Revascularization, or Hospitalization for Unstable Angina (UA) [Time Frame: Baseline to Study Completion (Up to 4 years)]
End point description: Time to first occurrence is the time from baseline to the first occurrence of any component event included in the composite primary endpoint of CV death, MI, stroke, coronary revascularization, or hospitalization for UA. For component endpoints, the number of participants includes those experiencing fatal events and account for all occurrences regardless of whether or not another component event occurred previously.	
End point type	Primary
End point timeframe: Baseline to Study Completion (Up to 4 years)	

End point values	Evacetrapib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6038 <sup>[1]</sup>	6054 <sup>[2]</sup>		
Units: participants	779	776		

Notes:

[1] - All randomized participants.

[2] - All randomized participants.

### Statistical analyses

Statistical analysis title	Statistical Analysis Composite Primary Endpoint
Comparison groups	Evacetrapib v Placebo

Number of subjects included in analysis	12092
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9054
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.006
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.911
upper limit	1.111

### Secondary: Mean Percent Change From Baseline to 3 Months in Low-Density (LDL-C) and High-Density Lipoprotein Cholesterol (HDL-C) Levels

End point title	Mean Percent Change From Baseline to 3 Months in Low-Density (LDL-C) and High-Density Lipoprotein Cholesterol (HDL-C) Levels
End point description:	
End point type	Secondary
End point timeframe:	
Baseline, 3 Months	

End point values	Evacetrapib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6038 <sup>[3]</sup>	6054 <sup>[4]</sup>		
Units: Percent				
arithmetic mean (standard deviation)				
LDL-C (n=5760, 5786)	-31.12 (± 27.583)	-5.99 (± 29.007)		
HDL-C (n=5760, 5788)	133.18 (± 57.204)	1.63 (± 17.455)		

Notes:

[3] - All randomized participants with evaluable LDL-C levels.

[4] - All randomized participants with evaluable HDL-C levels.

### Statistical analyses

Statistical analysis title	Statistical Analysis for LDL-C Levels
Comparison groups	Placebo v Evacetrapib
Number of subjects included in analysis	12092
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-37.11



Confidence interval	
level	95 %
sides	2-sided
lower limit	-38.15
upper limit	-36.08

<b>Statistical analysis title</b>	Statistical Analysis for HDL-C Levels
Comparison groups	Evacetrapib v Placebo
Number of subjects included in analysis	12092
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	131.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	130.01
upper limit	133.09

### **Secondary: Time to First Occurrence of the Composite Endpoint of All-Cause Mortality, MI, Stroke, Coronary Revascularization, or Hospitalization for UA**

End point title	Time to First Occurrence of the Composite Endpoint of All-Cause Mortality, MI, Stroke, Coronary Revascularization, or Hospitalization for UA
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#### End point description:

Time to first occurrence is the time from baseline to the first occurrence of any component event included in the composite endpoint of all-cause mortality, MI, stroke, coronary revascularization, or hospitalization for UA. For component endpoints, the number of participants includes those experiencing fatal events and account for all occurrences regardless of whether or not another component event occurred previously.

End point type	Secondary
End point timeframe:	
Baseline through End of Study (Up to 4 years)	

End point values	Evacetrapib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6038	6054		
Units: participants	857	867		

## Statistical analyses

Statistical analysis title	Statistical Analysis Composite Endpoint Mortality
Comparison groups	Evacetrapib v Placebo
Number of subjects included in analysis	12092
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8463
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.991
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.901
upper limit	1.089

## Secondary: Time to First Occurrence of the Composite Endpoint of CV Death, MI, or Coronary Revascularization

End point title	Time to First Occurrence of the Composite Endpoint of CV Death, MI, or Coronary Revascularization
End point description:	Time to first occurrence is the time from baseline to the first occurrence of any component event included in the composite endpoint. For component endpoints, the number of participants includes those experiencing fatal events and account for all occurrences regardless of whether or not another component event occurred previously.
End point type	Secondary
End point timeframe:	Baseline through End of Study (Up to 4 years)

End point values	Evacetrapib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6038	6054		
Units: participants	690	691		

## Statistical analyses

<b>Statistical analysis title</b>	Statistical Analysis for CV Death, MI, or Coronary
Comparison groups	Placebo v Evacetrapib
Number of subjects included in analysis	12092
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9874
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.001
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.901
upper limit	1.112

### Secondary: Time to First Occurrence of the Composite Endpoint of CV Death, MI, Stroke, or Hospitalization for UA

End point title	Time to First Occurrence of the Composite Endpoint of CV Death, MI, Stroke, or Hospitalization for UA
End point description:	
End point type	Secondary
End point timeframe:	
Baseline through End of Study (Up to 4 years)	

<b>End point values</b>	Evacetrapib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6038	6054		
Units: participants	571	570		

### Statistical analyses

<b>Statistical analysis title</b>	Statistical Analysis for CV Death, MI, Stroke
Comparison groups	Evacetrapib v Placebo
Number of subjects included in analysis	12092
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9574
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.003

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.893
upper limit	1.127

## Secondary: Time to First Occurrence of Triple Composite Endpoint of CV Death, MI, or Stroke

End point title	Time to First Occurrence of Triple Composite Endpoint of CV Death, MI, or Stroke
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End point description:

Time to first occurrence is the time from baseline to the first occurrence of any component event included in the composite endpoint. For component endpoints, the number of participants includes those experiencing fatal events and account for all occurrences regardless of whether or not another component event occurred previously.

End point type	Secondary
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End point timeframe:

Baseline through End of Study (Up to 4 years)

<b>End point values</b>	Evacetrapib	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6038	6054		
Units: participants	437	453		

## Statistical analyses

Statistical analysis title	Statistical Analysis for Triple Composite
Comparison groups	Evacetrapib v Placebo
Number of subjects included in analysis	12092
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5917
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.965
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.846
upper limit	1.1

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

I1V-MC-EIAN

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	15.1
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### Reporting groups

Reporting group title	TR1_LY2484595-130mg
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Reporting group description: -

Reporting group title	TR2_PLACEBO
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Reporting group description: -

Serious adverse events	TR1_LY2484595-130mg	TR2_PLACEBO	
Total subjects affected by serious adverse events			
subjects affected / exposed	2306 / 6036 (38.20%)	2341 / 6052 (38.68%)	
number of deaths (all causes)	240	287	
number of deaths resulting from adverse events	8	5	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
acute myeloid leukaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
adenocarcinoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
adenocarcinoma gastric			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
adenocarcinoma of colon alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
adenocarcinoma pancreas alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
adenosquamous cell lung cancer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
anal squamous cell carcinoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
anaplastic astrocytoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
b-cell lymphoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

b-cell lymphoma stage iv alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
basal cell carcinoma alternative dictionary used: MedDRA 15.1 subjects affected / exposed	17 / 6036 (0.28%)	13 / 6052 (0.21%)		
occurrences causally related to treatment / all	0 / 17	0 / 16		
deaths causally related to treatment / all	0 / 0	0 / 0		
basosquamous carcinoma alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
benign gastric neoplasm alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
benign neoplasm of adrenal gland alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
benign neoplasm of spinal cord alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
benign neoplasm of thyroid gland alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
benign renal neoplasm alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder cancer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 6036 (0.13%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder cancer recurrent alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder neoplasm alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder transitional cell carcinoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
borderline mucinous tumour of ovary alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	



bowen's disease alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 3	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
breast cancer alternative dictionary used: MedDRA 15.1 subjects affected / exposed	6 / 6036 (0.10%)	4 / 6052 (0.07%)		
occurrences causally related to treatment / all	0 / 6	0 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
breast cancer metastatic alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
bronchial carcinoma alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	1 / 2	0 / 3		
deaths causally related to treatment / all	1 / 1	0 / 1		
bronchial neoplasm alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
burkitt's lymphoma alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
buschke-lowenstein's tumour alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
carcinoid tumour			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
carcinoid tumour of the gastrointestinal tract			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cervix carcinoma stage 0			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[1]</sup>	1 / 1388 (0.07%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholangiocarcinoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
chronic lymphocytic leukaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic lymphocytic leukaemia stage 0			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic myeloid leukaemia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon adenoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	1 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon cancer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	1 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon cancer metastatic alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
colon cancer stage 0 alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon cancer stage iii alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

colon cancer stage iv alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
colorectal cancer alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 3	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
colorectal cancer metastatic alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
colorectal cancer stage iv alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
desmoplastic melanoma alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
diffuse large b-cell lymphoma alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 2	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
diffuse large b-cell lymphoma recurrent alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
diffuse large b-cell lymphoma stage ii			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diffuse large b-cell lymphoma stage iii			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
endometrial adenocarcinoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ewing's sarcoma metastatic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
fallopian tube cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[2]</sup>	0 / 6036 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
fibrous histiocytoma			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gallbladder adenocarcinoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric adenoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric cancer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	2 / 5	1 / 7	
deaths causally related to treatment / all	1 / 1	0 / 2	
gastrointestinal cancer metastatic alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal stromal tumour alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal tract adenoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

gastroesophageal cancer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
gingival cancer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
glioblastoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
haemangioma of liver alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic cancer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
hepatic cancer metastatic alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
hepatocellular carcinoma alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
hodgkin's disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hodgkin's disease stage iv			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal adenocarcinoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
invasive breast carcinoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	1 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
invasive lobular breast carcinoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	



kaposi's sarcoma alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0		
keratinising squamous cell carcinoma of nasopharynx alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 1	0 / 6052 (0.00%) 0 / 0 0 / 0		
keratoacanthoma alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0		
large intestine benign neoplasm alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0		
laryngeal cancer alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0		
laryngeal neoplasm alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0		
laryngeal squamous cell carcinoma alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lip squamous cell carcinoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lipoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung adenocarcinoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 5	
lung adenocarcinoma stage i alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung adenocarcinoma stage ii alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung adenocarcinoma stage iii alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

lung cancer metastatic alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
lung carcinoma cell type unspecified recurrent			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung carcinoma cell type unspecified stage ii			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung carcinoma cell type unspecified stage iii			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung carcinoma cell type unspecified stage iv			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
lung neoplasm			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung neoplasm malignant			

alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	14 / 6036 (0.23%)	13 / 6052 (0.21%)	
occurrences causally related to treatment / all	0 / 15	1 / 13	
deaths causally related to treatment / all	0 / 7	1 / 8	
lung squamous cell carcinoma metastatic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung squamous cell carcinoma stage i			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung squamous cell carcinoma stage iii			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lymphocytic lymphoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lymphoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
malignant fibrous histiocytoma			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
malignant melanoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
malignant melanoma in situ alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
malignant neoplasm of unknown primary site alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
malignant neoplasm progression alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
malignant pleural effusion alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
mediastinum neoplasm alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
meningioma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
meningioma malignant			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
metastases to bone			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastases to central nervous system			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
metastases to liver			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastases to lung			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastases to lymph nodes alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastases to salivary gland alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastatic malignant melanoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
metastatic squamous cell carcinoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myelodysplastic syndrome alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
myxofibrosarcoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

nasal sinus cancer alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
nasopharyngeal cancer alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
neoplasm progression alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
neoplasm prostate alternative dictionary used: MedDRA 15.1				
subjects affected / exposed <sup>[3]</sup>	0 / 6036 (0.00%)	1 / 4658 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
neoplasm skin alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
neuroendocrine carcinoma metastatic alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 2	0 / 0		
neuroendocrine tumour alternative dictionary used: MedDRA 15.1				



subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
non-hodgkin's lymphoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
non-small cell lung cancer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
non-small cell lung cancer metastatic alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
non-small cell lung cancer stage iii alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
non-small cell lung cancer stage iiia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
non-small cell lung cancer stage iv alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

oesophageal adenocarcinoma alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	3 / 6036 (0.05%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 3	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
oesophageal adenocarcinoma metastatic alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	2 / 2	0 / 1		
deaths causally related to treatment / all	1 / 1	0 / 1		
oesophageal adenocarcinoma stage 0 alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
oesophageal carcinoma alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 1		
oral cavity cancer metastatic alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
oropharyngeal cancer alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
oropharyngeal squamous cell carcinoma alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatic carcinoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 3	1 / 8	
deaths causally related to treatment / all	0 / 2	0 / 3	
pancreatic carcinoma metastatic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
pancreatic neoplasm			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatic neuroendocrine tumour			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
papillary cystadenoma lymphomatosum			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
papillary thyroid cancer			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
parathyroid tumour benign alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
phaeochromocytoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pituitary tumour alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
plasma cell myeloma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
polycythaemia vera alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostate cancer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[4]</sup>	26 / 4648 (0.56%)	28 / 4658 (0.60%)	
occurrences causally related to treatment / all	0 / 26	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 0	

prostate cancer metastatic alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[5]</sup>	0 / 6036 (0.00%)	1 / 4658 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
prostate cancer recurrent alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[6]</sup>	3 / 4648 (0.06%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 3	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
prostate cancer stage ii alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[7]</sup>	2 / 4648 (0.04%)	1 / 4658 (0.02%)		
occurrences causally related to treatment / all	0 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
prostate cancer stage iv alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[8]</sup>	0 / 6036 (0.00%)	1 / 4658 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
prostatic adenoma alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[9]</sup>	1 / 4648 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
rectal adenocarcinoma alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)		
occurrences causally related to treatment / all	0 / 1	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
rectal cancer alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal cancer metastatic alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
rectal cancer stage 0 alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal cancer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal cancer recurrent alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
renal cell carcinoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
sinonasal papilloma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

skin cancer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
small cell lung cancer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
small cell lung cancer metastatic alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
spinal cord neoplasm alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
squamous cell carcinoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
squamous cell carcinoma of lung alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
squamous cell carcinoma of skin alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	5 / 6036 (0.08%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
squamous cell carcinoma of the oral cavity			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
squamous cell carcinoma of the tongue			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
squamous cell carcinoma of the vulva			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
t-cell lymphoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
testicular neoplasm			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[10]</sup>	1 / 4648 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
testicular seminoma (pure)			
alternative dictionary used: MedDRA 15.1			



subjects affected / exposed <sup>[11]</sup>	0 / 6036 (0.00%)	1 / 4658 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
throat cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
thymoma malignant			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
thyroid cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
thyroid neoplasm			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tongue carcinoma stage iv			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tongue neoplasm malignant stage unspecified			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
tonsil cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tonsil cancer metastatic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
transitional cell carcinoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
transitional cell carcinoma recurrent			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ureteric cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
uterine cancer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[12]</sup>	0 / 6036 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

uterine leiomyoma alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[13]</sup>	1 / 1388 (0.07%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
uterine neoplasm alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[14]</sup>	0 / 6036 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
accelerated hypertension alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aneurysm alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic aneurysm alternative dictionary used: MedDRA 15.1 subjects affected / exposed	18 / 6036 (0.30%)	14 / 6052 (0.23%)	
occurrences causally related to treatment / all	0 / 18	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic aneurysm rupture alternative dictionary used: MedDRA 15.1 subjects affected / exposed	3 / 6036 (0.05%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
aortic dissection alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic elongation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic occlusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic rupture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
aortic stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	18 / 6036 (0.30%)	17 / 6052 (0.28%)	
occurrences causally related to treatment / all	0 / 18	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 1	
aortitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arterial disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

arterial haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arterial insufficiency			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
arterial occlusive disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
arterial perforation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arterial stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arterial thrombosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriosclerosis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
artery dissection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
axillary vein thrombosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood pressure inadequately controlled			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
brachiocephalic artery stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
circulatory collapse			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
deep vein thrombosis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	11 / 6036 (0.18%)	16 / 6052 (0.26%)	
occurrences causally related to treatment / all	0 / 12	1 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
dry gangrene			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
embolism arterial			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
extremity necrosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
femoral artery aneurysm			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
femoral artery occlusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
femoral artery perforation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

haematoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	21 / 6036 (0.35%)	18 / 6052 (0.30%)	
occurrences causally related to treatment / all	1 / 23	2 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertensive crisis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	9 / 6036 (0.15%)	14 / 6052 (0.23%)	
occurrences causally related to treatment / all	1 / 9	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertensive emergency			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypotension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	11 / 6036 (0.18%)	17 / 6052 (0.28%)	
occurrences causally related to treatment / all	0 / 12	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypovolaemic shock			
alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
iliac artery occlusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
iliac artery rupture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intermittent claudication			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	16 / 6052 (0.26%)	
occurrences causally related to treatment / all	0 / 7	1 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
jugular vein thrombosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
lymphatic fistula			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lymphorrhoea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

malignant hypertension alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	4 / 6036 (0.07%) 0 / 4 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0		
orthostatic hypotension alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	11 / 6036 (0.18%) 1 / 11 0 / 0	4 / 6052 (0.07%) 0 / 4 0 / 0		
peripheral arterial occlusive disease alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	52 / 6036 (0.86%) 0 / 66 0 / 1	50 / 6052 (0.83%) 1 / 66 0 / 0		
peripheral artery aneurysm alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 6036 (0.03%) 0 / 2 0 / 0	2 / 6052 (0.03%) 0 / 2 0 / 0		
peripheral artery stenosis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	19 / 6036 (0.31%) 0 / 21 0 / 0	10 / 6052 (0.17%) 0 / 10 0 / 0		
peripheral artery thrombosis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	6 / 6052 (0.10%) 0 / 7 0 / 0		
peripheral embolism alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral ischaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	12 / 6036 (0.20%)	20 / 6052 (0.33%)	
occurrences causally related to treatment / all	0 / 14	0 / 25	
deaths causally related to treatment / all	0 / 0	0 / 1	
peripheral vascular disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	21 / 6036 (0.35%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	0 / 25	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
shock			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
shock haemorrhagic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
subclavian artery occlusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
subclavian artery stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

subclavian artery thrombosis alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
temporal arteritis alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
thrombophlebitis alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
thrombophlebitis superficial alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
thrombosis alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
varicose vein alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 2	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
vascular occlusion alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vasculitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vena cava thrombosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
venous thrombosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
venous thrombosis limb			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
abdominal hernia repair			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
adrenalectomy			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
amputation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
analgesic therapy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
aneurysm repair			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
angioplasty			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	12 / 6036 (0.20%)	8 / 6052 (0.13%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
ankle arthroplasty			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic aneurysm repair			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

aortic bypass alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0		
aortic valve repair alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0		
aortic valve replacement alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	4 / 6036 (0.07%) 0 / 4 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0		
arterial stent insertion alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6036 (0.00%) 0 / 0 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0		
atherectomy alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0		
atrial septal defect repair alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0		
autonomic nerve operation alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder neck suspension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[15]</sup>	1 / 1388 (0.07%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bone operation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchial lesion excision			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cancer surgery			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac ablation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac pacemaker battery replacement			
alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac pacemaker insertion alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac pacemaker replacement alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac rehabilitation therapy alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac resynchronisation therapy alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardioversion alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
carotid angioplasty alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

carotid endarterectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
carotid revascularisation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
carpal tunnel decompression			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cataract operation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
catheter placement			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholecystectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
colectomy			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	4 / 6036 (0.07%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
colostomy closure			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary angioplasty			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	13 / 6036 (0.22%)	21 / 6052 (0.35%)	
occurrences causally related to treatment / all	0 / 16	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary arterial stent insertion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	11 / 6036 (0.18%)	12 / 6052 (0.20%)	
occurrences causally related to treatment / all	0 / 11	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery bypass			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	54 / 6036 (0.89%)	59 / 6052 (0.97%)	
occurrences causally related to treatment / all	0 / 54	0 / 59	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary revascularisation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	82 / 6036 (1.36%)	79 / 6052 (1.31%)	
occurrences causally related to treatment / all	0 / 92	0 / 89	
deaths causally related to treatment / all	0 / 0	0 / 0	
cox-maze procedure			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

debridement			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diaphragmatic operation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
elective surgery			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
endarterectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
endovenous ablation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
explorative laparotomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
exploratory operation			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
eye operation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
foot amputation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric bypass			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal endoscopic therapy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
haematoma evacuation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

heart valve replacement alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
hernia repair alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
high frequency ablation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hip arthroplasty alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	11 / 6036 (0.18%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 12	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
hip surgery alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hospitalisation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hysterectomy alternative dictionary used: MedDRA 15.1			

subjects affected / exposed <sup>[16]</sup>	1 / 1388 (0.07%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
implantable defibrillator insertion alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	11 / 6036 (0.18%)	13 / 6052 (0.21%)	
occurrences causally related to treatment / all	0 / 11	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
implantable defibrillator replacement alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
incisional drainage alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
incisional hernia repair alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
inguinal hernia repair alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc operation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

intraocular lens implant alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
joint arthroplasty alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
knee arthroplasty alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	12 / 6036 (0.20%)	12 / 6052 (0.20%)	
occurrences causally related to treatment / all	0 / 14	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
knee operation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
leg amputation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
lens extraction alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lipoma excision alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
mastectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
medical device change			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
medical device removal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
mitral valve replacement			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
nephrectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
open reduction of fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

osteosynthesis alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
osteotomy alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
pancreatectomy alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
pancreaticoduodenectomy alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
penile repair alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[17]</sup>	0 / 6036 (0.00%)	1 / 4658 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
percutaneous coronary intervention alternative dictionary used: MedDRA 15.1 subjects affected / exposed	192 / 6036 (3.18%)	182 / 6052 (3.01%)		
occurrences causally related to treatment / all	1 / 217	1 / 214		
deaths causally related to treatment / all	0 / 0	0 / 0		
peripheral artery angioplasty alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	3 / 6036 (0.05%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral artery bypass			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	1 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral artery stent insertion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral endarterectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral nerve transposition			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral revascularisation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostate ablation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

prostatectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[18]</sup>	0 / 6036 (0.00%)	2 / 4658 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
radioactive iodine therapy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal prolapse repair			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal artery angioplasty			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal sympathetic nerve ablation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
resection of rectum			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
resuscitation			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
retinopexy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
rotator cuff repair			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
shoulder arthroplasty			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
shoulder operation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
skin neoplasm excision			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal decompression			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

spinal fusion surgery			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal laminectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal operation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
stent placement			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
sympathectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tenotomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
therapeutic embolisation			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
therapy cessation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
thrombectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
thrombosis prophylaxis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
thyroidectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
toe amputation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
tongue operation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

total adrenalectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
transmyocardial revascularisation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
transurethral bladder resection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
transurethral prostatectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[19]</sup>	2 / 4648 (0.04%)	1 / 4658 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tricuspid valve repair			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tumour excision			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ureteral stent insertion			
alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ureteral stent removal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vaginal prolapse repair			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[20]</sup>	1 / 1388 (0.07%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
valvuloplasty cardiac			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular graft			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
venous stent insertion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ventricular assist device insertion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

vitrectomy alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6036 (0.00%) 0 / 0 0 / 0	2 / 6052 (0.03%) 0 / 2 0 / 0	
wound drainage alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0	
Pregnancy, puerperium and perinatal conditions abortion spontaneous alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[21]</sup> occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6036 (0.00%) 0 / 0 0 / 0	1 / 1394 (0.07%) 0 / 1 0 / 0	
pregnancy alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[22]</sup> occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6036 (0.00%) 0 / 0 0 / 0	1 / 1394 (0.07%) 0 / 1 0 / 0	
General disorders and administration site conditions adverse drug reaction alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6036 (0.00%) 0 / 0 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0	
asthenia alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	5 / 6036 (0.08%) 0 / 5 0 / 0	9 / 6052 (0.15%) 2 / 9 0 / 0	
cardiac death			

alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 5	
chest discomfort			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	12 / 6052 (0.20%)	
occurrences causally related to treatment / all	0 / 7	2 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
chest pain			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	37 / 6036 (0.61%)	34 / 6052 (0.56%)	
occurrences causally related to treatment / all	3 / 38	0 / 42	
deaths causally related to treatment / all	0 / 0	0 / 0	
death			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	20 / 6036 (0.33%)	14 / 6052 (0.23%)	
occurrences causally related to treatment / all	2 / 20	0 / 14	
deaths causally related to treatment / all	2 / 20	0 / 14	
device breakage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
device dislocation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
device end of service			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
device failure			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
device inappropriate shock delivery			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
device malfunction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
device material issue			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
device occlusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
drowning			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

drug withdrawal syndrome alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
exercise tolerance decreased alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
gait disturbance alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
general physical health deterioration alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
generalised oedema alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	3 / 6036 (0.05%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 3	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
granuloma alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
hyperthermia alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertrophy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypothermia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
impaired healing			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
implant site haematoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
incarcerated hernia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic ulcer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

lead dislodgement			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
multi-organ failure			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 4	
necrobiosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
necrosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
non-cardiac chest pain			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	107 / 6036 (1.77%)	108 / 6052 (1.78%)	
occurrences causally related to treatment / all	1 / 123	1 / 118	
deaths causally related to treatment / all	0 / 0	0 / 0	
oedema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
oedema peripheral			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
pain			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pelvic mass			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral swelling			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
precancerous mucosal lesion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyrexia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
stent-graft endoleak			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	



sudden cardiac death			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	16 / 6036 (0.27%)	15 / 6052 (0.25%)	
occurrences causally related to treatment / all	0 / 16	0 / 15	
deaths causally related to treatment / all	0 / 16	0 / 15	
sudden death			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
systemic inflammatory response syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
thrombosis in device			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ulcer haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular stent occlusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular stent restenosis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	6 / 6036 (0.10%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular stent stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular stent thrombosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
vessel puncture site haematoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
anaphylactic shock			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
drug hypersensitivity			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypersensitivity			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
amastia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[23]</sup>	10 / 4648 (0.22%)	12 / 4658 (0.26%)	
occurrences causally related to treatment / all	0 / 10	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 1	
cervical polyp			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[24]</sup>	0 / 6036 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cystocele			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[25]</sup>	1 / 1388 (0.07%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dysmenorrhoea			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed <sup>[26]</sup>	0 / 6036 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
menometrorrhagia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[27]</sup>	0 / 6036 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ovarian cyst			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[28]</sup>	2 / 1388 (0.14%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
penile necrosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[29]</sup>	0 / 6036 (0.00%)	1 / 4658 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peyronie's disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[30]</sup>	1 / 4648 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostatitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[31]</sup>	4 / 4648 (0.09%)	2 / 4658 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectocele			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[32]</sup>	0 / 6036 (0.00%)	1 / 1394 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

testicular disorder alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[33]</sup> occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4648 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0	
uterine polyp alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[34]</sup> occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 1388 (0.07%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0	
uterine prolapse alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[35]</sup> occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 1388 (0.14%) 0 / 2 0 / 0	2 / 1394 (0.14%) 0 / 2 0 / 0	
Respiratory, thoracic and mediastinal disorders acute pulmonary oedema alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	8 / 6036 (0.13%) 0 / 10 0 / 1	5 / 6052 (0.08%) 0 / 5 0 / 0	
acute respiratory distress syndrome alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 1	2 / 6052 (0.03%) 0 / 2 0 / 1	
acute respiratory failure alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	14 / 6036 (0.23%) 0 / 16 0 / 1	20 / 6052 (0.33%) 0 / 20 0 / 3	
alveolitis alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
asphyxia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
aspiration			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
asthma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 6036 (0.13%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
atelectasis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchiectasis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchitis chronic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

bronchospasm			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	43 / 6036 (0.71%)	47 / 6052 (0.78%)	
occurrences causally related to treatment / all	0 / 55	0 / 55	
deaths causally related to treatment / all	0 / 1	0 / 3	
chylothorax			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cough			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
dyspnoea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	26 / 6036 (0.43%)	23 / 6052 (0.38%)	
occurrences causally related to treatment / all	0 / 29	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
dyspnoea exertional			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
emphysema			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
epistaxis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemoptysis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemothorax			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
hiccups			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hydrothorax			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypercapnia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	



hypoxia alternative dictionary used: MedDRA 15.1 subjects affected / exposed	7 / 6036 (0.12%)	4 / 6052 (0.07%)		
occurrences causally related to treatment / all	0 / 7	0 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
idiopathic pulmonary fibrosis alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 1		
interstitial lung disease alternative dictionary used: MedDRA 15.1 subjects affected / exposed	4 / 6036 (0.07%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	1 / 4	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
lung consolidation alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
lung infiltration alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 1	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
mediastinal haemorrhage alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
nasal septum deviation alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
organising pneumonia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pickwickian syndrome alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pleural effusion alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 6036 (0.13%)	12 / 6052 (0.20%)	
occurrences causally related to treatment / all	0 / 8	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
pleurisy alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pleuritic pain alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumomediastinum alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

pneumonia aspiration alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	8 / 6052 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 3	0 / 0	
pneumonitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumothorax alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumothorax spontaneous alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary alveolar haemorrhage alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary arterial hypertension alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary congestion alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary embolism			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	21 / 6036 (0.35%)	20 / 6052 (0.33%)	
occurrences causally related to treatment / all	1 / 22	1 / 20	
deaths causally related to treatment / all	0 / 1	0 / 2	
pulmonary fibrosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 2	
pulmonary hypertension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary infarction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary mass			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
pulmonary oedema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 6036 (0.13%)	8 / 6052 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	

respiratory arrest alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
respiratory distress alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
respiratory failure alternative dictionary used: MedDRA 15.1 subjects affected / exposed	17 / 6036 (0.28%)	16 / 6052 (0.26%)	
occurrences causally related to treatment / all	0 / 17	0 / 17	
deaths causally related to treatment / all	0 / 4	0 / 5	
sleep apnoea syndrome alternative dictionary used: MedDRA 15.1 subjects affected / exposed	3 / 6036 (0.05%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
tracheomalacia alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders abnormal behaviour alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
acute psychosis alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
acute stress disorder alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
adjustment disorder with anxiety alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
adjustment disorder alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
adjustment disorder with depressed mood alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
adjustment disorder with mixed disturbance of emotion and conduct alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
aggression alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
alcohol abuse			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
alcohol withdrawal syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
alcoholism			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
anxiety			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
anxiety disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
completed suicide			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	

confusional state			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
delirium			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
delirium tremens			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
depression			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
depression suicidal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
generalised anxiety disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hallucination			
alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypomania			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
major depression			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
mental disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
mental status changes			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	13 / 6052 (0.21%)	
occurrences causally related to treatment / all	0 / 3	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
panic attack			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
post-traumatic stress disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

psychogenic seizure alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
psychotic disorder alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicidal ideation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicide attempt alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
autoimmune hepatitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bile duct obstruction alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
bile duct stenosis alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bile duct stone			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
biliary colic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
biliary tract disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholangitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholangitis acute			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholecystitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	19 / 6036 (0.31%)	16 / 6052 (0.26%)	
occurrences causally related to treatment / all	0 / 20	1 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	

cholecystitis acute alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	12 / 6036 (0.20%)	15 / 6052 (0.25%)	
occurrences causally related to treatment / all	0 / 12	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholecystitis chronic alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholelithiasis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	23 / 6036 (0.38%)	22 / 6052 (0.36%)	
occurrences causally related to treatment / all	0 / 23	1 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholestasis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gallbladder disorder alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic cirrhosis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
hepatic lesion alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic steatosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatitis alcoholic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatomegaly			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hydrocholecystis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic hepatitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
jaundice			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

jaundice cholestatic alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
jaundice extrahepatic obstructive alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
liver disorder alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
liver injury alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
portal vein thrombosis alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
angiogram alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	7 / 6036 (0.12%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
anticoagulation drug level above therapeutic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriogram			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriogram coronary			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	16 / 6036 (0.27%)	17 / 6052 (0.28%)	
occurrences causally related to treatment / all	0 / 16	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriogram renal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
biopsy brain			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood creatinine increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood glucose decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood glucose increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood osmolarity decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood pressure increased			
alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac function test			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac stress test abnormal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiovascular evaluation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiovascular examination			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
carotid bruit			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
catheterisation cardiac			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	10 / 6036 (0.17%)	14 / 6052 (0.23%)	
occurrences causally related to treatment / all	0 / 11	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	

clostridium test positive alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
colonoscopy alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
computerised tomogram alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
computerised tomogram thorax alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
diagnostic procedure alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ejection fraction decreased alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	5 / 6036 (0.08%)	4 / 6052 (0.07%)		
occurrences causally related to treatment / all	0 / 5	0 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
electrocardiogram abnormal alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
electrocardiogram qt prolonged alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
endoscopy gastrointestinal alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gamma-glutamyltransferase increased alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemoglobin decreased alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
heart rate irregular alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic enzyme increased alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
international normalised ratio decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
international normalised ratio increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
investigation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
liver function test abnormal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myocardial necrosis marker increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophagogastroduodenoscopy			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral arteriogram			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostatic specific antigen increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[36]</sup>	2 / 4648 (0.04%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
transaminases increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
troponin increased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ureteroscopy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vitamin b12 decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

weight decreased alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 1 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0	
Injury, poisoning and procedural complications abdominal wound dehiscence alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0	
accident alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 6036 (0.03%) 0 / 2 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0	
accidental exposure to product alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0	
accidental overdose alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0	
acetabulum fracture alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0	
alcohol poisoning alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
anaemia postoperative			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
anal injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
anastomotic stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
anastomotic ulcer haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ankle fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	9 / 6036 (0.15%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
back injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

brain contusion alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
cartilage injury alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
cervical vertebral fracture alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)		
occurrences causally related to treatment / all	0 / 2	0 / 3		
deaths causally related to treatment / all	0 / 1	0 / 0		
chemical burn of skin alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
chemical injury alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
chest injury alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
clavicle fracture alternative dictionary used: MedDRA 15.1				



subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
compression fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
concussion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
contrast media reaction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
contusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery restenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

craniocerebral injury alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
crush injury alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cystitis radiation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
extradural haematoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
eye injury alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
facial bones fracture alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
fall alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	39 / 6036 (0.65%)	50 / 6052 (0.83%)	
occurrences causally related to treatment / all	0 / 40	0 / 53	
deaths causally related to treatment / all	0 / 0	0 / 0	
femoral neck fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
femur fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
fibula fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
foot fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
foreign body			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

fractured sacrum alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
gastrointestinal anastomotic complication alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
gastrointestinal injury alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
gastrointestinal stoma complication alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
graft thrombosis alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)		
occurrences causally related to treatment / all	0 / 3	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
gun shot wound alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 1	0 / 1		
hand fracture alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
head injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
heat illness			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hip fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
humerus fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
incisional hernia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

intentional overdose				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
jaw fracture				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
joint dislocation				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	5 / 6036 (0.08%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 6	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
joint injury				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)		
occurrences causally related to treatment / all	0 / 2	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
laceration				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 2	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
ligament injury				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
ligament sprain				
alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
limb traumatic amputation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lower limb fracture alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
lumbar vertebral fracture alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
meniscus injury alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
multiple fractures alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
multiple injuries alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	

muscle contusion alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
muscle injury alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
muscle rupture alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
nerve root injury lumbar alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
overdose alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
patella fracture alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
pelvic fracture alternative dictionary used: MedDRA 15.1				



subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral arterial reocclusion alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral artery restenosis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
periprosthetic fracture alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
poisoning alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
post concussion syndrome alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
post laminectomy syndrome alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

post procedural bile leak alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
post procedural complication alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
post procedural haematoma alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
post procedural haemorrhage alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	4 / 6036 (0.07%)	4 / 6052 (0.07%)		
occurrences causally related to treatment / all	0 / 4	0 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
post procedural myocardial infarction alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	5 / 6036 (0.08%)	3 / 6052 (0.05%)		
occurrences causally related to treatment / all	0 / 6	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
post procedural stroke alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
postoperative fever alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
postoperative ileus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
postoperative respiratory failure			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
postoperative thoracic procedure complication			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
postoperative wound complication			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
procedural haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
procedural hypotension			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pubis fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary contusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
radius fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
rib fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	8 / 6052 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
road traffic accident			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	15 / 6036 (0.25%)	15 / 6052 (0.25%)	
occurrences causally related to treatment / all	0 / 15	0 / 15	
deaths causally related to treatment / all	0 / 3	0 / 4	
seroma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

skull fracture alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)		
occurrences causally related to treatment / all	0 / 1	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 1		
soft tissue injury alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	1 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
spinal compression fracture alternative dictionary used: MedDRA 15.1 subjects affected / exposed	3 / 6036 (0.05%)	5 / 6052 (0.08%)		
occurrences causally related to treatment / all	0 / 3	0 / 5		
deaths causally related to treatment / all	0 / 0	0 / 0		
spinal cord injury alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
spinal cord injury cervical alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
spinal fracture alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 2	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
splenic rupture alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
sternal fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
stoma site haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
subdural haematoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 7	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
subdural haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
tendon injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tendon rupture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 6036 (0.13%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	

thermal burn			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
thoracic vertebral fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tibia fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
tooth fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
toxicity to various agents			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
traumatic amputation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
traumatic fracture			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
traumatic haematoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
traumatic intracranial haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
traumatic liver injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ulna fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
upper limb fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular graft occlusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	



vascular graft thrombosis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular pseudoaneurysm alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular pseudoaneurysm ruptured alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
wound alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
wound complication alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
wound dehiscence alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
wound haemorrhage alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
wrist fracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
arteriovenous malformation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial septal defect			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dermoid cyst			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hydrocele			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[37]</sup>	0 / 6036 (0.00%)	2 / 4658 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertrophic cardiomyopathy			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
leukodystrophy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
phimosi			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[38]</sup>	0 / 6036 (0.00%)	1 / 4658 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	9 / 6036 (0.15%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 9	1 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
acute myocardial infarction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	146 / 6036 (2.42%)	137 / 6052 (2.26%)	
occurrences causally related to treatment / all	5 / 168	4 / 149	
deaths causally related to treatment / all	0 / 16	0 / 4	
adams-stokes syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
angina pectoris			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	102 / 6036 (1.69%)	98 / 6052 (1.62%)	
occurrences causally related to treatment / all	3 / 113	3 / 103	
deaths causally related to treatment / all	0 / 0	0 / 0	
angina unstable			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	298 / 6036 (4.94%)	289 / 6052 (4.78%)	
occurrences causally related to treatment / all	7 / 389	6 / 363	
deaths causally related to treatment / all	0 / 2	0 / 0	
aortic valve disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
aortic valve incompetence			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic valve sclerosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic valve stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
arrhythmia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	

arteriosclerosis coronary artery alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriospasm coronary alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial flutter alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	25 / 6036 (0.41%)	16 / 6052 (0.26%)	
occurrences causally related to treatment / all	0 / 27	1 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial fibrillation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	86 / 6036 (1.42%)	78 / 6052 (1.29%)	
occurrences causally related to treatment / all	1 / 109	2 / 94	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial tachycardia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial thrombosis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrioventricular block alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	5 / 6036 (0.08%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrioventricular block complete alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 6036 (0.13%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
atrioventricular block second degree alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bradyarrhythmia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
bradycardia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 6036 (0.13%)	11 / 6052 (0.18%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac arrest alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	17 / 6036 (0.28%)	30 / 6052 (0.50%)	
occurrences causally related to treatment / all	1 / 18	0 / 32	
deaths causally related to treatment / all	1 / 12	0 / 21	
cardiac discomfort alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

cardiac failure alternative dictionary used: MedDRA 15.1 subjects affected / exposed	67 / 6036 (1.11%)	63 / 6052 (1.04%)		
occurrences causally related to treatment / all	1 / 79	1 / 78		
deaths causally related to treatment / all	0 / 9	0 / 8		
cardiac failure acute alternative dictionary used: MedDRA 15.1 subjects affected / exposed	11 / 6036 (0.18%)	9 / 6052 (0.15%)		
occurrences causally related to treatment / all	0 / 13	0 / 9		
deaths causally related to treatment / all	0 / 1	0 / 1		
cardiac failure chronic alternative dictionary used: MedDRA 15.1 subjects affected / exposed	7 / 6036 (0.12%)	10 / 6052 (0.17%)		
occurrences causally related to treatment / all	0 / 7	0 / 12		
deaths causally related to treatment / all	0 / 3	0 / 4		
cardiac failure congestive alternative dictionary used: MedDRA 15.1 subjects affected / exposed	95 / 6036 (1.57%)	103 / 6052 (1.70%)		
occurrences causally related to treatment / all	1 / 134	0 / 138		
deaths causally related to treatment / all	0 / 4	0 / 12		
cardiac tamponade alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
cardio-respiratory arrest alternative dictionary used: MedDRA 15.1 subjects affected / exposed	5 / 6036 (0.08%)	6 / 6052 (0.10%)		
occurrences causally related to treatment / all	0 / 5	2 / 7		
deaths causally related to treatment / all	0 / 3	1 / 5		
cardiogenic shock alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	8 / 6036 (0.13%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	1 / 8	0 / 7	
deaths causally related to treatment / all	1 / 4	0 / 4	
cardiomyopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
cardiopulmonary failure			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
cardiorenal syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
cardiovascular insufficiency			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronotropic incompetence			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
conduction disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	



congestive cardiomyopathy alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
coronary artery disease alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	37 / 6036 (0.61%)	44 / 6052 (0.73%)	
occurrences causally related to treatment / all	1 / 40	2 / 45	
deaths causally related to treatment / all	0 / 3	1 / 4	
coronary artery dissection alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery occlusion alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery stenosis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
diastolic dysfunction alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
dressler's syndrome alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
extrasystoles			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertensive heart disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intracardiac thrombus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic cardiomyopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
left ventricular dysfunction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
left ventricular failure			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

microvascular coronary artery disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
mitral valve incompetence			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
mitral valve stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
myocardial infarction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	82 / 6036 (1.36%)	100 / 6052 (1.65%)	
occurrences causally related to treatment / all	1 / 88	0 / 107	
deaths causally related to treatment / all	0 / 14	0 / 17	
myocardial ischaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	15 / 6036 (0.25%)	9 / 6052 (0.15%)	
occurrences causally related to treatment / all	1 / 16	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 3	
myocardial rupture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
nodal rhythm			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
palpitations			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pericardial effusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pericardial haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
pericarditis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
postinfarction angina			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
prinzmetal angina			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

right ventricular failure alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
sinus arrest alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
sinus bradycardia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
sinus node dysfunction alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	12 / 6036 (0.20%)	9 / 6052 (0.15%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
sinus tachycardia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
stress cardiomyopathy alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
supraventricular tachycardia alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	3 / 6036 (0.05%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
systolic dysfunction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tachyarrhythmia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tachycardia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ventricle rupture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ventricular arrhythmia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 2	
ventricular extrasystoles			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

ventricular fibrillation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 10	
deaths causally related to treatment / all	0 / 2	0 / 3	
ventricular hypokinesia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ventricular tachyarrhythmia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ventricular tachycardia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	16 / 6036 (0.27%)	24 / 6052 (0.40%)	
occurrences causally related to treatment / all	0 / 21	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
wolff-parkinson-white syndrome alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
acute disseminated encephalomyelitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
amyotrophic lateral sclerosis alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
aphasia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ataxia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
autonomic nervous system imbalance			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
brain injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
brain mass			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
brain stem stroke			
alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
carotid arteriosclerosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
carotid artery disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
carotid artery occlusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
carotid artery stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	21 / 6036 (0.35%)	39 / 6052 (0.64%)	
occurrences causally related to treatment / all	0 / 21	0 / 42	
deaths causally related to treatment / all	0 / 0	0 / 0	
carotid sinus syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
carpal tunnel syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

cerebellar ischaemia alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
cerebellar syndrome alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
cerebral arteriosclerosis alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
cerebral artery occlusion alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
cerebral haemorrhage alternative dictionary used: MedDRA 15.1 subjects affected / exposed	3 / 6036 (0.05%)	3 / 6052 (0.05%)		
occurrences causally related to treatment / all	0 / 3	0 / 3		
deaths causally related to treatment / all	0 / 1	0 / 2		
cerebral infarction alternative dictionary used: MedDRA 15.1 subjects affected / exposed	5 / 6036 (0.08%)	4 / 6052 (0.07%)		
occurrences causally related to treatment / all	2 / 5	1 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
cerebral ischaemia alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
cerebrovascular accident alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	61 / 6036 (1.01%)	62 / 6052 (1.02%)	
occurrences causally related to treatment / all	0 / 63	0 / 65	
deaths causally related to treatment / all	0 / 7	0 / 10	
cerebrovascular insufficiency alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
cervical myelopathy alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cervical radiculopathy alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
cognitive disorder alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
complex partial seizures alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

complex regional pain syndrome alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
dementia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
dementia alzheimer's type alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
diabetic neuropathy alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 9	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
dizziness alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
embolic cerebral infarction alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
embolic stroke alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
encephalopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
epilepsy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
essential tremor			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
guillain-barre syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhage intracranial			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
haemorrhagic stroke			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 3	

haemorrhagic transformation stroke alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 1		
headache alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	7 / 6036 (0.12%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	1 / 7	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
hemiparesis alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	3 / 6036 (0.05%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 3	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
hypoesthesia alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
hypoglycaemic coma alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
hypoxic-ischaemic encephalopathy alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 1	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 1		
intraventricular haemorrhage alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic stroke			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	25 / 6036 (0.41%)	18 / 6052 (0.30%)	
occurrences causally related to treatment / all	1 / 25	0 / 19	
deaths causally related to treatment / all	0 / 1	0 / 3	
lacunar infarction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
loss of consciousness			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
lumbar radiculopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
lumbosacral radiculopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metabolic encephalopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	

migraine			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
moyamoya disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
myasthenia gravis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
myelitis transverse			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myoclonus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
nerve compression			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
nerve root compression			
alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
nervous system disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
neuralgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
neuropathy peripheral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
normal pressure hydrocephalus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
paraesthesia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
parkinson's disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

partial seizures			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
peroneal nerve palsy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
polyneuropathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
post herpetic neuralgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
postictal paralysis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
presyncope			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 6036 (0.13%)	9 / 6052 (0.15%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
quadriparesis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
quadriplegia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
radicular syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
radiculopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
restless legs syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sciatica			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
seizure			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	

spinal claudication			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal cord compression			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal cord infarction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal cord oedema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
status epilepticus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
syncope			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	46 / 6036 (0.76%)	52 / 6052 (0.86%)	
occurrences causally related to treatment / all	0 / 48	1 / 54	
deaths causally related to treatment / all	0 / 0	0 / 0	
thalamus haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
thrombotic stroke			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
toxic encephalopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
transient global amnesia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
transient ischaemic attack			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	37 / 6036 (0.61%)	39 / 6052 (0.64%)	
occurrences causally related to treatment / all	1 / 44	0 / 42	
deaths causally related to treatment / all	0 / 0	0 / 0	
tremor			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

trigeminal neuralgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
uraemic encephalopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular dementia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular encephalopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vasogenic cerebral oedema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vertebral artery stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vertebrobasilar insufficiency			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vertigo cns origin			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
viith nerve paralysis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
vith nerve paralysis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vith nerve paresis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	30 / 6036 (0.50%)	38 / 6052 (0.63%)	
occurrences causally related to treatment / all	0 / 31	2 / 46	
deaths causally related to treatment / all	0 / 0	0 / 0	
aplastic anaemia			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
coagulopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cytopenia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
disseminated intravascular coagulation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
febrile neutropenia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhagic anaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
heparin-induced thrombocytopenia			
alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
immune thrombocytopenic purpura alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
iron deficiency anaemia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
leukocytosis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
lymphadenitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lymphadenopathy alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lymphadenopathy mediastinal alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

microcytic anaemia alternative dictionary used: MedDRA 15.1 subjects affected / exposed	3 / 6036 (0.05%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 3	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
normochromic normocytic anaemia alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 0	1 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
pancytopenia alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 2	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
pernicious anaemia alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
splenic infarction alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
spontaneous haemorrhage alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
thrombocytopenia alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
conductive deafness			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
deafness neurosensory			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ear pain			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
eustachian tube dysfunction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
meniere's disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
otosclerosis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tinnitus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vertigo			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	15 / 6052 (0.25%)	
occurrences causally related to treatment / all	0 / 7	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
vertigo positional			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
age-related macular degeneration			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cataract			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	15 / 6036 (0.25%)	14 / 6052 (0.23%)	
occurrences causally related to treatment / all	0 / 19	2 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
cataract nuclear			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
conjunctival haemorrhage alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic retinopathy alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diplopia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ectropion alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
entropion alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
eye haemorrhage alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

eye pain			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
eyelid ptosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
glaucoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
idiopathic orbital inflammation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
iridocyclitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
iritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
keratitis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
keratopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lens dislocation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
macular fibrosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
open angle glaucoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
optic atrophy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
optic ischaemic neuropathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

optic neuropathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
retinal artery occlusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
retinal detachment			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
retinal haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
retinopathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
visual acuity reduced			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
visual impairment			
alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vitreous haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
abdominal adhesions			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal compartment syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal distension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal hernia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal mass			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal pain			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	18 / 6036 (0.30%)	8 / 6052 (0.13%)	
occurrences causally related to treatment / all	0 / 20	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal pain upper			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal strangulated hernia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal wall cyst			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal wall haematoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
alcoholic pancreatitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

anal haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ascites			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic gastritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
coeliac artery stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
colitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	9 / 6052 (0.15%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
colitis ischaemic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 4	2 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
colitis microscopic			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
colitis ulcerative			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
colonic fistula			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
constipation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	8 / 6052 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
crohn's disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diarrhoea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
dieulafoy's vascular malformation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

diverticular perforation alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
diverticulum alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
diverticulum intestinal alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
diverticulum intestinal haemorrhagic alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	5 / 6036 (0.08%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 5	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
duodenal stenosis alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
duodenal ulcer alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	3 / 6036 (0.05%)	3 / 6052 (0.05%)		
occurrences causally related to treatment / all	0 / 3	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
duodenal ulcer haemorrhage alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
duodenal ulcer perforation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
duodenitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
dyspepsia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
dysphagia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
enteritis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
enterocolitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

enterovesical fistula alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0		
erosive oesophagitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6036 (0.00%) 0 / 0 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0		
faecal incontinence alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6036 (0.00%) 0 / 0 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0		
faecaloma alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6036 (0.00%) 0 / 0 0 / 0	4 / 6052 (0.07%) 0 / 4 0 / 0		
femoral hernia alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 6036 (0.00%) 0 / 0 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0		
food poisoning alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0		
gastric disorder alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric cyst			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric polyps			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric ulcer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric ulcer haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	10 / 6036 (0.17%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	0 / 10	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	



gastric ulcer perforation alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
gastritis alcoholic alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
gastritis erosive alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
gastritis haemorrhagic alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
gastrointestinal angiodysplasia alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 1	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
gastrointestinal angiodysplasia haemorrhagic alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)		
occurrences causally related to treatment / all	0 / 0	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
gastrointestinal disorder alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal haemorrhage alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	32 / 6036 (0.53%)	26 / 6052 (0.43%)	
occurrences causally related to treatment / all	1 / 32	0 / 32	
deaths causally related to treatment / all	0 / 1	0 / 2	
gastrointestinal inflammation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal ulcer haemorrhage alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrooesophageal reflux disease alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	13 / 6036 (0.22%)	11 / 6052 (0.18%)	
occurrences causally related to treatment / all	1 / 13	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
gingival bleeding alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
glossitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

haematemesis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	   3 / 6036 (0.05%) 0 / 3 0 / 1	   1 / 6052 (0.02%) 0 / 1 0 / 0		
haematochezia alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	   3 / 6036 (0.05%) 0 / 3 0 / 0	   1 / 6052 (0.02%) 0 / 1 0 / 0		
haemorrhoidal haemorrhage alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	   2 / 6036 (0.03%) 0 / 2 0 / 0	   1 / 6052 (0.02%) 0 / 1 0 / 0		
haemorrhoids alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	   4 / 6036 (0.07%) 0 / 4 0 / 0	   2 / 6052 (0.03%) 0 / 2 0 / 0		
heyde's syndrome alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	   1 / 6036 (0.02%) 0 / 1 0 / 0	   0 / 6052 (0.00%) 0 / 0 0 / 0		
hiatus hernia alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	   4 / 6036 (0.07%) 0 / 4 0 / 0	   2 / 6052 (0.03%) 0 / 2 0 / 0		
ileus alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	5 / 6036 (0.08%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
impaired gastric emptying alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
inguinal hernia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	15 / 6036 (0.25%)	13 / 6052 (0.21%)	
occurrences causally related to treatment / all	0 / 15	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal haemorrhage alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal infarction alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal ischaemia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
intestinal obstruction alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	

intestinal perforation alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	   2 / 6036 (0.03%) 0 / 2 0 / 1	   3 / 6052 (0.05%) 0 / 3 0 / 1		
intestinal prolapse alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	   0 / 6036 (0.00%) 0 / 0 0 / 0	   1 / 6052 (0.02%) 0 / 1 0 / 0		
intra-abdominal haematoma alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	   1 / 6036 (0.02%) 0 / 1 0 / 0	   0 / 6052 (0.00%) 0 / 0 0 / 0		
intra-abdominal haemorrhage alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	   0 / 6036 (0.00%) 0 / 0 0 / 0	   1 / 6052 (0.02%) 0 / 1 0 / 0		
irritable bowel syndrome alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	   0 / 6036 (0.00%) 0 / 0 0 / 0	   1 / 6052 (0.02%) 0 / 1 0 / 0		
jejunal perforation alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	   1 / 6036 (0.02%) 0 / 1 0 / 0	   0 / 6052 (0.00%) 0 / 0 0 / 0		
large intestinal haemorrhage alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
large intestinal obstruction alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
large intestinal stenosis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
large intestine perforation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
large intestine polyp alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	11 / 6052 (0.18%)	
occurrences causally related to treatment / all	0 / 7	1 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
localised intraabdominal fluid collection alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lower gastrointestinal haemorrhage alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	6 / 6036 (0.10%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
mallory-weiss syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
melaena			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
mesenteric vascular insufficiency			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
mouth haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
nausea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 6036 (0.13%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	1 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
odynophagia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

oedematous pancreatitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal achalasia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal oedema alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal spasm alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal stenosis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal ulcer alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophagitis alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatic mass			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatic pseudocyst			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	12 / 6036 (0.20%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	1 / 13	2 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatitis acute			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	10 / 6036 (0.17%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 10	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatitis chronic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancreatitis haemorrhagic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

pancreatitis necrotising				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
peptic ulcer				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 1	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
peptic ulcer haemorrhage				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
peritoneal adhesions				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
pneumoperitoneum				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
rectal haemorrhage				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 2	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
rectal polyp				
alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal ulcer haemorrhage alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
retroperitoneal effusion alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
retroperitoneal haematoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
retroperitoneal haemorrhage alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
salivary gland mass alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
small intestinal obstruction alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	11 / 6036 (0.18%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	

small intestinal perforation			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
subileus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
swollen tongue			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tongue haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tongue oedema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
umbilical hernia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
upper gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	11 / 6036 (0.18%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	0 / 12	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
volvulus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vomiting			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	9 / 6036 (0.15%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	1 / 12	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
decubitus ulcer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dermal cyst			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
dermatomyositis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic foot			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	10 / 6036 (0.17%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 11	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic neuropathic ulcer			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
erythema multiforme			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
henoch-schonlein purpura			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperhidrosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperkeratosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

hypersensitivity vasculitis alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	1 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
psoriasis alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
rash alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 1	1 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
skin lesion alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
skin ulcer alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	9 / 6036 (0.15%)	5 / 6052 (0.08%)		
occurrences causally related to treatment / all	1 / 9	0 / 6		
deaths causally related to treatment / all	0 / 0	0 / 0		
urticaria alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	1 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
vasculitic rash alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	48 / 6036 (0.80%)	67 / 6052 (1.11%)	
occurrences causally related to treatment / all	0 / 58	2 / 81	
deaths causally related to treatment / all	0 / 0	0 / 3	
acute prerenal failure			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
azotaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder outlet obstruction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder prolapse			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
calculus ureteric			
alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	7 / 6036 (0.12%)	9 / 6052 (0.15%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
calculus urinary			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic kidney disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	9 / 6036 (0.15%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	1 / 10	3 / 11	
deaths causally related to treatment / all	0 / 0	1 / 1	
cystitis haemorrhagic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cystitis ulcerative			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic nephropathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
dysuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

glomerulonephritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
glomerulosclerosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
haematuria			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	11 / 6036 (0.18%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 14	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
hydronephrosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypotonic urinary bladder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
nephrolithiasis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	19 / 6036 (0.31%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	0 / 20	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
nephropathy			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
nephrosclerosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
nephrotic syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
obstructive uropathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pelvi-ureteric obstruction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
prerenal failure			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal artery stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	

renal colic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal cyst			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal failure			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	14 / 6036 (0.23%)	11 / 6052 (0.18%)	
occurrences causally related to treatment / all	0 / 16	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 2	
renal haematoma			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal impairment			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
renal infarct			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal injury			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal tubular necrosis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal vein thrombosis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
stress urinary incontinence alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tubulointerstitial nephritis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ureteral disorder alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
urethral haemorrhage alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

urethral stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary bladder haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary incontinence			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary retention			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	9 / 6052 (0.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract obstruction			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
autoimmune thyroiditis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
goitre			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperparathyroidism			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperparathyroidism primary			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
ankylosing spondylitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arthralgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	17 / 6052 (0.28%)	
occurrences causally related to treatment / all	0 / 8	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	9 / 6036 (0.15%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
arthropathy			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
back pain			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	15 / 6036 (0.25%)	14 / 6052 (0.23%)	
occurrences causally related to treatment / all	0 / 15	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
bone pain			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bursitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cervical spinal stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
chondrocalcinosis pyrophosphate			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
compartment syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	



costochondritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
dupuytren's contracture			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
facet joint syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
fibromyalgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
foot deformity			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
gouty arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
groin pain			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemarthrosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc degeneration			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc disorder			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc protrusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	14 / 6052 (0.23%)	
occurrences causally related to treatment / all	0 / 6	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
joint instability			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
joint swelling			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

kyphosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ligament laxity			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lumbar spinal stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	13 / 6036 (0.22%)	23 / 6052 (0.38%)	
occurrences causally related to treatment / all	0 / 13	1 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
mobility decreased			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
muscle haemorrhage			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
muscle spasms			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
muscular weakness			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	4 / 6036 (0.07%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
musculoskeletal chest pain alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	17 / 6036 (0.28%)	15 / 6052 (0.25%)	
occurrences causally related to treatment / all	0 / 18	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
musculoskeletal discomfort alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
musculoskeletal pain alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
musculoskeletal stiffness alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myalgia alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
neck pain alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

neuropathic arthropathy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
osteoarthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	70 / 6036 (1.16%)	66 / 6052 (1.09%)	
occurrences causally related to treatment / all	0 / 76	1 / 75	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteochondrosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteonecrosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pain in extremity			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	2 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pain in jaw			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
polymyalgia rheumatica			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pseudarthrosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rhabdomyolysis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	1 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
rheumatoid arthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
rotator cuff syndrome			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 6036 (0.13%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
scoliosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

spinal column stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 1	
spinal osteoarthritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	8 / 6052 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal pain			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
spondylolisthesis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
synovial cyst			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
synovitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tendon disorder			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tendonitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
trigger finger			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vertebral foraminal stenosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
abdominal abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal sepsis			
alternative dictionary used: MedDRA 15.1			



subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
abdominal wall abscess alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal wall infection alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
abscess alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
abscess limb alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
abscess neck alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
abscess of salivary gland alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

abscess oral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
acute sinusitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
anal abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
appendicitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	9 / 6036 (0.15%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
appendicitis perforated			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriosclerotic gangrene			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteritis infective			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arthritis bacterial			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
atypical pneumonia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bacteraemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
bacterial infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bacterial sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
biliary sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

biliary tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
breast cellulitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	25 / 6036 (0.41%)	18 / 6052 (0.30%)	
occurrences causally related to treatment / all	0 / 25	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchitis viral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bursitis infective			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	41 / 6036 (0.68%)	42 / 6052 (0.69%)	
occurrences causally related to treatment / all	0 / 48	0 / 45	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis staphylococcal			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholangitis infective			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholecystitis infective			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic sinusitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
clostridium difficile colitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	8 / 6052 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
clostridium difficile infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
clostridium difficile sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

colonic abscess alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0		
cystitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	6 / 6036 (0.10%) 0 / 6 0 / 0	2 / 6052 (0.03%) 0 / 2 0 / 0		
device related infection alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	2 / 6052 (0.03%) 0 / 2 0 / 0		
diabetic foot infection alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0		
diabetic gangrene alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 6036 (0.03%) 0 / 2 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0		
diverticulitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	13 / 6036 (0.22%) 0 / 13 0 / 0	5 / 6052 (0.08%) 0 / 5 0 / 0		
endocarditis alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
endocarditis bacterial			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
endocarditis enterococcal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
endophthalmitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
enterobacter infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
enterococcal bacteraemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
enterococcal infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

enterococcal sepsis alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
epididymitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed <sup>[39]</sup>	1 / 4648 (0.02%)	1 / 4658 (0.02%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
erysipelas alternative dictionary used: MedDRA 15.1 subjects affected / exposed	6 / 6036 (0.10%)	5 / 6052 (0.08%)		
occurrences causally related to treatment / all	0 / 8	0 / 5		
deaths causally related to treatment / all	0 / 0	0 / 0		
escherichia bacteraemia alternative dictionary used: MedDRA 15.1 subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
escherichia infection alternative dictionary used: MedDRA 15.1 subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
escherichia pyelonephritis alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
escherichia sepsis alternative dictionary used: MedDRA 15.1				



subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
escherichia urinary tract infection alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
extradural abscess alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
febrile infection alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
folliculitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gallbladder abscess alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gallbladder empyema alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

gangrene			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	7 / 6036 (0.12%)	11 / 6052 (0.18%)	
occurrences causally related to treatment / all	0 / 7	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastritis viral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	16 / 6036 (0.27%)	16 / 6052 (0.26%)	
occurrences causally related to treatment / all	0 / 19	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis norovirus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis viral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 6036 (0.13%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
giardiasis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
graft infection			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
groin abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
h1n1 influenza			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
haematoma infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatitis c			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatitis viral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
herpes zoster			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

implant site cellulitis				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
implant site infection				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
incision site infection				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
infected bite				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
infected fistula				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
infected seroma				
alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
infected skin ulcer				
alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	4 / 6036 (0.07%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
infectious colitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
infectious pleural effusion			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
infective exacerbation of chronic obstructive airways disease			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
influenza			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	11 / 6036 (0.18%)	9 / 6052 (0.15%)	
occurrences causally related to treatment / all	0 / 11	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
infusion site cellulitis			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
infusion site infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral discitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
keratitis bacterial			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
klebsiella sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
liver abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
localised infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	

lower respiratory tract infection alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
lung abscess alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung infection alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
mastoiditis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
mediastinitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myelitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
nail bed infection alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
necrotising fasciitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal candidiasis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
orbital infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteomyelitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	13 / 6036 (0.22%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 15	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteomyelitis acute			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteomyelitis bacterial			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	



osteomyelitis chronic alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
parainfluenzae virus infection alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
parotitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
parvovirus infection alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pelvic abscess alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
penile abscess alternative dictionary used: MedDRA 15.1			
subjects affected / exposed <sup>[40]</sup>	1 / 4648 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
perihepatic abscess alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
periodontitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
perirectal abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peritonitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
peritonitis bacterial			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peritonsillar abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pharyngitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

pilonidal cyst			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	115 / 6036 (1.91%)	112 / 6052 (1.85%)	
occurrences causally related to treatment / all	0 / 128	0 / 122	
deaths causally related to treatment / all	0 / 7	0 / 4	
pneumonia bacterial			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia chlamydial			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia fungal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia influenzal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia legionella			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia parainfluenzae viral alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia pneumococcal alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia staphylococcal alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
pneumonia streptococcal alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia viral alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
post procedural cellulitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

post procedural infection alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
post procedural sepsis alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
postoperative abscess alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
postoperative wound infection alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	4 / 6036 (0.07%)	6 / 6052 (0.10%)		
occurrences causally related to treatment / all	0 / 4	0 / 6		
deaths causally related to treatment / all	0 / 0	0 / 0		
pulmonary sepsis alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 1		
pulmonary tuberculosis alternative dictionary used: MedDRA 15.1				
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)		
occurrences causally related to treatment / all	0 / 1	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
pyelonephritis alternative dictionary used: MedDRA 15.1				

subjects affected / exposed	7 / 6036 (0.12%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	1 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyelonephritis acute			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyelonephritis chronic			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
respiratory syncytial virus infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
respiratory tract infection viral			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
rhinovirus infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

salmonellosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	44 / 6036 (0.73%)	28 / 6052 (0.46%)	
occurrences causally related to treatment / all	0 / 49	0 / 32	
deaths causally related to treatment / all	0 / 7	0 / 7	
septic shock			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	10 / 6036 (0.17%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 10	0 / 7	
deaths causally related to treatment / all	0 / 4	0 / 3	
sialoadenitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
sinusitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
sinusitis fungal			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
skin candida			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
soft tissue infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal cord abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
staphylococcal infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
staphylococcal mediastinitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
staphylococcal sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	



streptococcal bacteraemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
streptococcal sepsis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
subcutaneous abscess			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
tooth infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tracheobronchitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
upper respiratory tract infection			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract infection			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	19 / 6036 (0.31%)	32 / 6052 (0.53%)	
occurrences causally related to treatment / all	0 / 22	0 / 36	
deaths causally related to treatment / all	0 / 0	0 / 1	
urinary tract infection bacterial alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract infection pseudomonal alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
urosepsis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	16 / 6036 (0.27%)	14 / 6052 (0.23%)	
occurrences causally related to treatment / all	0 / 17	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 1	
vestibular neuronitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
viral infection alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	3 / 6052 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
viral labyrinthitis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

wound abscess alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0	
wound infection alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	4 / 6036 (0.07%) 0 / 4 0 / 0	7 / 6052 (0.12%) 0 / 8 0 / 0	
wound infection bacterial alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	0 / 6052 (0.00%) 0 / 0 0 / 0	
wound infection staphylococcal alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 6036 (0.03%) 0 / 2 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0	
Metabolism and nutrition disorders decreased appetite alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 6036 (0.02%) 0 / 1 0 / 0	1 / 6052 (0.02%) 0 / 1 0 / 0	
dehydration alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	15 / 6036 (0.25%) 1 / 15 0 / 1	26 / 6052 (0.43%) 0 / 28 0 / 0	
diabetes mellitus alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	11 / 6036 (0.18%)	20 / 6052 (0.33%)	
occurrences causally related to treatment / all	0 / 11	1 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetes mellitus inadequate control alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	8 / 6036 (0.13%)	14 / 6052 (0.23%)	
occurrences causally related to treatment / all	0 / 9	1 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic ketoacidosis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	3 / 6036 (0.05%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic metabolic decompensation alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
electrolyte imbalance alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
failure to thrive alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
fluid overload alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

gout			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	4 / 6036 (0.07%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypercalcaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperglycaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	13 / 6036 (0.22%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	0 / 13	1 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperkalaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	9 / 6036 (0.15%)	9 / 6052 (0.15%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 1	0 / 0	
hyperosmolar hyperglycaemic state			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypoglycaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	17 / 6036 (0.28%)	18 / 6052 (0.30%)	
occurrences causally related to treatment / all	1 / 17	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypokalaemia			
alternative dictionary used: MedDRA 15.1			

subjects affected / exposed	4 / 6036 (0.07%)	7 / 6052 (0.12%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypomagnesaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyponatraemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	9 / 6052 (0.15%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypovolaemia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	2 / 6052 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ketoacidosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lactic acidosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
malnutrition			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

metabolic acidosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	2 / 6036 (0.03%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
obesity			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	5 / 6036 (0.08%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	6 / 6036 (0.10%)	6 / 6052 (0.10%)	
occurrences causally related to treatment / all	4 / 6	2 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
vitamin b12 deficiency			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

#### Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in female subjects. The number of subjects exposed has been adjusted accordingly.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in female subjects. The number of subjects exposed has been adjusted accordingly.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male subjects. The number of subjects exposed has been adjusted accordingly.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male subjects. The number of subjects exposed has been adjusted accordingly.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male subjects. The number of subjects exposed has been adjusted accordingly.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male subjects. The number of subjects exposed has been adjusted accordingly.





[40] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed to this adverse event. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male subjects. The number of subjects exposed has been adjusted accordingly.

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

<b>Non-serious adverse events</b>	TR1_LY2484595-130mg	TR2_PLACEBO	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2659 / 6036 (44.05%)	2529 / 6052 (41.79%)	
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	453 / 6036 (7.50%)	403 / 6052 (6.66%)	
occurrences (all)	508	466	
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	389 / 6036 (6.44%)	352 / 6052 (5.82%)	
occurrences (all)	435	407	
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	472 / 6036 (7.82%)	414 / 6052 (6.84%)	
occurrences (all)	568	484	
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	327 / 6036 (5.42%)	279 / 6052 (4.61%)	
occurrences (all)	367	304	
dyspnoea			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	305 / 6036 (5.05%)	307 / 6052 (5.07%)	
occurrences (all)	339	341	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	375 / 6036 (6.21%)	370 / 6052 (6.11%)	
occurrences (all)	426	425	

back pain alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all)	399 / 6036 (6.61%) 442	379 / 6052 (6.26%) 412	
pain in extremity alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all)	339 / 6036 (5.62%) 412	329 / 6052 (5.44%) 388	
Infections and infestations bronchitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all)	363 / 6036 (6.01%) 456	375 / 6052 (6.20%) 443	
nasopharyngitis alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all)	452 / 6036 (7.49%) 603	465 / 6052 (7.68%) 602	
upper respiratory tract infection alternative dictionary used: MedDRA 15.1 subjects affected / exposed occurrences (all)	327 / 6036 (5.42%) 397	327 / 6052 (5.40%) 410	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported