



Clinical trial results:

The Effect of Dulaglutide on Major Cardiovascular Events in Patients with Type 2 Diabetes: Researching Cardiovascular Events with a Weekly INcretin in Diabetes (REWIND)

Summary

EudraCT number	2010-023799-21
Trial protocol	SE LT LV CZ HU GB PL ES BG DE
Global end of trial date	21 August 2018

Results information

Result version number	v1
This version publication date	25 August 2019
First version publication date	25 August 2019

Trial information

Trial identification

Sponsor protocol code	H9X-MC-GBDJ
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01394952
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 13438

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 877CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559,

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 October 2018
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	21 August 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this trial is to assess whether dulaglutide can reduce major cardiovascular events and other serious outcomes in persons with type 2 diabetes, when added to their anti-hyperglycemic regimen.

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	22 July 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Czech Republic: 213
Country: Number of subjects enrolled	United States: 943
Country: Number of subjects enrolled	Russian Federation: 101
Country: Number of subjects enrolled	Korea, Republic of: 122
Country: Number of subjects enrolled	Sweden: 236
Country: Number of subjects enrolled	Latvia: 78
Country: Number of subjects enrolled	Brazil: 275
Country: Number of subjects enrolled	Poland: 608
Country: Number of subjects enrolled	Chile: 128
Country: Number of subjects enrolled	Bulgaria: 101
Country: Number of subjects enrolled	Lithuania: 105
Country: Number of subjects enrolled	Colombia: 785
Country: Number of subjects enrolled	Argentina: 1395
Country: Number of subjects enrolled	Romania: 1085
Country: Number of subjects enrolled	Hungary: 223
Country: Number of subjects enrolled	United Kingdom: 136
Country: Number of subjects enrolled	Spain: 127
Country: Number of subjects enrolled	New Zealand: 234
Country: Number of subjects enrolled	Canada: 1128

Country: Number of subjects enrolled	Taiwan: 26
Country: Number of subjects enrolled	South Africa: 741
Country: Number of subjects enrolled	Mexico: 438
Country: Number of subjects enrolled	Australia: 88
Country: Number of subjects enrolled	Germany: 585
Worldwide total number of subjects	9901
EEA total number of subjects	3497

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)	4645
From 65 to 84 years	5213
85 years and over	43

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

Participants were randomized to either placebo or Dulaglutide. Completers included participants for whom vital status was ascertained during the study close-out period and endpoint completers.

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

Arms

Are arms mutually exclusive? Yes

Arm title	Placebo
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Arm description:

Placebo was administered once weekly, subcutaneously

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	Placebo
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered subcutaneously

Arm title	Dulaglutide
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Arm description:

Dulaglutide 1.5 mg was administered once weekly, subcutaneously

Arm type	Experimental
Investigational medicinal product name	Dulaglutide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

1.5 mg Dulaglutide was administered once weekly, subcutaneously

Number of subjects in period 1	Placebo	Dulaglutide
Started	4952	4949
Received at least one dose of study drug	4949	4943
Completed	4935	4932
Not completed	17	17
Consent withdrawn by subject	10	5
Physician decision	2	-
Sponsor Decision	5	7
Lost to follow-up	-	5

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	9901	9901	
Age categorical			
Units: Subjects			
<=18 years	0	0	
Between 18 and 65 years	4645	4645	
>=65 years	5256	5256	
Age continuous			
Units: years			
arithmetic mean	66.2	-	
standard deviation	± 6.5		
Gender categorical			
Units: Subjects			
Female	4589	4589	
Male	5312	5312	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	124	124	
Not Hispanic or Latino	802	802	
Unknown or Not Reported	8975	8975	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	1092	1092	
Asian	434	434	
Native Hawaiian or Other Pacific Islander	34	34	
Black or African American	677	677	
White	7498	7498	
More than one race	166	166	
Unknown or Not Reported	0	0	
Region of Enrollment			
Puerto Rico is combined with the United States for this study.			
Units: Subjects			
United States	943	943	
Czechia	213	213	
Russia	101	101	
South Korea	122	122	
Sweden	236	236	
Latvia	78	78	
Brazil	275	275	
Poland	608	608	
Chile	128	128	
Bulgaria	101	101	

Lithuania	105	105	
Colombia	785	785	
Argentina	1395	1395	
Romania	1085	1085	
Hungary	223	223	
United Kingdom	136	136	
Spain	127	127	
New Zealand	234	234	
Canada	1128	1128	
Taiwan	26	26	
South Africa	741	741	
Mexico	438	438	
Australia	88	88	
Germany	585	585	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Placebo was administered once weekly, subcutaneously	
Reporting group title	Dulaglutide
Reporting group description:	
Dulaglutide 1.5 mg was administered once weekly, subcutaneously	

Primary: Number of Participants Who Experienced an Event for Time From Randomization to First Occurrence of Cardiovascular Death, Non-fatal Myocardial Infarction, or Non-fatal Stroke (a Composite Cardiovascular Outcome)

End point title	Number of Participants Who Experienced an Event for Time From Randomization to First Occurrence of Cardiovascular Death, Non-fatal Myocardial Infarction, or Non-fatal Stroke (a Composite Cardiovascular Outcome)
End point description:	
The time from randomization to first occurrence of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke (a composite endpoint) was evaluated using time-to-event analysis. The primary analysis model was a Cox proportional hazards regression model for the time to the first occurrence of a primary endpoint event, with treatment as a fixed effect using the intent-to-treat population. The number of participants who experienced primary cardiovascular (CV) endpoint event is presented.	
End point type	Primary
End point timeframe:	
From randomization to first occurrence or death from any cause or study completion (Median Follow-Up of 5.4 Years)	

End point values	Placebo	Dulaglutide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4952 ^[1]	4949 ^[2]		
Units: participants	663	594		

Notes:

[1] - All randomized participants.

[2] - All randomized participants.

Statistical analyses

Statistical analysis title	Number of Participants Who Experienced an Event
Statistical analysis description:	
Primary CV endpoint	
Comparison groups	Placebo v Dulaglutide

Number of subjects included in analysis	9901
Analysis specification	Pre-specified
Analysis type	superiority ^[3]
P-value	= 0.026
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95.33 %
sides	2-sided
lower limit	0.79
upper limit	0.99

Notes:

[3] - Superiority was declared if the upper limit of the 2-sided 95.33% CI of the hazard ratio was below 1.0 (after adjustment for the interim analysis). Once superiority was achieved for the primary endpoint, multiplicity adjustments using the graphical approach were performed for secondary efficacy endpoints in order to control the overall Type I error rate at a 2-sided alpha level of 0.0467.

Secondary: Number of Participants Who Experienced an Event for Time to first occurrence after randomization of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke, individually

End point title	Number of Participants Who Experienced an Event for Time to first occurrence after randomization of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke, individually
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End point description:

The time from randomization to first occurrence of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke (individually) was evaluated using time-to-event analysis via the Cox proportional hazards regression model where response equals treatment. Death from CV causes is defined as a death resulting from an acute myocardial infarction (MI), sudden cardiac death, death due to heart failure, death due to stroke, or death due to other CV causes. The number of participants who experienced an event is presented.

End point type	Secondary
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End point timeframe:

From randomization to first occurrence or study completion (Median Follow-Up of 5.4 Years)

End point values	Placebo	Dulaglutide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4952 ^[4]	4949 ^[5]		
Units: participants				
Death from CV causes	346	317		
Nonfatal MI	212	205		
Nonfatal stroke	175	135		

Notes:

[4] - All randomized participants.

[5] - All randomized participants.

Statistical analyses

Statistical analysis title	Number of Participants Who Experienced an Event
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Statistical analysis description:

Death from CV causes

Comparison groups	Placebo v Dulaglutide
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Number of subjects included in analysis	9901
Analysis specification	Pre-specified
Analysis type	superiority ^[6]
P-value	= 0.211
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.06

Notes:

[6] - Death from CV causes. Multiplicity adjustments using the graphical approach were performed for secondary efficacy endpoints in order to control the overall Type I error rate at a 2-sided alpha level of 0.0467.

Statistical analysis title	Number of Participants Who Experienced an Event
Statistical analysis description:	
Nonfatal MI	
Comparison groups	Placebo v Dulaglutide
Number of subjects included in analysis	9901
Analysis specification	Pre-specified
Analysis type	superiority ^[7]
P-value	= 0.652
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.16

Notes:

[7] - Nonfatal MI. Multiplicity adjustments using the graphical approach were performed for secondary efficacy endpoints in order to control the overall Type I error rate at a 2-sided alpha level of 0.0467.

Statistical analysis title	Number of Participants Who Experienced an Event
Statistical analysis description:	
Nonfatal stroke	
Comparison groups	Placebo v Dulaglutide
Number of subjects included in analysis	9901
Analysis specification	Pre-specified
Analysis type	superiority ^[8]
P-value	= 0.017
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	0.95

Notes:

[8] - Nonfatal stroke. Multiplicity adjustments using the graphical approach were performed for secondary efficacy endpoints in order to control the overall Type I error rate at a 2-sided alpha level of 0.0467.

Secondary: Number of Participants Who Experienced an Event for Time to all-cause mortality

End point title	Number of Participants Who Experienced an Event for Time to all-cause mortality
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End point description:

The time to all-cause mortality was evaluated using time-to-event analysis via the Cox proportional hazards regression model where response equals treatment. The number of participants who experienced an event is presented.

End point type	Secondary
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End point timeframe:

From randomization to study completion (Median Follow-Up of 5.4 Years)

End point values	Placebo	Dulaglutide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4952 ^[9]	4949 ^[10]		
Units: participants	592	536		

Notes:

[9] - All randomized participants.

[10] - All randomized participants.

Statistical analyses

Statistical analysis title	Number of Participants Who Experienced an Event
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Statistical analysis description:

Time to all cause mortality

Comparison groups	Placebo v Dulaglutide
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Number of subjects included in analysis	9901
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Analysis specification	Pre-specified
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Analysis type	superiority ^[11]
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P-value	= 0.067
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Method	Regression, Cox
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Parameter estimate	Hazard ratio (HR)
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Point estimate	0.9
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Confidence interval	
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level	95 %
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sides	2-sided
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lower limit	0.8
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upper limit	1.01
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Notes:

[11] - Time to all cause mortality. Multiplicity adjustments using the graphical approach were performed for secondary efficacy endpoints in order to control the overall Type I error rate at a 2-sided alpha level of 0.0467.

Secondary: Number of Participants Who Experienced an Event for Time to first occurrence after randomization of the composite microvascular endpoint

End point title	Number of Participants Who Experienced an Event for Time to first occurrence after randomization of the composite
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End point description:

The time from randomization to first occurrence of the composite microvascular endpoint was evaluated using time-to-event analysis via the Cox proportional hazards regression model where response equals treatment. The composite microvascular endpoint is defined as diabetic retinopathy requiring laser therapy, vitrectomy, or anti-vascular endothelial growth factor therapy (VEGF), clinical proteinuria, a \geq 30% decline in estimated glomerular filtration rate, or need for chronic renal replacement therapy. The number of participants who experienced the composite microvascular endpoint event is presented.

End point type	Secondary
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End point timeframe:

From randomization to first occurrence or study completion (Median Follow-Up of 5.4 Years)

End point values	Placebo	Dulaglutide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4952 ^[12]	4949 ^[13]		
Units: participants	1241	1099		

Notes:

[12] - All randomized participants.

[13] - All randomized participants.

Statistical analyses

Statistical analysis title	Number of Participants Who Experienced an Event
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Statistical analysis description:

microvascular endpoint

Comparison groups	Placebo v Dulaglutide
Number of subjects included in analysis	9901
Analysis specification	Pre-specified
Analysis type	superiority ^[14]
P-value	< 0.001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	0.93

Notes:

[14] - microvascular endpoint. Multiplicity adjustments using the graphical approach were performed for secondary efficacy endpoints in order to control the overall Type I error rate at a 2-sided alpha level of 0.0467.

Secondary: Number of Participants Who Experienced An Event for Time to first occurrence after randomization of heart failure requiring hospitalization or an urgent heart failure clinic visit

End point title	Number of Participants Who Experienced An Event for Time to first occurrence after randomization of heart failure requiring hospitalization or an urgent heart failure clinic visit
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End point description:

The time to first occurrence after randomization of heart failure requiring hospitalization or an urgent heart failure clinic visit was evaluated using time-to-event analysis via the Cox proportional hazards regression model where response equals treatment. The number of participants who experienced an

event is presented.

End point type	Secondary
End point timeframe:	
From randomization to first occurrence or study completion (Median Follow-Up of 5.4 Years)	

End point values	Placebo	Dulaglutide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4952 ^[15]	4949 ^[16]		
Units: participants	226	213		

Notes:

[15] - All randomized participants.

[16] - All randomized participants.

Statistical analyses

Statistical analysis title	Number of Participants Who Experienced An Event
Statistical analysis description:	
Heart failure requiring hospitalization or an urgent heart failure clinic visit	
Comparison groups	Placebo v Dulaglutide
Number of subjects included in analysis	9901
Analysis specification	Pre-specified
Analysis type	superiority ^[17]
P-value	= 0.456
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.12

Notes:

[17] - Heart failure requiring hospitalization or an urgent heart failure clinic visit.

Multiplicity adjustments using the graphical approach were performed for secondary efficacy endpoints in order to control the overall Type I error rate at a 2-sided alpha level of 0.0467.

Secondary: Number of Participants Who Experienced an Event for Time to first occurrence after randomization of first hospitalization for unstable angina

End point title	Number of Participants Who Experienced an Event for Time to first occurrence after randomization of first hospitalization for unstable angina
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End point description:

Time to first occurrence after randomization of first hospitalization for unstable angina was evaluated using time-to-event analysis via the Cox proportional hazards regression model where response equals treatment. The number of participants who experienced an event is presented.

End point type	Secondary
End point timeframe:	
From randomization to first occurrence or study completion (Median Follow-Up of 5.4 Years)	

End point values	Placebo	Dulaglutide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4952 ^[18]	4949 ^[19]		
Units: participants	77	88		

Notes:

[18] - All randomized participants.

[19] - All randomized participants.

Statistical analyses

Statistical analysis title	Number of Participants Who Experienced an Event
Statistical analysis description:	
Hospitalization for unstable angina	
Comparison groups	Placebo v Dulaglutide
Number of subjects included in analysis	9901
Analysis specification	Pre-specified
Analysis type	superiority ^[20]
P-value	= 0.413
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.54

Notes:

[20] - Hospitalization for unstable angina.

Multiplicity adjustments using the graphical approach were performed for secondary efficacy endpoints in order to control the overall Type I error rate at a 2-sided alpha level of 0.0467.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to study completion (median follow-up of 5.4 years)

Adverse event reporting additional description:

All randomized participants who received at least one dose of study drug. Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Placebo was administered once weekly, subcutaneously

Reporting group title	Dulaglutide
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Reporting group description:

1.5 mg Dulaglutide was administered once weekly, subcutaneously

Serious adverse events	Placebo	Dulaglutide	
Total subjects affected by serious adverse events			
subjects affected / exposed	2044 / 4949 (41.30%)	1991 / 4943 (40.28%)	
number of deaths (all causes)	277	242	
number of deaths resulting from adverse events	13	8	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
acute myeloid leukaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
adenocarcinoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
adenocarcinoma gastric			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	10 / 4949 (0.20%)	7 / 4943 (0.14%)
occurrences causally related to treatment / all	1 / 11	1 / 7
deaths causally related to treatment / all	1 / 4	0 / 1
adenocarcinoma of colon alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	14 / 4949 (0.28%)	17 / 4943 (0.34%)
occurrences causally related to treatment / all	1 / 14	1 / 17
deaths causally related to treatment / all	0 / 1	1 / 4
adenocarcinoma of the cervix alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[1]	1 / 2282 (0.04%)	1 / 2303 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
adenocarcinoma pancreas alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	1 / 2
adenoma benign alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
adenosquamous cell carcinoma alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
adrenal adenoma alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0

adrenal neoplasm			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
anal squamous cell carcinoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
anaplastic astrocytoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
anogenital warts			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
astrocytoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
b-cell lymphoma stage i			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
b-cell lymphoma stage ii alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
b-cell small lymphocytic lymphoma alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
basal cell carcinoma alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	11 / 4949 (0.22%)	7 / 4943 (0.14%)
occurrences causally related to treatment / all	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
benign gastric neoplasm alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
benign hepatic neoplasm alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
benign neoplasm of adrenal gland alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

benign neoplasm of thyroid gland alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bile duct adenocarcinoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bile duct cancer alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
biliary cancer metastatic alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
bladder cancer alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
bladder cancer recurrent alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder neoplasm alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	5 / 4949 (0.10%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	1 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
bladder papilloma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
bladder transitional cell carcinoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	1 / 6	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0
bladder transitional cell carcinoma recurrent		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
bladder transitional cell carcinoma stage i		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
bone cancer		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
bone cancer metastatic		
alternative dictionary used: MedDRA 21.0		

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
bone neoplasm		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
borderline ovarian tumour		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[2]	0 / 2282 (0.00%)	1 / 2303 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
bowen's disease		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
brain neoplasm		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
brain neoplasm malignant		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
breast cancer		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	8 / 4949 (0.16%)	11 / 4943 (0.22%)
occurrences causally related to treatment / all	0 / 8	1 / 11
deaths causally related to treatment / all	0 / 0	0 / 0

breast cancer metastatic alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 3	1 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
breast cancer recurrent alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
breast cancer stage iii alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
brenner tumour alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[3]	0 / 2282 (0.00%)	1 / 2303 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchial carcinoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cancer pain alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
carcinoid tumour pulmonary alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
cardiac myxoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
cerebral haemangioma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
cervix carcinoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[4]	2 / 2282 (0.09%)	4 / 2303 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
cervix carcinoma stage 0		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[5]	2 / 2282 (0.09%)	0 / 2303 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
cholangiocarcinoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
chronic lymphocytic leukaemia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0

chronic myeloid leukaemia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
clear cell renal cell carcinoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	6 / 4943 (0.12%)	
occurrences causally related to treatment / all	0 / 3	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon adenoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	8 / 4949 (0.16%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon cancer alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	6 / 4943 (0.12%)	
occurrences causally related to treatment / all	2 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 2	
colon cancer metastatic alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon cancer stage ii alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
colon neoplasm alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
colorectal adenocarcinoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
colorectal cancer metastatic alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diffuse large b-cell lymphoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
diffuse large b-cell lymphoma stage iv alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
ductal adenocarcinoma of pancreas alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
endometrial adenocarcinoma alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[6]	9 / 2282 (0.39%)	6 / 2303 (0.26%)
occurrences causally related to treatment / all	1 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
endometrial cancer alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[7]	1 / 2282 (0.04%)	3 / 2303 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
extranodal marginal zone b-cell lymphoma (malt type) alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
fibroadenoma of breast alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
fibrosarcoma alternative dictionary used: MedDRA 21.0		

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
gallbladder cancer metastatic		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
gallbladder squamous cell carcinoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
gastric cancer		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 3
gastric neoplasm		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
gastrointestinal stromal cancer		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
gastrointestinal stromal tumour		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

glioblastoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
hepatic angiosarcoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
hepatic cancer			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 0	
hepatic cancer metastatic			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
hepatic neoplasm			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatocellular carcinoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	3 / 6	0 / 1	
deaths causally related to treatment / all	2 / 2	0 / 1	
hodgkin's disease			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
huerthle cell carcinoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
intraductal proliferative breast lesion		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
invasive breast carcinoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	11 / 4949 (0.22%)	7 / 4943 (0.14%)
occurrences causally related to treatment / all	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
invasive lobular breast carcinoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
keratoacanthoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

large intestine benign neoplasm alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
laryngeal cancer alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
laryngeal squamous cell carcinoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
leiomyosarcoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
leiomyosarcoma metastatic alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
lip squamous cell carcinoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
liposarcoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
liposarcoma metastatic		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	8 / 4949 (0.16%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 1
lung adenocarcinoma stage ii		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 iv		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1

lung cancer metastatic alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
lung neoplasm alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung neoplasm malignant alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	9 / 4943 (0.18%)	
occurrences causally related to treatment / all	1 / 6	0 / 9	
deaths causally related to treatment / all	1 / 4	0 / 3	
lymphoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
malignant joint neoplasm alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
malignant melanoma stage iii alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
malignant neoplasm of ampulla of vater		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
malignant pleural effusion		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
mediastinum neoplasm		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
medullary thyroid cancer		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
meningeal neoplasm		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		

subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
mesothelioma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
mesothelioma malignant			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastases to adrenals			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastases to bone			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastases to central nervous system			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
metastases to chest wall			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
metastases to kidney alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
metastases to liver alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	7 / 4943 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
metastases to lung alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
metastases to lymph nodes alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
metastases to pelvis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
metastases to peritoneum alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0

metastases to pleura alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metastatic bronchial carcinoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 1	
metastatic gastric cancer alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
metastatic neoplasm alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 0	
metastatic renal cell carcinoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
myelodysplastic syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
nasal sinus cancer alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
neoplasm			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
neoplasm malignant			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
neoplasm prostate			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[8]	0 / 2667 (0.00%)	3 / 2640 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
neuroendocrine carcinoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
neuroendocrine carcinoma of the skin			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
neuroendocrine tumour			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
non-hodgkin's lymphoma alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
non-small cell lung cancer alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
non-small cell lung cancer metastatic alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
non-small cell lung cancer stage ii alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
non-small cell lung cancer stage iv alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
oesophageal adenocarcinoma alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

oesophageal carcinoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
oesophageal squamous cell carcinoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ovarian adenoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[9]	2 / 2282 (0.09%)	0 / 2303 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ovarian cancer alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[10]	2 / 2282 (0.09%)	0 / 2303 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ovarian cancer metastatic alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[11]	1 / 2282 (0.04%)	0 / 2303 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ovarian cancer stage iii alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[12]	1 / 2282 (0.04%)	0 / 2303 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ovarian epithelial cancer alternative dictionary used: MedDRA 21.0			

subjects affected / exposed ^[13]	0 / 2282 (0.00%)	2 / 2303 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
pancreatic carcinoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	5 / 4949 (0.10%)	8 / 4943 (0.16%)
occurrences causally related to treatment / all	0 / 5	1 / 8
deaths causally related to treatment / all	0 / 2	0 / 1
pancreatic carcinoma metastatic		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	5 / 4949 (0.10%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	3 / 5	3 / 4
deaths causally related to treatment / all	0 / 0	1 / 2
pancreatic neoplasm		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
papillary thyroid cancer		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
paraganglion neoplasm		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
parathyroid tumour benign		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

penile squamous cell carcinoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[14]	1 / 2667 (0.04%)	0 / 2640 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pericardial effusion malignant alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
phaeochromocytoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pituitary tumour alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pituitary tumour benign alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
plasma cell leukaemia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 2
prostate cancer alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[15]	33 / 2667 (1.24%)	33 / 2640 (1.25%)
occurrences causally related to treatment / all	1 / 34	1 / 33
deaths causally related to treatment / all	0 / 2	0 / 0
prostate cancer metastatic alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[16]	4 / 2667 (0.15%)	2 / 2640 (0.08%)
occurrences causally related to treatment / all	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
prostate cancer recurrent alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[17]	1 / 2667 (0.04%)	1 / 2640 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
prostate cancer stage i alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[18]	1 / 2667 (0.04%)	0 / 2640 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
prostatic adenoma alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[19]	3 / 2667 (0.11%)	6 / 2640 (0.23%)
occurrences causally related to treatment / all	0 / 3	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
rectal adenocarcinoma alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0

rectal adenoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal cancer			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal cancer metastatic			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
rectal neoplasm			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectosigmoid cancer			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal cancer			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 4	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
renal cancer metastatic			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
renal cell carcinoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
renal neoplasm		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
renal oncocytoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
sarcoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
small cell lung cancer		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 2
small cell lung cancer metastatic		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

spinal meningioma benign alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
spindle cell sarcoma alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
squamous cell carcinoma alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	1 / 4949 (0.02%)	4 / 4943 (0.08%)		
occurrences causally related to treatment / all	0 / 1	1 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
squamous cell carcinoma of lung alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	7 / 4949 (0.14%)	3 / 4943 (0.06%)		
occurrences causally related to treatment / all	0 / 8	0 / 3		
deaths causally related to treatment / all	0 / 1	0 / 2		
squamous cell carcinoma of skin alternative dictionary used: MedDRA 21.0				
subjects affected / exposed	3 / 4949 (0.06%)	3 / 4943 (0.06%)		
occurrences causally related to treatment / all	0 / 4	0 / 3		
deaths causally related to treatment / all	0 / 0	0 / 0		
squamous cell carcinoma of the cervix alternative dictionary used: MedDRA 21.0				
subjects affected / exposed ^[20]	0 / 2282 (0.00%)	1 / 2303 (0.04%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
squamous cell carcinoma of the vagina alternative dictionary used: MedDRA 21.0				

subjects affected / exposed ^[21]	0 / 2282 (0.00%)	1 / 2303 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
squamous cell carcinoma of the vulva		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[22]	0 / 2282 (0.00%)	2 / 2303 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
sweat gland tumour		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
throat cancer		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
thymoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
thyroid adenoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
thyroid cancer		
alternative dictionary used: MedDRA 21.0		

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
tongue neoplasm malignant stage unspecified alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
tonsil cancer alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
transitional cell cancer of the renal pelvis and ureter alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
transitional cell carcinoma alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	7 / 4943 (0.14%)
occurrences causally related to treatment / all	0 / 3	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
transitional cell carcinoma recurrent alternative dictionary used: MedDRA 21.0		

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
tumour associated fever alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
tumour of ampulla of vater alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
urethral cancer alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
uterine cancer alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[23]	2 / 2282 (0.09%)	4 / 2303 (0.17%)
occurrences causally related to treatment / all	1 / 2	0 / 4
deaths causally related to treatment / all	1 / 1	0 / 1
uterine leiomyoma alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[24]	1 / 2282 (0.04%)	3 / 2303 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
uterine neoplasm alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[25]	1 / 2282 (0.04%)	1 / 2303 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

vascular neoplasm alternative dictionary used: MedDRA 21.0 subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
angiodyplasia alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0 subjects affected / exposed	2 / 4949 (0.04%)	10 / 4943 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 2	
aortic aneurysm rupture alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic arteriosclerosis alternative dictionary used: MedDRA 21.0 subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
aortic dissection alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
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 21.0			

subjects affected / exposed	16 / 4949 (0.32%)	21 / 4943 (0.42%)
occurrences causally related to treatment / all	0 / 17	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 1
arterial occlusive disease		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
arterial stenosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
arteriosclerosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
bleeding varicose vein		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
circulatory collapse		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 3
deep vein thrombosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	10 / 4949 (0.20%)	16 / 4943 (0.32%)
occurrences causally related to treatment / all	0 / 10	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0

dry gangrene			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
essential hypertension			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
haematoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	4 / 4943 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemodynamic instability			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
hypertension			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	27 / 4949 (0.55%)	22 / 4943 (0.45%)
occurrences causally related to treatment / all	0 / 29	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
hypertensive crisis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	21 / 4949 (0.42%)	14 / 4943 (0.28%)
occurrences causally related to treatment / all	0 / 21	1 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
hypertensive emergency		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
hypotension		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	2 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
hypovolaemic shock		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
iliac artery embolism		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

lymphatic fistula alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
lymphoedema alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
neurogenic shock alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
orthostatic hypotension alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	6 / 4943 (0.12%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral arterial occlusive disease alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	25 / 4949 (0.51%)	17 / 4943 (0.34%)	
occurrences causally related to treatment / all	0 / 26	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral artery occlusion alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	8 / 4943 (0.16%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral artery stenosis alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
peripheral artery thrombosis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
peripheral embolism alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
peripheral ischaemia alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	8 / 4949 (0.16%)	9 / 4943 (0.18%)
occurrences causally related to treatment / all	0 / 9	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
peripheral vascular disorder alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	8 / 4943 (0.16%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0
peripheral venous disease alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
phlebitis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0

shock			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
shock haemorrhagic			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
subclavian artery stenosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
superior vena cava syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
temporal arteritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
thrombophlebitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (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 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
varicose vein			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
vena cava thrombosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
adverse drug reaction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
asthenia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	5 / 4949 (0.10%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	1 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
chest discomfort alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
chest pain alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	14 / 4949 (0.28%)	7 / 4943 (0.14%)
occurrences causally related to treatment / all	1 / 15	1 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
death alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	9 / 4949 (0.18%)	9 / 4943 (0.18%)
occurrences causally related to treatment / all	1 / 9	1 / 9
deaths causally related to treatment / all	1 / 9	1 / 9
device intolerance alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
drug effect increased alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
drug intolerance alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

fatigue			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
gait disturbance			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
general physical health deterioration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	4 / 4943 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
generalised oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
hernia perforation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperthermia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
impaired healing			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	5 / 4949 (0.10%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
inflammation		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
malaise		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
metaplasia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
multiple organ dysfunction syndrome		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 3
necrosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
non-cardiac chest pain		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	37 / 4949 (0.75%)	26 / 4943 (0.53%)
occurrences causally related to treatment / all	0 / 44	1 / 28
deaths causally related to treatment / all	0 / 0	0 / 0

oedema peripheral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 4949 (0.14%)	4 / 4943 (0.08%)	
occurrences causally related to treatment / all	0 / 7	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral swelling			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyrexia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 4949 (0.14%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
strangulated hernia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sudden cardiac death			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
sudden death			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	5 / 4949 (0.10%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 5	0 / 3	
systemic inflammatory response syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular stent occlusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular stent stenosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
anti-neutrophil cytoplasmic antibody positive vasculitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
contrast media allergy			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
drug hypersensitivity			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypersensitivity			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
immunodeficiency			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sarcoidosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
diet noncompliance			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
organ donor			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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			
acquired phimosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed ^[26]	18 / 2667 (0.67%)	21 / 2640 (0.80%)	
occurrences causally related to treatment / all	1 / 20	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
breast pain			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cervical polyp			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[27]	1 / 2282 (0.04%)	2 / 2303 (0.09%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cystocele			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[28]	4 / 2282 (0.18%)	3 / 2303 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
endometrial hyperplasia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed ^[29]	0 / 2282 (0.00%)	1 / 2303 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
endometrial hypertrophy alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[30]	0 / 2282 (0.00%)	1 / 2303 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
endometriosis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[31]	0 / 2282 (0.00%)	1 / 2303 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
erectile dysfunction alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[32]	1 / 2667 (0.04%)	0 / 2640 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
female genital tract fistula alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[33]	0 / 2282 (0.00%)	2 / 2303 (0.09%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
fibrocystic breast disease alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
genital prolapse alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0

gynaecomastia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[34]	0 / 2667 (0.00%)	2 / 2640 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
metrorrhagia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[35]	0 / 2282 (0.00%)	2 / 2303 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ovarian cyst			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[36]	1 / 2282 (0.04%)	6 / 2303 (0.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
pelvic fluid collection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pelvic prolapse			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostatism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[37]	2 / 2667 (0.07%)	0 / 2640 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
prostatitis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed ^[38]	2 / 2667 (0.07%)	4 / 2640 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
prostatomegaly		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[39]	1 / 2667 (0.04%)	0 / 2640 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
rectocele		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[40]	1 / 2282 (0.04%)	1 / 2303 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
uterine disorder		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[41]	0 / 2282 (0.00%)	1 / 2303 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
uterine polyp		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[42]	2 / 2282 (0.09%)	3 / 2303 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
uterine prolapse		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[43]	0 / 2282 (0.00%)	3 / 2303 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
uterovaginal prolapse		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[44]	2 / 2282 (0.09%)	2 / 2303 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

vaginal haemorrhage alternative dictionary used: MedDRA 21.0 subjects affected / exposed ^[45]	1 / 2282 (0.04%)	1 / 2303 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vaginal polyp alternative dictionary used: MedDRA 21.0 subjects affected / exposed ^[46]	1 / 2282 (0.04%)	0 / 2303 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vaginal prolapse alternative dictionary used: MedDRA 21.0 subjects affected / exposed ^[47]	0 / 2282 (0.00%)	2 / 2303 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
acquired diaphragmatic eventration alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
acute pulmonary oedema alternative dictionary used: MedDRA 21.0 subjects affected / exposed	2 / 4949 (0.04%)	4 / 4943 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
acute respiratory failure alternative dictionary used: MedDRA 21.0 subjects affected / exposed	17 / 4949 (0.34%)	6 / 4943 (0.12%)	
occurrences causally related to treatment / all	0 / 17	0 / 7	
deaths causally related to treatment / all	0 / 4	0 / 1	
alveolitis allergic alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
asphyxia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
aspiration		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
asthma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	8 / 4949 (0.16%)	8 / 4943 (0.16%)
occurrences causally related to treatment / all	0 / 13	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
atelectasis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
bronchial hyperreactivity		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
bronchial polyp		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

bronchitis chronic			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchopneumopathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	35 / 4949 (0.71%)	25 / 4943 (0.51%)	
occurrences causally related to treatment / all	0 / 45	0 / 32	
deaths causally related to treatment / all	0 / 1	0 / 1	
chronic respiratory failure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cough			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
dysphonia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
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 21.0			

subjects affected / exposed	15 / 4949 (0.30%)	11 / 4943 (0.22%)
occurrences causally related to treatment / all	0 / 15	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 0
dyspnoea exertional		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
emphysema		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
epistaxis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	5 / 4949 (0.10%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
haemoptysis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
haemothorax		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
hypercapnia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

hyperventilation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypoxia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
interstitial lung disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 4949 (0.14%)	13 / 4943 (0.26%)	
occurrences causally related to treatment / all	0 / 7	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung disorder			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
lung infiltration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
nasal polyps			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
nasal septum deviation			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
obstructive airways disorder alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
pharyngeal haemorrhage alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
pickwickian syndrome alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
pleural effusion alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	8 / 4949 (0.16%)	13 / 4943 (0.26%)
occurrences causally related to treatment / all	0 / 10	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
pleural thickening alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
pleurisy alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
pneumonitis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumothorax alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	4 / 4943 (0.08%)	
occurrences causally related to treatment / all	1 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumothorax spontaneous alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary congestion alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pulmonary embolism alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	21 / 4949 (0.42%)	22 / 4943 (0.45%)	
occurrences causally related to treatment / all	1 / 22	1 / 23	
deaths causally related to treatment / all	0 / 0	0 / 5	
pulmonary fibrosis alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	4 / 4949 (0.08%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
pulmonary hypertension		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
pulmonary mass		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
pulmonary oedema		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	20 / 4949 (0.40%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 20	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
pulmonary thrombosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
respiratory arrest		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
respiratory distress		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1

respiratory failure alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	20 / 4949 (0.40%)	16 / 4943 (0.32%)	
occurrences causally related to treatment / all	0 / 22	0 / 16	
deaths causally related to treatment / all	0 / 6	0 / 5	
respiratory tract oedema alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
restrictive pulmonary disease alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
rhinitis hypertrophic alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sleep apnoea syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
abnormal behaviour alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
adjustment disorder with depressed mood			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
affective disorder			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aggression			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
alcohol abuse			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
alcohol withdrawal syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
anxiety			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
anxiety disorder		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
bipolar disorder		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
confusional state		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	9 / 4943 (0.18%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
delirium		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	8 / 4949 (0.16%)	10 / 4943 (0.20%)
occurrences causally related to treatment / all	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
delusion		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 8	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0

depression suicidal			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
disorientation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
emotional distress			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
generalised anxiety disorder			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
major depression			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
mania			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
mental disorder alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
mental status changes alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
panic disorder alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
personality change due to a general medical condition alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
psychogenic seizure alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
psychotic disorder alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
restlessness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
somatic delusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
somatic symptom disorder			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicidal ideation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicide attempt			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
device damage			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
device dislocation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
device failure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
device loosening			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
device occlusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
acute hepatic failure			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
bile duct obstruction		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
bile duct stenosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
bile duct stone		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	8 / 4943 (0.16%)
occurrences causally related to treatment / all	1 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
biliary colic		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
biliary dyspepsia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
cholangitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 2	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0

<p>cholangitis acute</p> <p>alternative dictionary used: MedDRA 21.0</p>			
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<p>cholangitis chronic</p> <p>alternative dictionary used: MedDRA 21.0</p>			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<p>cholecystitis</p> <p>alternative dictionary used: MedDRA 21.0</p>			
subjects affected / exposed	15 / 4949 (0.30%)	25 / 4943 (0.51%)	
occurrences causally related to treatment / all	0 / 15	6 / 28	
deaths causally related to treatment / all	0 / 1	0 / 0	
<p>cholecystitis acute</p> <p>alternative dictionary used: MedDRA 21.0</p>			
subjects affected / exposed	17 / 4949 (0.34%)	26 / 4943 (0.53%)	
occurrences causally related to treatment / all	0 / 17	4 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
<p>cholecystitis chronic</p> <p>alternative dictionary used: MedDRA 21.0</p>			
subjects affected / exposed	2 / 4949 (0.04%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
<p>cholelithiasis</p> <p>alternative dictionary used: MedDRA 21.0</p>			
subjects affected / exposed	49 / 4949 (0.99%)	42 / 4943 (0.85%)	
occurrences causally related to treatment / all	2 / 51	8 / 43	
deaths causally related to treatment / all	0 / 0	0 / 0	
<p>cholestasis</p> <p>alternative dictionary used: MedDRA 21.0</p>			

subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	1 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
drug-induced liver injury alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gallbladder cholesterolosis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gallbladder necrosis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gallbladder perforation alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
gallbladder polyp alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic cirrhosis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	

hepatic failure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
hepatic mass			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic steatosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatorenal syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
ischaemic hepatitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
jaundice			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
jaundice cholestatic alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
liver disorder alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
non-alcoholic fatty liver alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
non-alcoholic steatohepatitis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
portal hypertension alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
portal vein thrombosis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

post cholecystectomy syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
amylase increased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
anticoagulation drug level above therapeutic alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood calcitonin increased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood calcium increased alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
blood glucose decreased alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
blood glucose fluctuation alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
blood glucose increased alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
blood pressure increased alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
c-reactive protein increased alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
coagulation test abnormal alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
electrocardiogram abnormal alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
glomerular filtration rate decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
glycosylated haemoglobin increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemoglobin decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic enzyme increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
oxygen saturation decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
transaminases increased			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
troponin t increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
troponin increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
urine albumin/creatinine ratio increased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
weight decreased			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	1 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
accident			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
accident at work			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
accidental overdose alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	8 / 4943 (0.16%)
occurrences causally related to treatment / all	0 / 2	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
acetabulum fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
anaemia postoperative alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
anastomotic complication alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
anastomotic leak alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

ankle fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	20 / 4949 (0.40%)	21 / 4943 (0.42%)	
occurrences causally related to treatment / all	0 / 20	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
arterial injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriovenous fistula occlusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arthropod bite			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
back injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
burns second degree			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
burns third degree alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
carbon monoxide poisoning alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
cartilage injury alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
cervical vertebral fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
chemical poisoning alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
clavicle fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

concussion alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	4 / 4943 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
contusion alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	6 / 4943 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary vascular graft occlusion alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
craniocerebral injury alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 2	
craniofacial fracture alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
deep vein thrombosis postoperative alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
delayed recovery from anaesthesia alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
failure to anastomose alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
fall alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	124 / 4949 (2.51%)	110 / 4943 (2.23%)
occurrences causally related to treatment / all	0 / 137	2 / 123
deaths causally related to treatment / all	0 / 2	0 / 0
femoral neck fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
femur fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	21 / 4949 (0.42%)	18 / 4943 (0.36%)
occurrences causally related to treatment / all	0 / 22	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 1
fibula fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0

foot fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
forearm fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
foreign body			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
foreign body aspiration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
foreign body in gastrointestinal tract			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis radiation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal injury			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
gastrointestinal stoma complication		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
graft thrombosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
gun shot wound		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
hand fracture		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
head injury		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
hip fracture		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	17 / 4949 (0.34%)	12 / 4943 (0.24%)
occurrences causally related to treatment / all	0 / 17	0 / 12
deaths causally related to treatment / all	0 / 2	0 / 0

humerus fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	20 / 4949 (0.40%)	12 / 4943 (0.24%)	
occurrences causally related to treatment / all	1 / 20	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyphaema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
incisional hernia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	6 / 4943 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
incisional hernia, obstructive			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
intentional overdose			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal anastomosis complication			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
jaw fracture			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
joint injury alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
laceration alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
ligament rupture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
ligament sprain alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
limb crushing injury alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

limb injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
lower limb fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
lumbar vertebral fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
lumbosacral plexus injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
meniscus injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	12 / 4943 (0.24%)	
occurrences causally related to treatment / all	0 / 4	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
multiple fractures			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
multiple injuries			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
muscle rupture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
muscle strain alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
overdose alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
patella fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
pelvic fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
periprosthetic fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

pneumothorax traumatic alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
post concussion syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
post procedural bile leak alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
post procedural complication alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
post procedural discharge alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
post procedural haematuria alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
post procedural haemorrhage alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	7 / 4943 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
post procedural swelling alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
post-traumatic pain alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
postoperative adhesion alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
postoperative delirium alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
postoperative thoracic procedure complication alternative dictionary used: MedDRA 21.0		

subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
postoperative wound complication alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
procedural hypotension alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
procedural pain alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
pubis fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
radiation pneumonitis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
radius fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	8 / 4943 (0.16%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0

rib fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	14 / 4949 (0.28%)	10 / 4943 (0.20%)	
occurrences causally related to treatment / all	0 / 14	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
road traffic accident			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	9 / 4949 (0.18%)	13 / 4943 (0.26%)	
occurrences causally related to treatment / all	0 / 10	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 1	
scapula fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
sciatic nerve injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
scrotal haematoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[48]	1 / 2667 (0.04%)	0 / 2640 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
skin injury			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
skull fracture			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
skull fractured base alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
soft tissue injury alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
spinal compression fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
spinal cord injury cervical alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
spinal fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
splenic rupture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

stab wound			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sternal fracture			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
stoma site haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
subdural haematoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 4949 (0.14%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 2	
subdural haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
suture rupture			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
tendon injury alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
tendon rupture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
thermal burn alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (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 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
tibia fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	8 / 4949 (0.16%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
tongue injury alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

toxicity to various agents alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
transfusion-related acute lung injury alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
traumatic fracture alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
traumatic haematoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
traumatic haemothorax alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ulna fracture alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
upper limb fracture alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
vascular graft occlusion alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
wound alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
wound dehiscence alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
wound secretion alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0 subjects affected / exposed	5 / 4949 (0.10%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
adenomatous polyposis coli alternative dictionary used: MedDRA 21.0 subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0 subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic granulomatous disease alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
congenital cerebrovascular anomaly alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
developmental hip dysplasia alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
exomphalos alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
gastrointestinal arteriovenous malformation		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
heart disease congenital		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
hereditary motor and sensory neuropathy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed ^[49]	0 / 2667 (0.00%)	2 / 2640 (0.08%)
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 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
phimosis		
alternative dictionary used: MedDRA 21.0		

subjects affected / exposed ^[50]	1 / 2667 (0.04%)	3 / 2640 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular malformation alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
acute coronary syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	41 / 4949 (0.83%)	43 / 4943 (0.87%)	
occurrences causally related to treatment / all	0 / 43	0 / 44	
deaths causally related to treatment / all	0 / 9	0 / 7	
acute left ventricular failure alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
acute myocardial infarction alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	53 / 4949 (1.07%)	39 / 4943 (0.79%)	
occurrences causally related to treatment / all	4 / 59	0 / 40	
deaths causally related to treatment / all	0 / 14	0 / 15	
angina pectoris alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	58 / 4949 (1.17%)	56 / 4943 (1.13%)	
occurrences causally related to treatment / all	1 / 67	1 / 61	
deaths causally related to treatment / all	0 / 0	0 / 0	
angina unstable alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	54 / 4949 (1.09%)	44 / 4943 (0.89%)
occurrences causally related to treatment / all	1 / 58	1 / 47
deaths causally related to treatment / all	0 / 1	0 / 0
aortic valve disease mixed alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
aortic valve incompetence alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
aortic valve stenosis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	9 / 4943 (0.18%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
arrhythmia alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
arteriosclerosis coronary artery alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	9 / 4949 (0.18%)	7 / 4943 (0.14%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 1
atrial fibrillation alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	62 / 4949 (1.25%)	90 / 4943 (1.82%)
occurrences causally related to treatment / all	2 / 79	3 / 107
deaths causally related to treatment / all	0 / 0	0 / 0

atrial flutter			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	18 / 4949 (0.36%)	15 / 4943 (0.30%)	
occurrences causally related to treatment / all	1 / 19	1 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
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 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrioventricular block			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
atrioventricular block complete			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	11 / 4949 (0.22%)	8 / 4943 (0.16%)	
occurrences causally related to treatment / all	0 / 12	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrioventricular block first degree			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrioventricular block second degree			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	9 / 4949 (0.18%)	8 / 4943 (0.16%)
occurrences causally related to treatment / all	0 / 9	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
bifascicular block alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
bradyarrhythmia alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
bradycardia alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	10 / 4949 (0.20%)	16 / 4943 (0.32%)
occurrences causally related to treatment / all	0 / 10	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
bundle branch block left alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
bundle branch block right alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
cardiac arrest alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	14 / 4949 (0.28%)	11 / 4943 (0.22%)
occurrences causally related to treatment / all	0 / 15	0 / 14
deaths causally related to treatment / all	0 / 7	0 / 6

cardiac disorder alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac failure alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	104 / 4949 (2.10%)	78 / 4943 (1.58%)	
occurrences causally related to treatment / all	3 / 124	2 / 87	
deaths causally related to treatment / all	0 / 21	0 / 10	
cardiac failure acute alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	9 / 4949 (0.18%)	8 / 4943 (0.16%)	
occurrences causally related to treatment / all	0 / 10	0 / 11	
deaths causally related to treatment / all	0 / 2	0 / 3	
cardiac failure chronic alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	21 / 4949 (0.42%)	14 / 4943 (0.28%)	
occurrences causally related to treatment / all	0 / 24	0 / 15	
deaths causally related to treatment / all	0 / 1	0 / 0	
cardiac failure congestive alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	47 / 4949 (0.95%)	38 / 4943 (0.77%)	
occurrences causally related to treatment / all	5 / 52	4 / 42	
deaths causally related to treatment / all	0 / 4	0 / 8	
cardiac tamponade alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardio-respiratory arrest alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	7 / 4949 (0.14%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	1 / 7	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 3
cardiogenic shock		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 2
cardiomyopathy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	5 / 4949 (0.10%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
cardiomyopathy alcoholic		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
cardiopulmonary failure		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
cardiorenal syndrome		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
cardiovascular disorder		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

cardiovascular insufficiency alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic left ventricular failure alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
congestive cardiomyopathy alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	1 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
cor pulmonale alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery disease alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	57 / 4949 (1.15%)	57 / 4943 (1.15%)	
occurrences causally related to treatment / all	1 / 64	0 / 63	
deaths causally related to treatment / all	0 / 2	0 / 0	
coronary artery insufficiency alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
coronary artery occlusion alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
coronary artery perforation alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
coronary artery stenosis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
defect conduction intraventricular alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
diastolic dysfunction alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
dressler's syndrome alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
extrasystoles alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

gastrocardiac syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic cardiomyopathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	10 / 4943 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
left ventricular dysfunction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
left ventricular failure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	8 / 4949 (0.16%)	13 / 4943 (0.26%)	
occurrences causally related to treatment / all	0 / 8	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
metabolic cardiomyopathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
microvascular coronary artery disease			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
mitral valve disease alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
mitral valve incompetence alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	9 / 4943 (0.18%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
mitral valve prolapse alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
mitral valve stenosis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
myocardial infarction alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	35 / 4949 (0.71%)	30 / 4943 (0.61%)
occurrences causally related to treatment / all	0 / 37	4 / 30
deaths causally related to treatment / all	0 / 8	2 / 8
myocardial ischaemia alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	23 / 4949 (0.46%)	19 / 4943 (0.38%)
occurrences causally related to treatment / all	0 / 23	0 / 20
deaths causally related to treatment / all	0 / 2	0 / 1

myocarditis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
nodal rhythm			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
palpitations			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pericardial effusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pericarditis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 6	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
prinzmetal angina			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
right ventricular dysfunction			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
right ventricular failure alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
silent myocardial infarction alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
sinoatrial block alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
sinus arrest alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
sinus bradycardia alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
sinus node dysfunction alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	9 / 4949 (0.18%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0

sinus tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
stress cardiomyopathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
supraventricular extrasystoles			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
supraventricular tachycardia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	9 / 4949 (0.18%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
tachyarrhythmia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 2	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
tachycardia induced cardiomyopathy			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tricuspid valve incompetence alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ventricular arrhythmia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
ventricular extrasystoles alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	4 / 4943 (0.08%)	
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 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	4 / 4943 (0.08%)	
occurrences causally related to treatment / all	0 / 3	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
ventricular tachycardia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	0 / 10	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders acoustic neuritis alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
altered state of consciousness alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
amnesia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
amputation stump pain alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
aphasia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
ataxia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
autonomic nervous system imbalance alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
balance disorder		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
basal ganglia haemorrhage		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
brain injury		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
brain stem haemorrhage		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
brain stem infarction		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
carotid arteriosclerosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

carotid artery occlusion alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
carotid artery stenosis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	9 / 4949 (0.18%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
carotid sinus syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
carpal tunnel syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cauda equina syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cerebellar ataxia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cerebellar atrophy alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
cerebellar infarction		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
cerebral atrophy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
cerebral circulatory failure		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
cerebral haematoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
cerebral haemorrhage		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1

cerebral infarction			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
cerebral ischaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
cerebrovascular accident			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	31 / 4949 (0.63%)	24 / 4943 (0.49%)	
occurrences causally related to treatment / all	1 / 34	0 / 25	
deaths causally related to treatment / all	1 / 2	0 / 1	
cerebrovascular disorder			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
cerebrovascular insufficiency			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cervical radiculopathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cervicobrachial syndrome			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
cognitive disorder		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
coma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
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 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
dementia alzheimer's type		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
demyelinating polyneuropathy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
depressed level of consciousness		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

diabetic coma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
diabetic hyperglycaemic coma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic hyperosmolar coma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic mononeuropathy alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic neuropathy alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	8 / 4949 (0.16%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
dizziness alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	9 / 4943 (0.18%)	
occurrences causally related to treatment / all	0 / 2	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
dizziness postural alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
dysarthria		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
embolic stroke		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
encephalopathy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
epilepsy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	8 / 4949 (0.16%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
facial paralysis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
frontal lobe epilepsy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

generalised tonic-clonic seizure alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
guillain-barre syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhage intracranial alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
haemorrhagic cerebral infarction alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhagic stroke alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	4 / 4943 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
headache alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
hemiparesis alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	5 / 4949 (0.10%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
hemiplegia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
hepatic encephalopathy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
hydrocephalus		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
hypertensive encephalopathy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
hypoesthesia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
iiiird nerve paralysis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

intracranial aneurysm alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
intracranial haematoma alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic cerebral infarction alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
ischaemic neuropathy alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic stroke alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	18 / 4949 (0.36%)	14 / 4943 (0.28%)	
occurrences causally related to treatment / all	1 / 22	0 / 15	
deaths causally related to treatment / all	0 / 5	0 / 1	
lacunar infarction alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
lacunar stroke alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
language disorder alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
loss of consciousness alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
lumbar radiculopathy alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
lumbosacral radiculopathy alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
metabolic encephalopathy alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
migraine alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0

mixed dementia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
monoparesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
motor neurone disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
myasthenia gravis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
myelopathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
myoclonus			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
nerve root compression			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
nervous system disorder alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
neuritis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
neuropathy peripheral alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 2	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
normal pressure hydrocephalus alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
optic neuritis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
paralysis recurrent laryngeal nerve alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
parkinsonism			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
partial seizures			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral nerve paresis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peripheral sensorimotor neuropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
peroneal nerve palsy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
piriformis syndrome			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
polyneuropathy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
post herpetic neuralgia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
presyncope		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
pseudobulbar palsy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
psychomotor hyperactivity		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
quadriplegia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0

radiculopathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
sciatica			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 4949 (0.14%)	6 / 4943 (0.12%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
seizure			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
sensory disturbance			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
serotonin syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
spinal claudication			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
syncope			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	33 / 4949 (0.67%)	36 / 4943 (0.73%)
occurrences causally related to treatment / all	1 / 34	5 / 38
deaths causally related to treatment / all	0 / 1	0 / 0
thrombotic stroke		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
transient ischaemic attack		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	23 / 4949 (0.46%)	22 / 4943 (0.45%)
occurrences causally related to treatment / all	0 / 24	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
tremor		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
trigeminal neuralgia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

uraemic encephalopathy alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vith nerve paralysis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular dementia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular encephalopathy alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vascular parkinsonism alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
wernicke's encephalopathy alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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			
agranulocytosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	23 / 4949 (0.46%)	29 / 4943 (0.59%)	
occurrences causally related to treatment / all	1 / 24	0 / 30	
deaths causally related to treatment / all	0 / 0	0 / 0	
anaemia folate deficiency			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
anaemia macrocytic			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
anaemia of malignant disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
anaemia vitamin b12 deficiency			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
blood disorder		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
deficiency anaemia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
disseminated intravascular coagulation		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
febrile neutropenia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
haemolytic anaemia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
haemorrhagic anaemia		
alternative dictionary used: MedDRA 21.0		

subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
histiocytosis haematophagic alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
hypochromic anaemia alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
immune thrombocytopenic purpura alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	9 / 4949 (0.18%)	14 / 4943 (0.28%)
occurrences causally related to treatment / all	1 / 10	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
lymphadenopathy alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
lymphadenopathy mediastinal alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

microcytic anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
nephrogenic anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
neutropenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
normochromic normocytic anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
normocytic anaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pancytopenia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
polycythaemia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
splenic haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
splenomegaly			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
deafness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
deafness neurosensory			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
deafness unilateral			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
hypoacusis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
sudden hearing loss		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
vertigo		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
vertigo positional		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
vestibular ataxia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
vestibular disorder		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

Eye disorders			
amaurosis fugax			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
amblyopia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
angle closure glaucoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
blepharochalasis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	29 / 4949 (0.59%)	19 / 4943 (0.38%)	
occurrences causally related to treatment / all	0 / 34	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
cataract diabetic			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cataract nuclear			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
cataract subcapsular		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
dacryostenosis acquired		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
diabetic retinopathy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 8	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
diplopia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
glaucoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0

hypermetropia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
iridodialysis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
macular fibrosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
macular hole			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
macular oedema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
maculopathy			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
neurotrophic keratopathy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
open angle glaucoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
ophthalmic vein thrombosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
retinal artery embolism		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
retinal artery occlusion		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

retinal detachment alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
retinal haemorrhage alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
retinal tear alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
strabismus alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
vitreous haemorrhage alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
abdominal adhesions alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal compartment syndrome alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
abdominal discomfort alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	7 / 4943 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
abdominal hernia obstructive alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
abdominal incarcerated hernia alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
abdominal mass alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	10 / 4949 (0.20%)	10 / 4943 (0.20%)
occurrences causally related to treatment / all	1 / 11	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 2

abdominal pain upper			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal wall haematoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
acute abdomen			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
anal fistula			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
anal incontinence			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ascites			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
barrett's oesophagus			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
chronic gastritis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
colitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
colitis ischaemic		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 3	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
colitis microscopic		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
colitis ulcerative		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
constipation		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0

crohn's disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dental cyst			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic gastroparesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diaphragmatic hernia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diarrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	8 / 4949 (0.16%)	10 / 4943 (0.20%)	
occurrences causally related to treatment / all	0 / 8	4 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
diverticular perforation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (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 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 2	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
diverticulum intestinal		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 2	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
diverticulum intestinal haemorrhagic		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
duodenal ulcer		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
duodenal ulcer haemorrhage		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
duodenitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
dyspepsia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

dysphagia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
enteritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
enterovesical fistula			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
erosive duodenitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
faecaloma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
fistula of small intestine			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
food poisoning			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
gallstone ileus		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
gastric dilatation		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
gastric dysplasia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
gastric haemorrhage		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
gastric polyps		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
gastric ulcer		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0

gastric ulcer haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	8 / 4943 (0.16%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	17 / 4949 (0.34%)	13 / 4943 (0.26%)	
occurrences causally related to treatment / all	1 / 17	3 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastritis erosive			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroduodenitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	13 / 4949 (0.26%)	12 / 4943 (0.24%)	
occurrences causally related to treatment / all	1 / 14	1 / 13	
deaths causally related to treatment / all	0 / 2	0 / 3	
gastrointestinal inflammation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal motility disorder			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
gastrointestinal mucocoele		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
gastrointestinal necrosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
gastrointestinal polyp		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
gastrointestinal polyp haemorrhage		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
gastrointestinal ulcer		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
gastrointestinal ulcer haemorrhage		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

gastrointestinal vascular malformation haemorrhagic			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	9 / 4943 (0.18%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
haematemesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
haematochezia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhagic erosive gastritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
haemorrhoids			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
haemorrhoids thrombosed		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
hernial eventration		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
heyde's syndrome		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
hiatus hernia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	7 / 4943 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
ileus		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
ileus paralytic		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

impaired gastric emptying alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
incarcerated inguinal hernia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
incarcerated umbilical hernia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
inguinal hernia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	11 / 4949 (0.22%)	17 / 4943 (0.34%)	
occurrences causally related to treatment / all	0 / 11	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal haemorrhage alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
intestinal ischaemia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
intestinal mass alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
intestinal obstruction alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	14 / 4949 (0.28%)	9 / 4943 (0.18%)
occurrences causally related to treatment / all	1 / 15	2 / 9
deaths causally related to treatment / all	0 / 2	0 / 0
intestinal perforation alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
intestinal polyp alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
intestinal stenosis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
intra-abdominal haemorrhage alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
intussusception alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

irritable bowel syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
large intestine perforation alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
large intestine polyp alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	4 / 4943 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
lower gastrointestinal haemorrhage alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	6 / 4943 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
mallory-weiss syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
mechanical ileus alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
megacolon alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
melaena		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
mesenteric arterial occlusion		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
mesenteric artery thrombosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
mouth haemorrhage		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
nausea		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
necrotising oesophagitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

obstructive pancreatitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal achalasia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal spasm			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal stenosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal varices haemorrhage			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophagitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
palatal disorder			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
pancreatic cyst		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
pancreatic pseudocyst		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	5 / 4949 (0.10%)	9 / 4943 (0.18%)
occurrences causally related to treatment / all	1 / 5	5 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
pancreatitis acute		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	8 / 4949 (0.16%)	15 / 4943 (0.30%)
occurrences causally related to treatment / all	5 / 10	5 / 15
deaths causally related to treatment / all	1 / 1	0 / 0
pancreatitis chronic		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
peptic ulcer		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

peritoneal adhesions			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peritoneal haematoma			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
peritoneal hernia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
portal venous gas			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
proctitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal polyp			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
retroperitoneal haemorrhage alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
salivary gland calculus alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	10 / 4949 (0.20%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 12	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
spigelian hernia alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
strangulated umbilical hernia alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
thrombosis mesenteric vessel alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0

umbilical hernia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	7 / 4949 (0.14%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
umbilical hernia, obstructive alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
upper gastrointestinal haemorrhage alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	10 / 4949 (0.20%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	0 / 10	1 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
varices oesophageal alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
volvulus of small bowel alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (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 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	6 / 4943 (0.12%)	
occurrences causally related to treatment / all	0 / 5	2 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders angioedema alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
decubitus ulcer alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
dermatitis allergic alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
dermatitis atopic alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	19 / 4949 (0.38%)	14 / 4943 (0.28%)
occurrences causally related to treatment / all	0 / 24	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 1
diabetic neuropathic ulcer alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
diabetic ulcer alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

erythrodermic psoriasis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic skin ulcer alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
neuropathic ulcer alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
pemphigoid alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyoderma gangrenosum alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
rash generalised		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
rash papular		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
skin disorder		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
skin lesion		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	15 / 4949 (0.30%)	9 / 4943 (0.18%)
occurrences causally related to treatment / all	0 / 16	0 / 13
deaths causally related to treatment / all	0 / 2	0 / 0
stasis dermatitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

subcutaneous emphysema alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
urticaria alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vasculitic ulcer alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
acute kidney injury alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	67 / 4949 (1.35%)	61 / 4943 (1.23%)	
occurrences causally related to treatment / all	7 / 74	2 / 72	
deaths causally related to treatment / all	1 / 7	1 / 2	
atonic urinary bladder alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
azotaemia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder dysfunction alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
bladder fibrosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
bladder hypertrophy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
bladder mass		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
bladder neck obstruction		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
bladder neck sclerosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
bladder obstruction		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bladder pain alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
calculus bladder alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
calculus urethral alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
calculus urinary alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic kidney disease alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	19 / 4949 (0.38%)	13 / 4943 (0.26%)	
occurrences causally related to treatment / all	0 / 20	0 / 13	
deaths causally related to treatment / all	0 / 2	0 / 0	
cystitis haemorrhagic alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	5 / 4949 (0.10%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
dysuria		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
end stage renal disease		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	2 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
haematuria		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
haemorrhage urinary tract		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
hydronephrosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

hydroureter			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertensive nephropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypertonic bladder			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
kidney perforation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
nephrolithiasis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	17 / 4949 (0.34%)	18 / 4943 (0.36%)	
occurrences causally related to treatment / all	0 / 18	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
nephropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pelvi-ureteric obstruction			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
proteinuria		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
renal colic		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	7 / 4943 (0.14%)
occurrences causally related to treatment / all	0 / 7	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
renal cyst		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (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 21.0		
subjects affected / exposed	17 / 4949 (0.34%)	16 / 4943 (0.32%)
occurrences causally related to treatment / all	1 / 17	0 / 16
deaths causally related to treatment / all	1 / 6	0 / 4
renal haematoma		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
renal haemorrhage		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

renal impairment			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
renal infarct			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
renal mass			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
stress urinary incontinence			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
tubulointerstitial nephritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ureteric dilatation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ureteric stenosis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
ureterolithiasis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	9 / 4949 (0.18%)	9 / 4943 (0.18%)
occurrences causally related to treatment / all	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
urethral caruncle alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
urethral disorder alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
urinary bladder polyp alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	1 / 4943 (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 21.0 subjects affected / exposed	9 / 4949 (0.18%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	1 / 9	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract obstruction alternative dictionary used: MedDRA 21.0 subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
acromegaly alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
adrenal insufficiency alternative dictionary used: MedDRA 21.0 subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
adrenocortical insufficiency acute alternative dictionary used: MedDRA 21.0 subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
autoimmune thyroiditis alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cushing's syndrome alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	8 / 4949 (0.16%)	12 / 4943 (0.24%)
occurrences causally related to treatment / all	0 / 8	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
hyperaldosteronism		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
hyperparathyroidism		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
hyperparathyroidism primary		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
hyperparathyroidism secondary		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
hyperthyroidism		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

hypoparathyroidism secondary alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
parathyroid disorder alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
primary hyperaldosteronism alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
thyroid mass alternative dictionary used: MedDRA 21.0 subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
thyroiditis subacute alternative dictionary used: MedDRA 21.0 subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
toxic nodular goitre alternative dictionary used: MedDRA 21.0 subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	6 / 4949 (0.12%)	9 / 4943 (0.18%)
occurrences causally related to treatment / all	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
arthritis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
arthritis reactive		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
arthrofibrosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
arthropathy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
articular calcification		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
back pain		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	9 / 4949 (0.18%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0

bone lesion alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bursitis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cervical spinal stenosis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
chondrocalcinosis pyrophosphate alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
chondromalacia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
chondropathy alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
costochondritis alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
diabetic amyotrophy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
diabetic arthropathy		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
exostosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
fistula		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

fracture malunion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gouty arthritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gouty tophus			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc degeneration			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc disorder			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc protrusion			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	21 / 4949 (0.42%)	15 / 4943 (0.30%)	
occurrences causally related to treatment / all	0 / 22	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
joint ankylosis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
joint noise		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
joint swelling		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0		
subjects affected / exposed	11 / 4949 (0.22%)	10 / 4943 (0.20%)
occurrences causally related to treatment / all	0 / 14	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
mobility decreased		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
muscle haemorrhage		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
muscle spasms		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

muscular weakness alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
musculoskeletal chest pain alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	10 / 4943 (0.20%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
musculoskeletal pain alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
myalgia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
neck pain alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
neuropathic arthropathy alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteitis deformans alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
osteoarthritis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	110 / 4949 (2.22%)	136 / 4943 (2.75%)
occurrences causally related to treatment / all	0 / 128	0 / 155
deaths causally related to treatment / all	0 / 0	0 / 0
osteochondrosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
osteonecrosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
osteopenia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
osteoporosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
pain in extremity		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

patellofemoral pain syndrome alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pathological fracture alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
periarthritits alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
plantar fascial fibromatosis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pseudarthrosis alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
rhabdomyolysis alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
rheumatic disorder alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
rheumatoid arthritis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
rotator cuff syndrome alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	10 / 4949 (0.20%)	8 / 4943 (0.16%)
occurrences causally related to treatment / all	0 / 11	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
spinal column stenosis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	7 / 4949 (0.14%)	13 / 4943 (0.26%)
occurrences causally related to treatment / all	0 / 7	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
spinal osteoarthritis alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	21 / 4949 (0.42%)	16 / 4943 (0.32%)
occurrences causally related to treatment / all	0 / 23	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 1
spinal pain alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	5 / 4943 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0

spondylitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
spondyloarthropathy			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
spondylolisthesis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	6 / 4943 (0.12%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
spondylolysis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
synovial cyst			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
synovitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
tendon disorder			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tendonitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tenosynovitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
vertebral foraminal stenosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
vertebral osteophyte			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
abdominal abscess			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
abscess			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
abscess intestinal		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
abscess limb		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
abscess neck		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
abscess oral		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
anal abscess		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	4 / 4949 (0.08%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
anal infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

aortitis salmonella			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
appendiceal abscess			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
appendicitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	6 / 4943 (0.12%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
appendicitis perforated			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
arthritis bacterial			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
arthritis infective			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
atypical pneumonia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
bacteraemia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	6 / 4949 (0.12%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
bacterial infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
biliary sepsis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
brain abscess		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
breast abscess		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
breast cellulitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	12 / 4949 (0.24%)	13 / 4943 (0.26%)	
occurrences causally related to treatment / all	0 / 12	0 / 13	
deaths causally related to treatment / all	0 / 1	0 / 1	
bronchitis bacterial			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchitis fungal			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bronchitis viral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
burn infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
campylobacter gastroenteritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
candida sepsis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
candiduria		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
carbuncle		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
cellulitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	42 / 4949 (0.85%)	38 / 4943 (0.77%)
occurrences causally related to treatment / all	0 / 48	0 / 39
deaths causally related to treatment / all	0 / 0	0 / 1
cellulitis streptococcal		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
cervicitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[51]	0 / 2282 (0.00%)	1 / 2303 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
cholecystitis infective		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

chronic hepatitis b			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
clostridium colitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
clostridium difficile colitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
clostridium difficile infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
corneal abscess			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cystitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
cystitis escherichia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
cytomegalovirus colitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
dengue fever		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
dengue haemorrhagic fever		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
device related infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
device related sepsis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
diabetic foot infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	5 / 4949 (0.10%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

diabetic gangrene			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
diarrhoea infectious			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diverticulitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	10 / 4949 (0.20%)	15 / 4943 (0.30%)	
occurrences causally related to treatment / all	0 / 12	1 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
dysentery			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
echinococcosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
empyema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
endocarditis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
endocarditis bacterial		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
enterococcal sepsis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
enterocolitis bacterial		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed ^[52]	0 / 2667 (0.00%)	4 / 2640 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
erysipelas		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	15 / 4949 (0.30%)	11 / 4943 (0.22%)
occurrences causally related to treatment / all	0 / 18	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
escherichia bacteraemia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0

escherichia sepsis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
escherichia urinary tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
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 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
gallbladder abscess			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gallbladder empyema			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	11 / 4949 (0.22%)	8 / 4943 (0.16%)	
occurrences causally related to treatment / all	0 / 11	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	10 / 4949 (0.20%)	21 / 4943 (0.42%)
occurrences causally related to treatment / all	0 / 10	1 / 22
deaths causally related to treatment / all	0 / 1	0 / 0
gastroenteritis clostridial		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
gastroenteritis norovirus		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
gastroenteritis viral		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	5 / 4949 (0.10%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
gastrointestinal infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
genitourinary tract infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
groin abscess		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
haematoma infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
helicobacter gastritis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
helicobacter infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatitis b			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatitis e			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
hepatitis infectious mononucleosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	5 / 4949 (0.10%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
herpes zoster meningoencephalitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
herpes zoster pharyngitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
hydrocele male infected		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[53]	0 / 2667 (0.00%)	1 / 2640 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
implant site infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

infected skin ulcer			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	4 / 4943 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
infective exacerbation of chronic obstructive airways disease			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	6 / 4949 (0.12%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
influenza			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	8 / 4949 (0.16%)	5 / 4943 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
injection site abscess			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
intestinal sepsis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
joint abscess		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
kidney infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
labyrinthitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
laryngitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
liver abscess		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0

localised infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	8 / 4949 (0.16%)	8 / 4943 (0.16%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
lower respiratory tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	11 / 4949 (0.22%)	12 / 4943 (0.24%)	
occurrences causally related to treatment / all	0 / 12	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
lower respiratory tract infection bacterial			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lower respiratory tract infection viral			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lung abscess			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
lymphangitis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
mastitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
mediastinitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
medical device site infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
medical device site joint infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
meningitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0

meningitis aseptic			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
myiasis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
necrotising fasciitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
neutropenic sepsis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
oesophageal candidiasis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
orchitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[54]	2 / 2667 (0.07%)	3 / 2640 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
osteomyelitis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	11 / 4949 (0.22%)	10 / 4943 (0.20%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
osteomyelitis acute alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
osteomyelitis chronic alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
otitis externa alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
otitis media chronic alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
pancreatic abscess alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
paronychia alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

pelvic abscess			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pelvic infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
perineal abscess			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
periodontitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
perirectal abscess			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
peritonitis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
pharyngeal abscess		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
pneumonia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	151 / 4949 (3.05%)	135 / 4943 (2.73%)
occurrences causally related to treatment / all	0 / 174	1 / 152
deaths causally related to treatment / all	0 / 15	0 / 14
pneumonia bacterial		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
pneumonia influenzal		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
pneumonia klebsiella		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
pneumonia legionella		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

pneumonia streptococcal alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia viral alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	3 / 4943 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
post procedural pneumonia alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (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 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
postoperative abscess alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
postoperative wound infection alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	3 / 4949 (0.06%)	7 / 4943 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
pseudomonal sepsis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
pulmonary mycosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
pulmonary sepsis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
pulmonary tuberculosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
pyelitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
pyelonephritis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	15 / 4949 (0.30%)	8 / 4943 (0.16%)
occurrences causally related to treatment / all	0 / 15	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0

pyelonephritis acute			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	8 / 4949 (0.16%)	7 / 4943 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyelonephritis chronic			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyonephrosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal abscess			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal cyst infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
respiratory syncytial virus infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
salmonella sepsis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
salmonellosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
scrotal infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed ^[55]	1 / 2667 (0.04%)	0 / 2640 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
sepsis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	35 / 4949 (0.71%)	30 / 4943 (0.61%)
occurrences causally related to treatment / all	2 / 37	0 / 33
deaths causally related to treatment / all	1 / 7	0 / 4
septic shock		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	22 / 4949 (0.44%)	15 / 4943 (0.30%)
occurrences causally related to treatment / all	0 / 24	0 / 16
deaths causally related to treatment / all	0 / 9	0 / 5
sinusitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

skin graft infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
skin infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
soft tissue infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
staphylococcal bacteraemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
staphylococcal infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
staphylococcal mediastinitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
staphylococcal sepsis			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
staphylococcal skin infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
streptococcal bacteraemia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
subcutaneous abscess		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	2 / 4949 (0.04%)	3 / 4943 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
subdiaphragmatic abscess		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
systemic candida		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
tooth abscess		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

tracheobronchitis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
tuberculosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tuberculosis gastrointestinal			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract infection			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	61 / 4949 (1.23%)	64 / 4943 (1.29%)	
occurrences causally related to treatment / all	2 / 65	0 / 78	
deaths causally related to treatment / all	0 / 1	0 / 1	
urinary tract infection bacterial			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract infection pseudomonal			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	2 / 4949 (0.04%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
urosepsis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	19 / 4949 (0.38%)	24 / 4943 (0.49%)
occurrences causally related to treatment / all	0 / 20	1 / 26
deaths causally related to treatment / all	0 / 1	0 / 2
vestibular neuronitis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	4 / 4943 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
viraemia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
viral myocarditis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
wound infection		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	5 / 4949 (0.10%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0

wound sepsis alternative dictionary used: MedDRA 21.0 subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
abnormal loss of weight alternative dictionary used: MedDRA 21.0 subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cachexia alternative dictionary used: MedDRA 21.0 subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
decreased appetite alternative dictionary used: MedDRA 21.0 subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
dehydration alternative dictionary used: MedDRA 21.0 subjects affected / exposed	14 / 4949 (0.28%)	23 / 4943 (0.47%)	
occurrences causally related to treatment / all	0 / 15	3 / 24	
deaths causally related to treatment / all	0 / 0	0 / 1	
diabetes mellitus alternative dictionary used: MedDRA 21.0 subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetes mellitus inadequate control alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	3 / 4949 (0.06%)	4 / 4943 (0.08%)	
occurrences causally related to treatment / all	1 / 3	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic ketoacidosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	6 / 4943 (0.12%)	
occurrences causally related to treatment / all	0 / 2	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
electrolyte imbalance			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
failure to thrive			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
fluid overload			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
food intolerance			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gout			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	4 / 4949 (0.08%)	4 / 4943 (0.08%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

hypercalcaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperglycaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	67 / 4949 (1.35%)	46 / 4943 (0.93%)	
occurrences causally related to treatment / all	3 / 75	0 / 52	
deaths causally related to treatment / all	0 / 1	0 / 0	
hyperglycaemic hyperosmolar nonketotic syndrome			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	2 / 4949 (0.04%)	2 / 4943 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperkalaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	12 / 4949 (0.24%)	8 / 4943 (0.16%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 1	
hyperosmolar state			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
hypocalcaemia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypoglycaemia			
alternative dictionary used: MedDRA 21.0			

subjects affected / exposed	72 / 4949 (1.45%)	62 / 4943 (1.25%)
occurrences causally related to treatment / all	34 / 80	31 / 69
deaths causally related to treatment / all	0 / 0	0 / 0
hypokalaemia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	5 / 4949 (0.10%)	6 / 4943 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
hypomagnesaemia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	0 / 4949 (0.00%)	2 / 4943 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
hyponatraemia		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	11 / 4949 (0.22%)	8 / 4943 (0.16%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
iron deficiency		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
ketoacidosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	1 / 4949 (0.02%)	1 / 4943 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
lactic acidosis		
alternative dictionary used: MedDRA 21.0		
subjects affected / exposed	3 / 4949 (0.06%)	0 / 4943 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

metabolic acidosis			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	3 / 4949 (0.06%)	1 / 4943 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
obesity			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	5 / 4949 (0.10%)	5 / 4943 (0.10%)	
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 21.0			
subjects affected / exposed	0 / 4949 (0.00%)	1 / 4943 (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 male or 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 male or 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 or female 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 or female 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 or female 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[7] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[8] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

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

subjects exposed has been adjusted accordingly.

[43] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[44] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[45] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[46] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[47] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[48] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[49] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[50] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[51] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[52] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[53] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[54] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

[55] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

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

Non-serious adverse events	Placebo	Dulaglutide	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3363 / 4949 (67.95%)	3574 / 4943 (72.30%)	
Vascular disorders hypertension alternative dictionary used: MedDRA 21.0			

subjects affected / exposed occurrences (all)	432 / 4949 (8.73%) 491	345 / 4943 (6.98%) 405	
Nervous system disorders dizziness alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	296 / 4949 (5.98%) 339	318 / 4943 (6.43%) 373	
headache alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	288 / 4949 (5.82%) 382	324 / 4943 (6.55%) 414	
Eye disorders cataract alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	368 / 4949 (7.44%) 417	363 / 4943 (7.34%) 427	
Reproductive system and breast disorders benign prostatic hyperplasia alternative dictionary used: MedDRA 21.0 subjects affected / exposed ^[56] occurrences (all)	135 / 2667 (5.06%) 137	140 / 2640 (5.30%) 144	
Gastrointestinal disorders constipation alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	208 / 4949 (4.20%) 223	361 / 4943 (7.30%) 409	
diarrhoea alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	436 / 4949 (8.81%) 546	665 / 4943 (13.45%) 843	
dyspepsia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences (all)	147 / 4949 (2.97%) 150	291 / 4943 (5.89%) 331	
nausea			

<p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>269 / 4949 (5.44%)</p> <p>310</p>	<p>735 / 4943 (14.87%)</p> <p>968</p>	
<p>vomiting</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>154 / 4949 (3.11%)</p> <p>165</p>	<p>325 / 4943 (6.57%)</p> <p>498</p>	
<p>Respiratory, thoracic and mediastinal disorders</p> <p>cough</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>256 / 4949 (5.17%)</p> <p>292</p>	<p>239 / 4943 (4.84%)</p> <p>265</p>	
<p>Renal and urinary disorders</p> <p>microalbuminuria</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>259 / 4949 (5.23%)</p> <p>263</p>	<p>232 / 4943 (4.69%)</p> <p>241</p>	
<p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>back pain</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>osteoarthritis</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pain in extremity</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>389 / 4949 (7.86%)</p> <p>469</p> <p>416 / 4949 (8.41%)</p> <p>484</p> <p>318 / 4949 (6.43%)</p> <p>373</p> <p>245 / 4949 (4.95%)</p> <p>280</p>	<p>371 / 4943 (7.51%)</p> <p>446</p> <p>447 / 4943 (9.04%)</p> <p>494</p> <p>329 / 4943 (6.66%)</p> <p>372</p> <p>260 / 4943 (5.26%)</p> <p>296</p>	

<p>Infections and infestations</p> <p>bronchitis</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed occurrences (all)</p>	<p>421 / 4949 (8.51%)</p> <p>554</p>	<p>408 / 4943 (8.25%)</p> <p>528</p>	
<p>influenza</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed occurrences (all)</p>	<p>404 / 4949 (8.16%)</p> <p>488</p>	<p>369 / 4943 (7.47%)</p> <p>435</p>	
<p>nasopharyngitis</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed occurrences (all)</p>	<p>535 / 4949 (10.81%)</p> <p>771</p>	<p>564 / 4943 (11.41%)</p> <p>800</p>	
<p>upper respiratory tract infection</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed occurrences (all)</p>	<p>407 / 4949 (8.22%)</p> <p>589</p>	<p>368 / 4943 (7.44%)</p> <p>533</p>	
<p>urinary tract infection</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed occurrences (all)</p>	<p>517 / 4949 (10.45%)</p> <p>749</p>	<p>545 / 4943 (11.03%)</p> <p>795</p>	
<p>Metabolism and nutrition disorders</p> <p>decreased appetite</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed occurrences (all)</p>	<p>104 / 4949 (2.10%)</p> <p>109</p>	<p>325 / 4943 (6.57%)</p> <p>379</p>	
<p>hyperglycaemia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed occurrences (all)</p>	<p>315 / 4949 (6.36%)</p> <p>445</p>	<p>158 / 4943 (3.20%)</p> <p>190</p>	
<p>hypoglycaemia</p> <p>alternative dictionary used: MedDRA 21.0</p> <p>subjects affected / exposed occurrences (all)</p>	<p>354 / 4949 (7.15%)</p> <p>1160</p>	<p>413 / 4943 (8.36%)</p> <p>1477</p>	

Notes:

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

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

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