

**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	Slovakia: 233
Country: Number of subjects enrolled	South Africa: 153
Country: Number of subjects enrolled	Spain: 131
Country: Number of subjects enrolled	Sweden: 66
Country: Number of subjects enrolled	Switzerland: 29
Country: Number of subjects enrolled	Taiwan: 105
Country: Number of subjects enrolled	Turkey: 3
Country: Number of subjects enrolled	Ukraine: 133
Country: Number of subjects enrolled	United Kingdom: 116
Country: Number of subjects enrolled	United States: 4475
Country: Number of subjects enrolled	Argentina: 180
Country: Number of subjects enrolled	Australia: 319
Country: Number of subjects enrolled	Austria: 68
Country: Number of subjects enrolled	Belgium: 84
Country: Number of subjects enrolled	Brazil: 110
Country: Number of subjects enrolled	Bulgaria: 231
Country: Number of subjects enrolled	Canada: 1245

Country: Number of subjects enrolled	China: 445
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	Hong Kong: 52
Country: Number of subjects enrolled	Hungary: 233
Country: Number of subjects enrolled	Israel: 146
Country: Number of subjects enrolled	Italy: 83
Country: Number of subjects enrolled	Japan: 407
Country: Number of subjects enrolled	Korea, Republic of: 181
Country: Number of subjects enrolled	Lithuania: 28
Country: Number of subjects enrolled	Mexico: 466
Country: Number of subjects enrolled	Netherlands: 340
Country: Number of subjects enrolled	New Zealand: 127
Country: Number of subjects enrolled	Poland: 483
Country: Number of subjects enrolled	Romania: 130
Country: Number of subjects enrolled	Russian Federation: 167
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
Arm title	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).

Arm title	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.

Number of subjects in period 1	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 ^[1]	6054 ^[2]		
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 ^[3]	6054 ^[4]		
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

Statistical analysis title	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

Statistical analysis title	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)	

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

Statistical analyses

Statistical analysis title	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
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	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 ^[1]	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 ^[2]	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	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	
keratinising squamous cell carcinoma of nasopharynx alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 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	
keratoacanthoma alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	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 benign 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	
laryngeal 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	
laryngeal 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	
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 ^[3]	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 iiiia alternative dictionary used: MedDRA 15.1		
subjects affected / exposed	1 / 6036 (0.02%)	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 ^[4]	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 ^[5]	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 ^[6]	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 ^[7]	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 ^[8]	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 ^[9]	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 ^[10]	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 ^[11]	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 ^[12]	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 ^[13]	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 ^[14]	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	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	
orthostatic hypotension alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	11 / 6036 (0.18%)	4 / 6052 (0.07%)	
occurrences causally related to treatment / all	1 / 11	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral arterial occlusive disease alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	52 / 6036 (0.86%)	50 / 6052 (0.83%)	
occurrences causally related to treatment / all	0 / 66	1 / 66	
deaths causally related to treatment / all	0 / 1	0 / 0	
peripheral artery aneurysm 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	
peripheral artery stenosis alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	19 / 6036 (0.31%)	10 / 6052 (0.17%)	
occurrences causally related to treatment / all	0 / 21	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral artery thrombosis 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 / 7	
deaths causally related to treatment / all	0 / 0	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	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	
aortic valve 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	
aortic valve replacement			
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	
arterial stent 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	
atherectomy			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	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 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	
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 ^[15]	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 ^[16]	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 ^[17]	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 ^[18]	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 ^[19]	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 ^[20]	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 ^[21] 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 ^[22] 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 ^[23]	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 ^[24]	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 ^[25]	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 ^[26]	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 ^[27]	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 ^[28]	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 ^[29]	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 ^[30]	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 ^[31]	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 ^[32]	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 ^[33]	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	
uterine polyp alternative dictionary used: MedDRA 15.1 subjects affected / exposed ^[34]	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 prolapse alternative dictionary used: MedDRA 15.1 subjects affected / exposed ^[35]	2 / 1388 (0.14%)	2 / 1394 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
acute pulmonary oedema alternative dictionary used: MedDRA 15.1 subjects affected / exposed	8 / 6036 (0.13%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
acute respiratory distress 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 / 1	0 / 1	
acute respiratory failure alternative dictionary used: MedDRA 15.1 subjects affected / exposed	14 / 6036 (0.23%)	20 / 6052 (0.33%)	
occurrences causally related to treatment / all	0 / 16	0 / 20	
deaths causally related to treatment / all	0 / 1	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 ^[36]	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	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	
Injury, poisoning and procedural complications abdominal 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	
accident 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	
accidental exposure to product alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
accidental overdose alternative dictionary used: MedDRA 15.1 subjects affected / exposed	1 / 6036 (0.02%)	0 / 6052 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
acetabulum 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	
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 ^[37]	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	
phimosis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed ^[38]	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	
quadripareisis			
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	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	
erosive oesophagitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
faecal 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	
faecaloma			
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	
femoral 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	
food poisoning			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	1 / 6036 (0.02%)	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 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	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	
haematochezia			
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	
haemorrhoidal 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	
haemorrhoids			
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	
heyde's 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	
hiatus 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	
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	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 / 1	
intestinal prolapse alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	0 / 6036 (0.00%)	1 / 6052 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
intra-abdominal 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	
intra-abdominal 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	
irritable bowel 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	
jejunal 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	
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	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	
cystitis			
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	
device related 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	
diabetic foot 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	
diabetic gangrene			
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	
diverticulitis			
alternative dictionary used: MedDRA 15.1			
subjects affected / exposed	13 / 6036 (0.22%)	5 / 6052 (0.08%)	
occurrences causally related to treatment / all	0 / 13	0 / 5	
deaths causally related to treatment / all	0 / 0	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 ^[39]	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 ^[40]	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	1 / 6036 (0.02%)	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 infection 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 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
wound infection 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	
wound infection staphylococcal 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	
Metabolism and nutrition disorders decreased appetite 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	
dehydration alternative dictionary used: MedDRA 15.1 subjects affected / exposed	15 / 6036 (0.25%)	26 / 6052 (0.43%)	
occurrences causally related to treatment / all	1 / 15	0 / 28	
deaths causally related to treatment / all	0 / 1	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.

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 %

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

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported