



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

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
Statistical analysis description:	
Death from CV causes	
Comparison groups	Placebo v Dulaglutide

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

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 occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	2 / 4943 (0.04%) 0 / 2 0 / 0		
rectal cancer alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	3 / 4949 (0.06%) 1 / 3 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0		
rectal cancer metastatic alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 1		
rectal neoplasm alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0		
rectosigmoid cancer alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0		
renal cancer alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	4 / 4949 (0.08%) 0 / 4 0 / 0	5 / 4943 (0.10%) 1 / 5 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 occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0	
Vascular disorders angiodyplasia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0	
aortic aneurysm alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 4949 (0.04%) 0 / 2 0 / 0	10 / 4943 (0.20%) 0 / 10 0 / 2	
aortic aneurysm rupture alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0	
aortic arteriosclerosis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0	
aortic dissection alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	2 / 4943 (0.04%) 0 / 2 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	
utero vaginal 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] occurrences causally related to treatment / all deaths causally related to treatment / all	 1 / 2282 (0.04%) 0 / 1 0 / 0	 1 / 2303 (0.04%) 0 / 1 0 / 0	
vaginal polyp alternative dictionary used: MedDRA 21.0 subjects affected / exposed ^[46] occurrences causally related to treatment / all deaths causally related to treatment / all	 1 / 2282 (0.04%) 0 / 1 0 / 0	 0 / 2303 (0.00%) 0 / 0 0 / 0	
vaginal prolapse alternative dictionary used: MedDRA 21.0 subjects affected / exposed ^[47] occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 2282 (0.00%) 0 / 0 0 / 0	 2 / 2303 (0.09%) 0 / 2 0 / 0	
Respiratory, thoracic and mediastinal disorders acquired diaphragmatic eventration alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 4949 (0.00%) 0 / 0 0 / 0	 1 / 4943 (0.02%) 0 / 1 0 / 0	
acute pulmonary oedema alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 2 / 4949 (0.04%) 0 / 2 0 / 1	 4 / 4943 (0.08%) 0 / 5 0 / 0	
acute respiratory failure alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 17 / 4949 (0.34%) 0 / 17 0 / 4	 6 / 4943 (0.12%) 0 / 7 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	

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

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 occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	2 / 4943 (0.04%) 0 / 2 0 / 0	
Investigations amylase increased alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	1 / 4943 (0.02%) 1 / 1 0 / 0	
anticoagulation drug level above therapeutic alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0	
blood calcitonin increased alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 1 / 1 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0	
blood calcium increased alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0	
blood creatinine increased alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 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 occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 4949 (0.04%) 0 / 2 0 / 0	4 / 4943 (0.08%) 0 / 4 0 / 0		
contusion alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	3 / 4949 (0.06%) 0 / 3 0 / 0	6 / 4943 (0.12%) 0 / 6 0 / 0		
coronary vascular graft occlusion alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0		
craniocerebral injury alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	4 / 4949 (0.08%) 0 / 4 0 / 0	7 / 4943 (0.14%) 0 / 7 0 / 2		
craniofacial fracture alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0		
deep vein thrombosis postoperative alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	1 / 4943 (0.02%) 0 / 1 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 occurrences causally related to treatment / all deaths causally related to treatment / all	4 / 4949 (0.08%) 0 / 4 0 / 0	3 / 4943 (0.06%) 0 / 3 0 / 0		
forearm fracture alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 4949 (0.04%) 0 / 2 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0		
foreign body alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0		
foreign body aspiration alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0		
foreign body in gastrointestinal tract alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0		
gastroenteritis radiation alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 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 occurrences causally related to treatment / all deaths causally related to treatment / all	14 / 4949 (0.28%) 0 / 14 0 / 0	10 / 4943 (0.20%) 0 / 10 0 / 0		
road traffic accident alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	9 / 4949 (0.18%) 0 / 10 0 / 1	13 / 4943 (0.26%) 0 / 13 0 / 1		
scapula fracture alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	3 / 4943 (0.06%) 0 / 3 0 / 0		
sciatic nerve injury alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 4949 (0.04%) 0 / 2 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0		
scrotal haematoma alternative dictionary used: MedDRA 21.0 subjects affected / exposed ^[48] occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2667 (0.04%) 0 / 1 0 / 0	0 / 2640 (0.00%) 0 / 0 0 / 0		
skin injury alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 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 occurrences causally related to treatment / all deaths causally related to treatment / all	5 / 4949 (0.10%) 0 / 5 0 / 0	2 / 4943 (0.04%) 0 / 2 0 / 0	
Congenital, familial and genetic disorders adenomatous polyposis coli alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0	
atrial septal defect alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0	
chronic granulomatous disease alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0	
congenital cerebrovascular anomaly alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0	
developmental hip dysplasia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	1 / 4943 (0.02%) 0 / 1 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	
phimosi			
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 occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0		
cardiac failure alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	104 / 4949 (2.10%) 3 / 124 0 / 21	78 / 4943 (1.58%) 2 / 87 0 / 10		
cardiac failure acute alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	9 / 4949 (0.18%) 0 / 10 0 / 2	8 / 4943 (0.16%) 0 / 11 0 / 3		
cardiac failure chronic alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	21 / 4949 (0.42%) 0 / 24 0 / 1	14 / 4943 (0.28%) 0 / 15 0 / 0		
cardiac failure congestive alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	47 / 4949 (0.95%) 5 / 52 0 / 4	38 / 4943 (0.77%) 4 / 42 0 / 8		
cardiac tamponade alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 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	
hypoaesthesia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	1 / 4949 (0.02%)	0 / 4943 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
iiird 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	
with 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 occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0		
bursitis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 4949 (0.04%) 0 / 2 0 / 0	2 / 4943 (0.04%) 0 / 2 0 / 0		
cervical spinal stenosis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 4949 (0.04%) 0 / 2 0 / 0	5 / 4943 (0.10%) 0 / 5 0 / 0		
chondrocalcinosis pyrophosphate alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	1 / 4943 (0.02%) 0 / 2 0 / 0		
chondromalacia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 4949 (0.00%) 0 / 0 0 / 0	1 / 4943 (0.02%) 0 / 2 0 / 0		
chondropathy alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	3 / 4949 (0.06%) 0 / 3 0 / 0	0 / 4943 (0.00%) 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		
periarthritis 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 occurrences causally related to treatment / all deaths causally related to treatment / all	 2 / 4949 (0.04%) 0 / 2 0 / 0	 1 / 4943 (0.02%) 0 / 1 0 / 0		
spondyloarthropathy alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 1 / 4949 (0.02%) 0 / 1 0 / 0	 0 / 4943 (0.00%) 0 / 0 0 / 0		
spondylolisthesis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 3 / 4949 (0.06%) 0 / 3 0 / 0	 6 / 4943 (0.12%) 0 / 6 0 / 0		
spondylolysis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 1 / 4949 (0.02%) 0 / 1 0 / 0	 0 / 4943 (0.00%) 0 / 0 0 / 0		
synovial cyst alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 1 / 4949 (0.02%) 0 / 1 0 / 0	 2 / 4943 (0.04%) 0 / 2 0 / 0		
synovitis alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 4949 (0.00%) 0 / 0 0 / 0	 2 / 4943 (0.04%) 0 / 2 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 occurrences causally related to treatment / all deaths causally related to treatment / all	3 / 4949 (0.06%) 0 / 3 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0	
Metabolism and nutrition disorders abnormal loss of weight alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0	
cachexia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 0 / 0 0 / 0	
decreased appetite alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	2 / 4949 (0.04%) 1 / 2 0 / 0	1 / 4943 (0.02%) 0 / 1 0 / 0	
dehydration alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	14 / 4949 (0.28%) 0 / 15 0 / 0	23 / 4943 (0.47%) 3 / 24 0 / 1	
diabetes mellitus alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 4949 (0.02%) 0 / 1 0 / 0	0 / 4943 (0.00%) 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 occurrences causally related to treatment / all deaths causally related to treatment / all	 2 / 4949 (0.04%) 1 / 2 0 / 0	 1 / 4943 (0.02%) 0 / 1 0 / 0		
hyperglycaemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 67 / 4949 (1.35%) 3 / 75 0 / 1	 46 / 4943 (0.93%) 0 / 52 0 / 0		
hyperglycaemic hyperosmolar nonketotic syndrome alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 2 / 4949 (0.04%) 0 / 2 0 / 0	 2 / 4943 (0.04%) 0 / 2 0 / 0		
hyperkalaemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 12 / 4949 (0.24%) 0 / 12 0 / 1	 8 / 4943 (0.16%) 0 / 9 0 / 1		
hyperosmolar state alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 1 / 4949 (0.02%) 0 / 1 0 / 1	 1 / 4943 (0.02%) 0 / 1 0 / 0		
hypocalcaemia alternative dictionary used: MedDRA 21.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 4949 (0.00%) 0 / 0 0 / 0	 1 / 4943 (0.02%) 0 / 1 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	432 / 4949 (8.73%)	345 / 4943 (6.98%)	
occurrences (all)	491	405	
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	296 / 4949 (5.98%)	318 / 4943 (6.43%)	
occurrences (all)	339	373	
headache			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	288 / 4949 (5.82%)	324 / 4943 (6.55%)	
occurrences (all)	382	414	
Eye disorders			
cataract			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	368 / 4949 (7.44%)	363 / 4943 (7.34%)	
occurrences (all)	417	427	
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed ^[56]	135 / 2667 (5.06%)	140 / 2640 (5.30%)	
occurrences (all)	137	144	
Gastrointestinal disorders			
constipation			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	208 / 4949 (4.20%)	361 / 4943 (7.30%)	
occurrences (all)	223	409	
diarrhoea			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	436 / 4949 (8.81%)	665 / 4943 (13.45%)	
occurrences (all)	546	843	
dyspepsia			
alternative dictionary used: MedDRA 21.0			
subjects affected / exposed	147 / 4949 (2.97%)	291 / 4943 (5.89%)	
occurrences (all)	150	331	
nausea			

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

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

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