



## Clinical trial results:

### Allopurinol and cardiovascular outcomes in patients with ischaemic heart disease (ALL-HEART)

#### Summary

EudraCT number	2013-003559-39
Trial protocol	GB
Global end of trial date	31 March 2022

#### Results information

Result version number	v1 (current)
This version publication date	16 April 2023
First version publication date	16 April 2023

#### Trial information

##### Trial identification

Sponsor protocol code	2011PP02
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##### Additional study identifiers

ISRCTN number	ISRCTN32017426
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	University of Dundee and NHS Tayside
Sponsor organisation address	Ninewells Hospital and Medical School, Dundee, UK, Dundee, United Kingdom, DD1 9SY
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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	01 July 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 October 2021
Global end of trial reached?	Yes
Global end of trial date	31 March 2022
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary aim is to determine whether the addition of allopurinol up to 600mg daily to usual therapy in patients with ischaemic heart disease (IHD) improves cardiovascular outcomes ie reduces the risk of heart attack, stroke or death from cardiovascular disease.

Protection of trial subjects:

To minimise the chance of pain or discomfort whilst blood samples were taken, samples were taken by appropriately experienced nurses/doctors, following standard local blood sampling guidance.

There was a potential risk that a small number of subjects randomised to the 'allopurinol' arm might develop skin reactions to allopurinol. Most of these were likely to be mild rashes, but occasionally serious rashes could occur. Any patient developing a rash on allopurinol was advised to stop treatment immediately and seek medical advice.

Safety blood tests were checked at 6 weeks (+/-1 week) for patients randomised to allopurinol.

The IDMC met regularly throughout the trial and reviewed pharmacovigilance data, protecting the safety of trial subjects.

Background therapy:

Participants in both arms of the trial received usual care from their own healthcare providers as background therapy.

Evidence for comparator:

Previous studies suggested a potential beneficial role of allopurinol in patients with ischaemic heart disease.

Usual care, rather than placebo, was chosen as the comparator as this was a pragmatic clinical trial.

Actual start date of recruitment	07 February 2014
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	United Kingdom: 6134
Worldwide total number of subjects	6134
EEA total number of subjects	0

Notes:

### Subjects enrolled per age group

In utero	0
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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)	948
From 65 to 84 years	4946
85 years and over	240

## Subject disposition

### Recruitment

Recruitment details:

Screening period was from 7 February 2014 to 29 September 2017. A total of 6134 patients from England and Scotland (UK) consented to be enrolled in the trial and were assessed for eligibility. Eligible patients were aged over 60 years, with ischaemic heart disease but no history of gout.

### Pre-assignment

Screening details:

Of the 6134 patients who were consented and assessed for eligibility, 5937 were randomised. Of the 5937 patients randomised, 216 were excluded post-randomisation (184 did not meet eGFR entry criteria on screening bloods and 32 did not meet other inclusion/exclusion criteria), leaving 5721 validly randomised participants for the efficacy analyses.

### Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

The primary and secondary clinical endpoints adjudication was carried out by an independent adjudication committee blinded to randomisation/treatment group. Recruitment and blinded accumulation of study endpoints were reviewed by the trial steering committee on an ongoing basis. The pharmacovigilance group reviewed blinded SAEs.

### Arms

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

Arm description:

Patients randomised to the allopurinol treatment arm with screening visit eGFR blood result greater than 60mL/min/1.73m<sup>2</sup> received 100mg allopurinol daily for two weeks, then 300mg daily for two weeks then 600mg daily thereafter (given as 300mg twice daily). Participants with screening visit eGFR blood result 30-59mL/min/1.73m<sup>2</sup> received 100mg allopurinol daily for two weeks, then 300mg daily thereafter. The daily dose of allopurinol could be reduced to lower than the maximum listed above if necessary by a physician during the study. Allopurinol could be stopped if necessary during the study.

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

Dosage and administration details:

Up to 600mg daily given as 300mg twice daily if screening visit eGFR result greater than 60mL/min or up to 300mg daily if screening visit eGFR result 30-59mL/min/1.73m<sup>2</sup>

<b>Arm title</b>	Usual care
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Arm description:

Subjects randomised to the usual care arm continued their usual care

Arm type	No intervention
No investigational medicinal product assigned in this arm	

<b>Number of subjects in period 1<sup>[1]</sup></b>	Allopurinol	Usual care
Started	2853	2868
Completed	2307	2489
Not completed	546	379
Adverse event, serious fatal	288	303
Consent withdrawn by subject	258	76

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Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The worldwide no. of participants enrolled (consented and assessed for eligibility) was 6134. 197 were excluded and not randomised (167 ineligible pre-randomisation, 30 not randomised (screening visit not completed or participant withdrew consent before randomisation)). Age data was not available for 148 enrolled participants (these have been added into the most frequent 65-84yrs category). The no. of participants validly randomised and included in the mITT efficacy analysis population is 5721.

## Baseline characteristics

### Reporting groups

Reporting group title	Allopurinol
Reporting group description:	
Patients randomised to the allopurinol treatment arm with screening visit eGFR blood result greater than 60mL/min/1.73m <sup>2</sup> received 100mg allopurinol daily for two weeks, then 300mg daily for two weeks then 600mg daily thereafter (given as 300mg twice daily). Participants with screening visit eGFR blood result 30-59mL/min/1.73m <sup>2</sup> received 100mg allopurinol daily for two weeks, then 300mg daily thereafter. The daily dose of allopurinol could be reduced to lower than the maximum listed above if necessary by a physician during the study. Allopurinol could be stopped if necessary during the study.	
Reporting group title	Usual care
Reporting group description:	
Subjects randomised to the usual care arm continued their usual care	

Reporting group values	Allopurinol	Usual care	Total
Number of subjects	2853	2868	5721
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Age at study entry			
Units: years			
arithmetic mean	71.9	72.0	
standard deviation	± 6.7	± 6.8	-
Gender categorical			
Gender at study entry			
Units: Subjects			
Female	685	713	1398
Male	2168	2153	4321
Transgender	0	2	2

### Subject analysis sets

Subject analysis set title	Efficacy analysis set
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
All validly randomised participants	
Subject analysis set title	Safety analysis set
Subject analysis set type	Safety analysis

Subject analysis set description:

All validly randomised participants in the allopurinol arm who started randomised medication plus all validly randomised participants in the usual care arm.

Reporting group values	Efficacy analysis set	Safety analysis set	
Number of subjects	5721	5673	
Age categorical			
Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous			
Age at study entry			
Units: years			
arithmetic mean	72.0	71.9	
standard deviation	± 6.8	± 6.7	
Gender categorical			
Gender at study entry			
Units: Subjects			
Female	1398	1383	
Male	4321	4288	
Transgender	2	2	

## End points

### End points reporting groups

Reporting group title	Allopurinol
Reporting group description: Patients randomised to the allopurinol treatment arm with screening visit eGFR blood result greater than 60mL/min/1.73m <sup>2</sup> received 100mg allopurinol daily for two weeks, then 300mg daily for two weeks then 600mg daily thereafter (given as 300mg twice daily). Participants with screening visit eGFR blood result 30-59mL/min/1.73m <sup>2</sup> received 100mg allopurinol daily for two weeks, then 300mg daily thereafter. The daily dose of allopurinol could be reduced to lower than the maximum listed above if necessary by a physician during the study. Allopurinol could be stopped if necessary during the study.	
Reporting group title	Usual care
Reporting group description: Subjects randomised to the usual care arm continued their usual care	
Subject analysis set title	Efficacy analysis set
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: All validly randomised participants	
Subject analysis set title	Safety analysis set
Subject analysis set type	Safety analysis
Subject analysis set description: All validly randomised participants in the allopurinol arm who started randomised medication plus all validly randomised participants in the usual care arm.	

### Primary: Primary outcome (modified ITT)

End point title	Primary outcome (modified ITT)
End point description: Composite endpoint: non-fatal myocardial infarction, non-fatal stroke or cardiovascular death	
End point type	Primary
End point timeframe: Time from randomisation to first occurrence of a primary endpoint event.	

End point values	Allopurinol	Usual care	Efficacy analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2853	2868	5721	
Units: Participants with a first event	314	325	639	

Attachments (see zip file)	Primary outcome mITT/Figure 2.jpg
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### Statistical analyses

Statistical analysis title	Modified intention-to-treat analysis
Statistical analysis description: The mITT analysis censored follow-up after death from any cause not included in the endpoint being considered, date of withdrawal of all consent to participate further in the study, or the end of the study, whichever occurred first.	



Comparison groups	Usual care v Allopurinol
Number of subjects included in analysis	5721
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.65 <sup>[1]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.21

Notes:

[1] - P-value was calculated with the Wald test

### Secondary: Secondary - non-fatal myocardial infarction

End point title	Secondary - non-fatal myocardial infarction
End point description:	
Non-fatal myocardial infarction	
End point type	Secondary
End point timeframe:	
From randomisation to first occurrence of event in participant	

End point values	Allopurinol	Usual care	Efficacy analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2853	2868	5721	
Units: Participants with a first event	156	172	328	

<b>Attachments (see zip file)</b>	Secondary outcome: non-fatal myocardial infarction/Figure 3a.
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### Statistical analyses

<b>Statistical analysis title</b>	Modified intention-to-treat analysis
Statistical analysis description:	
The mITT analysis censored follow-up after death from any cause not included in the endpoint being considered, date of withdrawal of all consent to participate further in the study, or the end of the study, whichever occurred first.	
Comparison groups	Allopurinol v Usual care

Number of subjects included in analysis	5721
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.81 <sup>[2]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.21

Notes:

[2] - P-value was calculated with the Wald test

## Secondary: Secondary - non-fatal stroke

End point title	Secondary - non-fatal stroke
End point description:	
Non-fatal stroke	
End point type	Secondary
End point timeframe:	
From randomisation to first occurrence of event in participant	

End point values	Allopurinol	Usual care	Efficacy analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2853	2868	5721	
Units: Participants with a first event	96	86	182	

<b>Attachments (see zip file)</b>	Secondary outcome: non-fatal stroke/Figure 3b.pdf
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## Statistical analyses

<b>Statistical analysis title</b>	Modified intention-to-treat analysis
Statistical analysis description:	
The mITT analysis censored follow-up after death from any cause not included in the endpoint being considered, date of withdrawal of all consent to participate further in the study, or the end of the study, whichever occurred first.	
Comparison groups	Usual care v Allopurinol
Number of subjects included in analysis	5721
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.23 <sup>[3]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	1.6

Notes:

[3] - P-value was calculated with the Wald test

## Secondary: Secondary - cardiovascular death

End point title	Secondary - cardiovascular death
End point description: Cardiovascular death	
End point type	Secondary
End point timeframe: From randomisation to first occurrence of event in participant	

End point values	Allopurinol	Usual care	Efficacy analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2853	2868	5721	
Units: Participants with a first event	112	109	221	

<b>Attachments (see zip file)</b>	Secondary outcome: cardiovascular death/Figure 3c.pdf
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## Statistical analyses

<b>Statistical analysis title</b>	Modified intention-to-treat analysis
Statistical analysis description: The mITT analysis censored follow-up after death from any cause not included in the endpoint being considered, date of withdrawal of all consent to participate further in the study, or the end of the study, whichever occurred first.	
Comparison groups	Allopurinol v Usual care
Number of subjects included in analysis	5721
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.48 <sup>[4]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.43

Notes:

[4] - P-value was calculated with the Wald test

## Secondary: Secondary - all-cause mortality

End point title	Secondary - all-cause mortality
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End point description:

All-cause mortality

End point type	Secondary
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End point timeframe:

From randomisation to first occurrence of event in participant

End point values	Allopurinol	Usual care	Efficacy analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2853	2868	5721	
Units: Participants with a first event	288	303	591	

## Attachments (see zip file)

Secondary outcome: all-cause mortality/Figure 3d CORRECTED

## Statistical analyses

Statistical analysis title	Modified intention-to-treat analysis
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Statistical analysis description:

The mITT analysis censored follow-up after death from any cause not included in the endpoint being considered, date of withdrawal of all consent to participate further in the study, or the end of the study, whichever occurred first.

Comparison groups	Allopurinol v Usual care
Number of subjects included in analysis	5721
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.77 <sup>[5]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.2

Notes:

[5] - P-value was calculated with the Wald test

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Summaries of AEs are presented from randomisation to the end of the study treatment period, withdrawal of consent or death (whichever came first).

Adverse event reporting additional description:

SAEs (related or unrelated to study treatment) and AEs only considered related to treatment were recorded during the study and collected separately. Related SAE data do not overlap with related AE data.

SAEs were followed up for 30 days after the end of the study unless participants had withdrawn consent.

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	15.1
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### Reporting groups

Reporting group title	Safety analysis set - allopurinol arm
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Reporting group description:

All validly randomised participants allocated to the allopurinol arm who took at least one dose of randomised medication. Non-serious AE above threshold of 5% are reported here.

Reporting group title	Safety analysis set - usual care arm
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Reporting group description:

All validly randomised participants allocated to the usual care arm.

Serious adverse events	Safety analysis set - allopurinol arm	Safety analysis set - usual care arm	
Total subjects affected by serious adverse events			
subjects affected / exposed	2036 / 2805 (72.58%)	2194 / 2868 (76.50%)	
number of deaths (all causes)	288	303	
number of deaths resulting from adverse events	288	303	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin cancer			
subjects affected / exposed	104 / 2805 (3.71%)	129 / 2868 (4.50%)	
occurrences causally related to treatment / all	0 / 124	0 / 175	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	78 / 2805 (2.78%)	71 / 2868 (2.48%)	
occurrences causally related to treatment / all	0 / 100	0 / 89	
deaths causally related to treatment / all	0 / 2	0 / 1	
Large intestine benign neoplasm			

subjects affected / exposed	35 / 2805 (1.25%)	58 / 2868 (2.02%)	
occurrences causally related to treatment / all	0 / 36	0 / 60	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	23 / 2805 (0.82%)	35 / 2868 (1.22%)	
occurrences causally related to treatment / all	0 / 29	0 / 48	
deaths causally related to treatment / all	0 / 10	0 / 14	
Benign colonic neoplasm			
subjects affected / exposed	16 / 2805 (0.57%)	31 / 2868 (1.08%)	
occurrences causally related to treatment / all	0 / 17	0 / 32	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	23 / 2805 (0.82%)	19 / 2868 (0.66%)	
occurrences causally related to treatment / all	0 / 29	0 / 31	
deaths causally related to treatment / all	0 / 2	0 / 3	
External ear neoplasm malignant			
subjects affected / exposed	13 / 2805 (0.46%)	19 / 2868 (0.66%)	
occurrences causally related to treatment / all	0 / 15	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung carcinoma cell type unspecified stage 0			
subjects affected / exposed	15 / 2805 (0.53%)	17 / 2868 (0.59%)	
occurrences causally related to treatment / all	0 / 17	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 2	
Colon cancer			
subjects affected / exposed	15 / 2805 (0.53%)	15 / 2868 (0.52%)	
occurrences causally related to treatment / all	0 / 20	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			
subjects affected / exposed	11 / 2805 (0.39%)	13 / 2868 (0.45%)	
occurrences causally related to treatment / all	0 / 12	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 2	
Carcinoma in situ of skin			

subjects affected / exposed	10 / 2805 (0.36%)	13 / 2868 (0.45%)	
occurrences causally related to treatment / all	0 / 10	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign anorectal neoplasm			
subjects affected / exposed	7 / 2805 (0.25%)	13 / 2868 (0.45%)	
occurrences causally related to treatment / all	0 / 8	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	8 / 2805 (0.29%)	11 / 2868 (0.38%)	
occurrences causally related to treatment / all	0 / 10	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of eyelid			
subjects affected / exposed	8 / 2805 (0.29%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic			
subjects affected / exposed	9 / 2805 (0.32%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 9	0 / 8	
deaths causally related to treatment / all	0 / 7	0 / 6	
Malignant melanoma			
subjects affected / exposed	9 / 2805 (0.32%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 11	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	9 / 2805 (0.32%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 14	0 / 16	
deaths causally related to treatment / all	0 / 2	0 / 2	
Bladder neoplasm			
subjects affected / exposed	9 / 2805 (0.32%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 12	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			

subjects affected / exposed	5 / 2805 (0.18%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 6	0 / 16	
deaths causally related to treatment / all	0 / 2	0 / 1	
Rectal cancer			
subjects affected / exposed	5 / 2805 (0.18%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 5	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 2	
Pancreatic carcinoma			
subjects affected / exposed	6 / 2805 (0.21%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 10	0 / 14	
deaths causally related to treatment / all	0 / 4	0 / 5	
Metastatic neoplasm			
subjects affected / exposed	5 / 2805 (0.18%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 4	0 / 7	
Chronic lymphocytic leukaemia			
subjects affected / exposed	7 / 2805 (0.25%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma in situ			
subjects affected / exposed	8 / 2805 (0.29%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma			
subjects affected / exposed	3 / 2805 (0.11%)	9 / 2868 (0.31%)	
occurrences causally related to treatment / all	0 / 3	0 / 16	
deaths causally related to treatment / all	0 / 2	0 / 0	
Prostate cancer metastatic			
subjects affected / exposed	5 / 2805 (0.18%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 4	
Renal cancer			



subjects affected / exposed	6 / 2805 (0.21%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seborrhoeic keratosis			
subjects affected / exposed	6 / 2805 (0.21%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer stage 0, with cancer in situ			
subjects affected / exposed	5 / 2805 (0.18%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melanocytic naevus			
subjects affected / exposed	6 / 2805 (0.21%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	3 / 2805 (0.11%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 4	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal carcinoma			
subjects affected / exposed	4 / 2805 (0.14%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to bone			
subjects affected / exposed	3 / 2805 (0.11%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer female			
subjects affected / exposed	5 / 2805 (0.18%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of unknown primary site			

subjects affected / exposed	4 / 2805 (0.14%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 3	0 / 1	
Myelodysplastic syndrome			
subjects affected / exposed	6 / 2805 (0.21%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 14	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bronchial carcinoma			
subjects affected / exposed	5 / 2805 (0.18%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Multiple myeloma			
subjects affected / exposed	1 / 2805 (0.04%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 2	
Ovarian cancer			
subjects affected / exposed	5 / 2805 (0.18%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 10	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Brain neoplasm malignant			
subjects affected / exposed	3 / 2805 (0.11%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to central nervous system			
subjects affected / exposed	2 / 2805 (0.07%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	4 / 2805 (0.14%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			

subjects affected / exposed	1 / 2805 (0.04%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of skin			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to liver			
subjects affected / exposed	3 / 2805 (0.11%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma metastatic			
subjects affected / exposed	3 / 2805 (0.11%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 2	
Benign laryngeal neoplasm			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer metastatic			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic neoplasm malignant			

subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 0	
Lip and/or oral cavity cancer			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 8	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to pleura			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoclonal gammopathy			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Squamous cell carcinoma			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			

subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Benign salivary gland neoplasm			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Colon cancer metastatic			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Connective tissue neoplasm			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Glioblastoma			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Haemangioma			
subjects affected / exposed	3 / 2805 (0.11%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer			

subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to lymph nodes			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral neoplasm benign			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer metastatic			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Pleural mesothelioma			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage 0			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyogenic granuloma			

subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal neoplasm			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer stage unspecified			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Tonsil cancer			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Waldenstrom's macroglobulinaemia			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
B-cell lymphoma			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Benign gastric neoplasm			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign ovarian tumour			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign renal neoplasm			

subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct cancer			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Breast cancer metastatic			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Breast cancer recurrent			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer stage 0			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential thrombocythaemia			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder cancer			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer metastatic			



subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hepatocellular carcinoma			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hodgkin's disease			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hodgkin's disease mixed cellularity stage unspecified			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypopharyngeal cancer			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lip and/or oral cavity cancer stage 0			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoma			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant peritoneal neoplasm			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma benign			

subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to abdominal cavity			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic renal cell carcinoma			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myeloproliferative neoplasm			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm skin			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer metastatic			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Oesophageal adenocarcinoma			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pancreatic neoplasm			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parathyroid tumour benign			

subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer recurrent			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer metastatic			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestine carcinoma			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Superficial spreading melanoma stage unspecified			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acoustic neuroma			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myelomonocytic leukaemia			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenoid cystic carcinoma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenoma benign			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenosquamous cell lung cancer			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal gland cancer			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaplastic large-cell lymphoma			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign duodenal neoplasm			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of adrenal gland			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of bladder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of spinal cord			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of thymus			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign pancreatic neoplasm			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (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 II			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone neoplasm malignant			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bowen's disease			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Carcinoma in situ of penis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix carcinoma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix carcinoma stage I			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer stage I			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon neoplasm			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diffuse large B-cell lymphoma recurrent			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Fallopian tube cancer			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gammopathy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer stage 0			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric neoplasm			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal cancer metastatic			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital neoplasm malignant female			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Glottis carcinoma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematological malignancy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary cancer			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hodgkin's disease lymphocyte predominance type stage unspecified			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive lobular breast carcinoma			



subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine carcinoma			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal cancer stage 0			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal neoplasm			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Light chain disease			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lip neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma metastatic			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung carcinoma cell type unspecified stage I			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung carcinoma cell type unspecified stage II			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lung squamous cell carcinoma recurrent			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung squamous cell carcinoma stage unspecified			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma of eyelid			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma stage I			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm progression			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant pleural effusion			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant urinary tract neoplasm			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningioma			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesothelioma malignant advanced			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to lung			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to spine			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastasis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic carcinoma of the bladder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic gastric cancer			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic lymphoma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastatic malignant melanoma			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelofibrosis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myeloid leukaemia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myeloproliferative disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal neoplasm			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system neoplasm benign			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma metastatic			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neuroendocrine carcinoma of the skin			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Non-small cell lung cancer stage I			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular neoplasm			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal cancer metastatic			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal carcinoma stage 0			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal neoplasm			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (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			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile malignant neoplasm			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penis carcinoma			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal neoplasm			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasmacytoma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia vera			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary mediastinal large B-cell lymphoma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage IV			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomyxoma peritonei			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer metastatic			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rectal cancer stage 0			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal neoplasm			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal oncocytoma			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland cancer			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland neoplasm			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin papilloma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Small cell lung cancer metastatic			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Small intestine adenocarcinoma			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Soft tissue sarcoma			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal meningioma benign			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (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 of lung			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
T-cell lymphoma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Teratoma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thymoma malignant			



subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma metastatic			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tumour haemorrhage			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer metastatic			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Hodgkin's lymphoma stage IV			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	101 / 2805 (3.60%)	96 / 2868 (3.35%)	
occurrences causally related to treatment / all	0 / 117	0 / 109	
deaths causally related to treatment / all	0 / 5	0 / 2	
Circulatory collapse			

subjects affected / exposed	67 / 2805 (2.39%)	75 / 2868 (2.62%)	
occurrences causally related to treatment / all	0 / 78	0 / 81	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	18 / 2805 (0.64%)	21 / 2868 (0.73%)	
occurrences causally related to treatment / all	0 / 21	0 / 22	
deaths causally related to treatment / all	0 / 1	0 / 1	
Aortic aneurysm			
subjects affected / exposed	22 / 2805 (0.78%)	15 / 2868 (0.52%)	
occurrences causally related to treatment / all	0 / 26	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	19 / 2805 (0.68%)	15 / 2868 (0.52%)	
occurrences causally related to treatment / all	0 / 20	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	9 / 2805 (0.32%)	12 / 2868 (0.42%)	
occurrences causally related to treatment / all	0 / 11	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	11 / 2805 (0.39%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 11	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	4 / 2805 (0.14%)	12 / 2868 (0.42%)	
occurrences causally related to treatment / all	0 / 4	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arterial stenosis			
subjects affected / exposed	4 / 2805 (0.14%)	11 / 2868 (0.38%)	
occurrences causally related to treatment / all	0 / 4	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			

subjects affected / exposed	4 / 2805 (0.14%)	11 / 2868 (0.38%)	
occurrences causally related to treatment / all	0 / 4	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	5 / 2805 (0.18%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	4 / 2805 (0.14%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	6 / 2805 (0.21%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 4	0 / 4	
Temporal arteritis			
subjects affected / exposed	4 / 2805 (0.14%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential hypertension			
subjects affected / exposed	2 / 2805 (0.07%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 2	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	3 / 2805 (0.11%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diabetic vascular disorder			
subjects affected / exposed	3 / 2805 (0.11%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent claudication			

subjects affected / exposed	3 / 2805 (0.11%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery aneurysm			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicophlebitis			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose ulceration			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoedema			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral venous disease			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			

subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic embolus			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arterial disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bleeding varicose vein			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism venous			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic infarction			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iliac artery embolism			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal haematoma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microscopic polyangiitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Phlebitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post thrombotic syndrome			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular compression			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vein disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous insufficiency			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Percutaneous coronary intervention			
subjects affected / exposed	36 / 2805 (1.28%)	52 / 2868 (1.81%)	
occurrences causally related to treatment / all	0 / 39	0 / 54	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hip arthroplasty			
subjects affected / exposed	30 / 2805 (1.07%)	34 / 2868 (1.19%)	
occurrences causally related to treatment / all	0 / 32	0 / 36	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee arthroplasty			

subjects affected / exposed	26 / 2805 (0.93%)	32 / 2868 (1.12%)	
occurrences causally related to treatment / all	0 / 28	0 / 37	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker insertion			
subjects affected / exposed	26 / 2805 (0.93%)	23 / 2868 (0.80%)	
occurrences causally related to treatment / all	0 / 27	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery bypass			
subjects affected / exposed	22 / 2805 (0.78%)	24 / 2868 (0.84%)	
occurrences causally related to treatment / all	0 / 22	0 / 26	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary arterial stent insertion			
subjects affected / exposed	22 / 2805 (0.78%)	17 / 2868 (0.59%)	
occurrences causally related to treatment / all	0 / 23	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative care			
subjects affected / exposed	16 / 2805 (0.57%)	22 / 2868 (0.77%)	
occurrences causally related to treatment / all	0 / 18	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve replacement			
subjects affected / exposed	17 / 2805 (0.61%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 18	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device implantation			
subjects affected / exposed	13 / 2805 (0.46%)	13 / 2868 (0.45%)	
occurrences causally related to treatment / all	0 / 17	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioplasty			
subjects affected / exposed	9 / 2805 (0.32%)	15 / 2868 (0.52%)	
occurrences causally related to treatment / all	0 / 9	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract operation			



subjects affected / exposed	8 / 2805 (0.29%)	14 / 2868 (0.49%)	
occurrences causally related to treatment / all	0 / 12	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker adjustment			
subjects affected / exposed	11 / 2805 (0.39%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 11	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystectomy			
subjects affected / exposed	8 / 2805 (0.29%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stent placement			
subjects affected / exposed	8 / 2805 (0.29%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia repair			
subjects affected / exposed	4 / 2805 (0.14%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 4	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac ablation			
subjects affected / exposed	6 / 2805 (0.21%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable defibrillator insertion			
subjects affected / exposed	4 / 2805 (0.14%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm repair			
subjects affected / exposed	3 / 2805 (0.11%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardioversion			

subjects affected / exposed	4 / 2805 (0.14%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral prostatectomy			
subjects affected / exposed	5 / 2805 (0.18%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal decompression			
subjects affected / exposed	3 / 2805 (0.11%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac resynchronisation therapy			
subjects affected / exposed	5 / 2805 (0.18%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colectomy			
subjects affected / exposed	4 / 2805 (0.14%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hospitalisation			
subjects affected / exposed	6 / 2805 (0.21%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary angioplasty			
subjects affected / exposed	1 / 2805 (0.04%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leg amputation			
subjects affected / exposed	1 / 2805 (0.04%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery angioplasty			

subjects affected / exposed	4 / 2805 (0.14%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hysterectomy			
subjects affected / exposed	1 / 2805 (0.04%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve replacement			
subjects affected / exposed	3 / 2805 (0.11%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shoulder arthroplasty			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft			
subjects affected / exposed	1 / 2805 (0.04%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve repair			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker replacement			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hernia repair			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery bypass			

subjects affected / exposed	0 / 2805 (0.00%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatectomy			
subjects affected / exposed	0 / 2805 (0.00%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal stone removal			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin neoplasm excision			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stoma care			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac pacemaker revision			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid endarterectomy			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colostomy			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary revascularisation			

subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Elective procedure			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc operation			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenectomy			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral endarterectomy			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal operation			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transurethral bladder resection			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethrotomy			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic bypass			

subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthrodesis			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm surgery			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac operation			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac pacemaker removal			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cautery to nose			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystoprostatectomy			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Elective surgery			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endarterectomy			

subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot amputation			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrectomy			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart valve replacement			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepaticojejunostomy			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip surgery			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable cardiac monitor insertion			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular lens implant			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratoplasty			

subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastectomy			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrectomy			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open reduction of fracture			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polypectomy			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prolapse repair			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prophylactic chemotherapy			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic operation			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Resection of rectum			



subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salpingo-oophorectomy bilateral			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shoulder operation			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fusion surgery			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Therapeutic procedure			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroidectomy			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toe amputation			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia repair			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal operation			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess drainage			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adhesiolysis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol detoxification			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amputation of penis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm repair			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle arthroplasty			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial stent insertion			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atherectomy			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balloon atrial septostomy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast lump removal			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bunion operation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stent insertion			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carpal tunnel decompression			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Choledocholithotomy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithotomy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circumcision			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon polypectomy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal transplant			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cyst removal			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Debridement			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drain placement			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug therapy changed			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endotracheal intubation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterostomy			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epidural injection			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye laser surgery			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye operation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fasciectomy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma surgery			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart valve operation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia repair			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Internal fixation of fracture			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal adhesion lysis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal operation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal stent insertion			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint manipulation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Knee operation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laparotomy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngectomy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lesion excision			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lithotripsy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung operation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant tumour excision			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device change			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus removal			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve repair			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal cavity packing			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Omentectomy			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthopaedic procedure			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain management			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stent insertion			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal operation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Preoperative care			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary bullectomy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyloromyotomy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radical cystectomy			



subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radical prostatectomy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radioactive iodine therapy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiotherapy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiotherapy to skin			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rehabilitation therapy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Removal of internal fixation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Resuscitation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff repair			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland operation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal resection			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestine operation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal laminectomy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgery			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon operation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Therapy cessation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tonsillectomy			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheostomy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour excision			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteral stent insertion			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral operation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stent insertion			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urostomy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polypectomy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein operation			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular operation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent insertion			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous stent insertion			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Wrist surgery			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	188 / 2805 (6.70%)	184 / 2868 (6.42%)	
occurrences causally related to treatment / all	1 / 241	0 / 247	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	24 / 2805 (0.86%)	33 / 2868 (1.15%)	
occurrences causally related to treatment / all	0 / 28	0 / 36	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	26 / 2805 (0.93%)	18 / 2868 (0.63%)	
occurrences causally related to treatment / all	2 / 26	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ill-defined disorder			

subjects affected / exposed	15 / 2805 (0.53%)	15 / 2868 (0.52%)	
occurrences causally related to treatment / all	0 / 16	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	5 / 2805 (0.18%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 2	
Death			
subjects affected / exposed	4 / 2805 (0.14%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 4	0 / 5	
Gait disturbance			
subjects affected / exposed	7 / 2805 (0.25%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	4 / 2805 (0.14%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 4	
Malaise			
subjects affected / exposed	7 / 2805 (0.25%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	2 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	4 / 2805 (0.14%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 4	0 / 3	
Oedema peripheral			
subjects affected / exposed	6 / 2805 (0.21%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised oedema			

subjects affected / exposed	3 / 2805 (0.11%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device complication			
subjects affected / exposed	6 / 2805 (0.21%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	5 / 2805 (0.18%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	3 / 2805 (0.11%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye complication associated with device			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multi-organ failure			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 2	
Fatigue			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adverse drug reaction			

subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exercise tolerance decreased			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abasia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adverse food reaction			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chills			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Condition aggravated			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device issue			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device lead issue			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device occlusion			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Effusion			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hanging			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hernia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site haematoma			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mass			



subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perforated ulcer			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (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			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Thrombosis in device			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (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			
Amyloidosis			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 2	
Hypersensitivity			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	2 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyloidosis senile			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anti-neutrophil cytoplasmic antibody positive vasculitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypogammaglobulinaemia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Contraindication to medical treatment			
subjects affected / exposed	2 / 2805 (0.07%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bereavement			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac assistance device user			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social problem			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tobacco user			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	25 / 2805 (0.89%)	36 / 2868 (1.26%)	
occurrences causally related to treatment / all	0 / 29	0 / 40	
deaths causally related to treatment / all	0 / 1	0 / 0	
Uterovaginal prolapse			
subjects affected / exposed	5 / 2805 (0.18%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukoplakia of penis			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			

subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Male reproductive tract disorder			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic disorder			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balanoposthitis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital disorder male			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic pain			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic haemorrhage			

subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectocele			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast necrosis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic prolapse			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile haemorrhage			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penis disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycystic ovaries			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine disorder			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval leukoplakia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal inflammation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	51 / 2805 (1.82%)	65 / 2868 (2.27%)	
occurrences causally related to treatment / all	0 / 57	0 / 90	
deaths causally related to treatment / all	0 / 1	0 / 3	
Dyspnoea			
subjects affected / exposed	39 / 2805 (1.39%)	44 / 2868 (1.53%)	
occurrences causally related to treatment / all	0 / 41	0 / 47	
deaths causally related to treatment / all	0 / 1	0 / 1	
Epistaxis			
subjects affected / exposed	26 / 2805 (0.93%)	27 / 2868 (0.94%)	
occurrences causally related to treatment / all	1 / 39	0 / 38	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	19 / 2805 (0.68%)	30 / 2868 (1.05%)	
occurrences causally related to treatment / all	0 / 23	0 / 36	
deaths causally related to treatment / all	0 / 4	0 / 3	
Pleural effusion			

subjects affected / exposed	10 / 2805 (0.36%)	17 / 2868 (0.59%)	
occurrences causally related to treatment / all	0 / 11	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	10 / 2805 (0.36%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 11	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	9 / 2805 (0.32%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 9	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pulmonary fibrosis			
subjects affected / exposed	9 / 2805 (0.32%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 2	
Pulmonary oedema			
subjects affected / exposed	12 / 2805 (0.43%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 12	0 / 5	
deaths causally related to treatment / all	0 / 6	0 / 2	
Sleep apnoea syndrome			
subjects affected / exposed	6 / 2805 (0.21%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 8	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	9 / 2805 (0.32%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 11	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	4 / 2805 (0.14%)	11 / 2868 (0.38%)	
occurrences causally related to treatment / all	0 / 4	0 / 15	
deaths causally related to treatment / all	0 / 3	0 / 5	
Haemoptysis			

subjects affected / exposed	7 / 2805 (0.25%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			
subjects affected / exposed	7 / 2805 (0.25%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
Emphysema			
subjects affected / exposed	7 / 2805 (0.25%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 1	
Cough			
subjects affected / exposed	6 / 2805 (0.21%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic pulmonary fibrosis			
subjects affected / exposed	6 / 2805 (0.21%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 3	0 / 2	
Respiratory failure			
subjects affected / exposed	3 / 2805 (0.11%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 2	
Respiration abnormal			
subjects affected / exposed	3 / 2805 (0.11%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	4 / 2805 (0.14%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			



subjects affected / exposed	3 / 2805 (0.11%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hypertension			
subjects affected / exposed	2 / 2805 (0.07%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Dyspnoea exertional			
subjects affected / exposed	1 / 2805 (0.04%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic respiratory failure			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal disorder			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal polyps			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord disorder			

subjects affected / exposed	0 / 2805 (0.00%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal disorder			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal disorder			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural fibrosis			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiccups			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonitis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Productive cough			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wheezing			

subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asphyxia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial polyp			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Choking			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphonia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydropneumothorax			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity pneumonitis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperventilation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoventilation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinal disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth breathing			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal pain			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthopnoea			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal pouch			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous tension			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary eosinophilia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sarcoidosis			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus polyp			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic haemorrhage			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Psychiatric disorders			
Delirium			
subjects affected / exposed	12 / 2805 (0.43%)	12 / 2868 (0.42%)	
occurrences causally related to treatment / all	0 / 13	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 2	
Confusional state			
subjects affected / exposed	9 / 2805 (0.32%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 11	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Disorientation			
subjects affected / exposed	4 / 2805 (0.14%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	5 / 2805 (0.18%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			

subjects affected / exposed	3 / 2805 (0.11%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination, Visual			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asperger's disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Behaviour disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium tremens			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delusional disorder, unspecified type			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressed mood			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dissociative disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hallucination			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropsychiatric symptoms			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Restlessness			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somatic symptom disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			



subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product size issue			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	22 / 2805 (0.78%)	15 / 2868 (0.52%)	
occurrences causally related to treatment / all	0 / 22	0 / 15	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cholecystitis			
subjects affected / exposed	20 / 2805 (0.71%)	16 / 2868 (0.56%)	
occurrences causally related to treatment / all	0 / 21	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cholelithiasis			
subjects affected / exposed	20 / 2805 (0.71%)	15 / 2868 (0.52%)	
occurrences causally related to treatment / all	0 / 22	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	8 / 2805 (0.29%)	11 / 2868 (0.38%)	
occurrences causally related to treatment / all	0 / 11	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			

subjects affected / exposed	6 / 2805 (0.21%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			
subjects affected / exposed	3 / 2805 (0.11%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct obstruction			
subjects affected / exposed	4 / 2805 (0.14%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hepatic cirrhosis			
subjects affected / exposed	3 / 2805 (0.11%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver disorder			
subjects affected / exposed	4 / 2805 (0.14%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic steatosis			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract disorder			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder perforation			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			

subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic fibrosis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic lesion			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal hypertension			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis sclerosing			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cirrhosis alcoholic			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cyst			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nonalcoholic fatty liver disease			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Angiogram			
subjects affected / exposed	32 / 2805 (1.14%)	38 / 2868 (1.32%)	
occurrences causally related to treatment / all	0 / 33	0 / 38	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiocardiogram			
subjects affected / exposed	24 / 2805 (0.86%)	36 / 2868 (1.26%)	
occurrences causally related to treatment / all	0 / 24	0 / 36	
deaths causally related to treatment / all	0 / 0	0 / 0	
Physical examination			
subjects affected / exposed	11 / 2805 (0.39%)	14 / 2868 (0.49%)	
occurrences causally related to treatment / all	0 / 14	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriogram coronary			
subjects affected / exposed	9 / 2805 (0.32%)	9 / 2868 (0.31%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood test abnormal			

subjects affected / exposed	9 / 2805 (0.32%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical observation			
subjects affected / exposed	7 / 2805 (0.25%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigation			
subjects affected / exposed	5 / 2805 (0.18%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood osmolarity decreased			
subjects affected / exposed	4 / 2805 (0.14%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	4 / 2805 (0.14%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystoscopy			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriogram coronary abnormal			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diagnostic procedure			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			

subjects affected / exposed	3 / 2805 (0.11%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthroscopy			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular function test abnormal			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheterisation cardiac			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endoscopy upper gastrointestinal tract			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate irregular			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scan myocardial perfusion			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress echocardiogram			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			

subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
X-ray abnormal			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticoagulation drug level below therapeutic			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriogram coronary normal			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy adrenal gland			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biopsy bladder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood culture positive			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood electrolytes abnormal			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood folate decreased			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood osmolarity increased			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium decreased			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium increased			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood sodium decreased			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchoscopy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac monitoring			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonoscopy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Computerised tomogram thorax			



subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device function test			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction normal			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram ST segment elevation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram abnormal			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endoscopic retrograde cholangiopancreatography			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate abnormal			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate decreased			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate increased			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza A virus test positive			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laparoscopy abnormal			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Magnetic resonance imaging brain			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinoscopy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oxygen consumption increased			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SARS-CoV-2 test positive			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin normal			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urological examination			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	44 / 2805 (1.57%)	40 / 2868 (1.39%)	
occurrences causally related to treatment / all	0 / 53	0 / 46	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	18 / 2805 (0.64%)	27 / 2868 (0.94%)	
occurrences causally related to treatment / all	0 / 18	0 / 29	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	19 / 2805 (0.68%)	14 / 2868 (0.49%)	
occurrences causally related to treatment / all	0 / 20	0 / 17	
deaths causally related to treatment / all	0 / 1	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	14 / 2805 (0.50%)	16 / 2868 (0.56%)	
occurrences causally related to treatment / all	0 / 14	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	7 / 2805 (0.25%)	12 / 2868 (0.42%)	
occurrences causally related to treatment / all	0 / 7	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin injury			

subjects affected / exposed	10 / 2805 (0.36%)	9 / 2868 (0.31%)	
occurrences causally related to treatment / all	0 / 10	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	7 / 2805 (0.25%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	7 / 2805 (0.25%)	9 / 2868 (0.31%)	
occurrences causally related to treatment / all	0 / 7	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	9 / 2805 (0.32%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	8 / 2805 (0.29%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	4 / 2805 (0.14%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 4	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	8 / 2805 (0.29%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	7 / 2805 (0.25%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			

subjects affected / exposed	3 / 2805 (0.11%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	1 / 2805 (0.04%)	9 / 2868 (0.31%)	
occurrences causally related to treatment / all	0 / 1	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	3 / 2805 (0.11%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open wound			
subjects affected / exposed	5 / 2805 (0.18%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pubis fracture			
subjects affected / exposed	6 / 2805 (0.21%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	3 / 2805 (0.11%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asbestosis			
subjects affected / exposed	2 / 2805 (0.07%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 3	
Incisional hernia			
subjects affected / exposed	6 / 2805 (0.21%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			

subjects affected / exposed	6 / 2805 (0.21%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest injury			
subjects affected / exposed	4 / 2805 (0.14%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	4 / 2805 (0.14%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	2 / 2805 (0.07%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Facial bones fracture			
subjects affected / exposed	3 / 2805 (0.11%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body			
subjects affected / exposed	4 / 2805 (0.14%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed	1 / 2805 (0.04%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	3 / 2805 (0.11%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			

subjects affected / exposed	2 / 2805 (0.07%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	4 / 2805 (0.14%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Contusion			
subjects affected / exposed	4 / 2805 (0.14%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis radiation			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	3 / 2805 (0.11%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	3 / 2805 (0.11%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			

subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Foot fracture			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal stoma complication			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	3 / 2805 (0.11%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back injury			



subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	3 / 2805 (0.11%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Forearm fracture			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laceration			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle injury			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venom poisoning			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			

subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical vertebral fracture			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Excoriation			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma traumatic			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ilium fracture			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus lesion			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck injury			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Patella fracture			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periprosthetic fracture			

subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax traumatic			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound complication			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural complication			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation proctitis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue injury			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic injury			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial rupture			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			

subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accident			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accident at home			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Airway burns			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (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			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (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			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Burns third degree			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve replacement complication			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chemical poisoning			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Closed globe injury			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exposure to chemical pollution			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye injury			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid contusion			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid injury			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body in gastrointestinal tract			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital injury			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated parastomal hernia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal anastomosis complication			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament injury			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve injury			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumoconiosis			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post concussion syndrome			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural constipation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural discharge			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematuria			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural myocardial infarction			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural pulmonary embolism			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural stroke			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural swelling			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiation skin injury			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory fume inhalation disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scapula fracture			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scar			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seroma			



subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fracture			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fractured base			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord injury			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal fracture			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomal hernia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superficial injury of eye			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth fracture			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic anuria			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract stoma complication			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urostomy complication			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft complication			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal injury			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Phimosis			
subjects affected / exposed	10 / 2805 (0.36%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal dystrophy			

subjects affected / exposed	4 / 2805 (0.14%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	4 / 2805 (0.14%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Birth mark			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous malformation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial septal defect			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital aortic valve stenosis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital cystic kidney disease			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital endocrine anomaly			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital foot malformation			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystic lymphangioma			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart disease congenital			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hereditary sideroblastic anaemia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melkersson-Rosenthal syndrome			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syndactyly			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	152 / 2805 (5.42%)	162 / 2868 (5.65%)	
occurrences causally related to treatment / all	4 / 198	0 / 229	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			

subjects affected / exposed	132 / 2805 (4.71%)	169 / 2868 (5.89%)	
occurrences causally related to treatment / all	0 / 184	0 / 275	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute myocardial infarction			
subjects affected / exposed	125 / 2805 (4.46%)	121 / 2868 (4.22%)	
occurrences causally related to treatment / all	0 / 145	0 / 141	
deaths causally related to treatment / all	0 / 13	0 / 16	
Cardiac failure			
subjects affected / exposed	47 / 2805 (1.68%)	54 / 2868 (1.88%)	
occurrences causally related to treatment / all	0 / 55	0 / 64	
deaths causally related to treatment / all	0 / 4	0 / 9	
Myocardial infarction			
subjects affected / exposed	48 / 2805 (1.71%)	47 / 2868 (1.64%)	
occurrences causally related to treatment / all	0 / 49	0 / 48	
deaths causally related to treatment / all	0 / 19	0 / 17	
Angina unstable			
subjects affected / exposed	36 / 2805 (1.28%)	50 / 2868 (1.74%)	
occurrences causally related to treatment / all	0 / 45	0 / 65	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	39 / 2805 (1.39%)	42 / 2868 (1.46%)	
occurrences causally related to treatment / all	0 / 45	0 / 48	
deaths causally related to treatment / all	0 / 3	0 / 11	
Myocardial ischaemia			
subjects affected / exposed	32 / 2805 (1.14%)	41 / 2868 (1.43%)	
occurrences causally related to treatment / all	0 / 32	0 / 44	
deaths causally related to treatment / all	0 / 15	0 / 18	
Aortic valve stenosis			
subjects affected / exposed	14 / 2805 (0.50%)	21 / 2868 (0.73%)	
occurrences causally related to treatment / all	0 / 18	0 / 25	
deaths causally related to treatment / all	0 / 0	0 / 1	
Left ventricular failure			

subjects affected / exposed	14 / 2805 (0.50%)	19 / 2868 (0.66%)	
occurrences causally related to treatment / all	0 / 16	0 / 19	
deaths causally related to treatment / all	0 / 2	0 / 7	
Bradycardia			
subjects affected / exposed	11 / 2805 (0.39%)	19 / 2868 (0.66%)	
occurrences causally related to treatment / all	0 / 11	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	11 / 2805 (0.39%)	15 / 2868 (0.52%)	
occurrences causally related to treatment / all	0 / 11	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	13 / 2805 (0.46%)	13 / 2868 (0.45%)	
occurrences causally related to treatment / all	0 / 16	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	11 / 2805 (0.39%)	11 / 2868 (0.38%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	6 / 2805 (0.21%)	16 / 2868 (0.56%)	
occurrences causally related to treatment / all	0 / 6	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	11 / 2805 (0.39%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 3	0 / 6	
Palpitations			
subjects affected / exposed	6 / 2805 (0.21%)	11 / 2868 (0.38%)	
occurrences causally related to treatment / all	0 / 6	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			

subjects affected / exposed	5 / 2805 (0.18%)	9 / 2868 (0.31%)	
occurrences causally related to treatment / all	0 / 5	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	9 / 2805 (0.32%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	8 / 2805 (0.29%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	4 / 2805 (0.14%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 4	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block first degree			
subjects affected / exposed	5 / 2805 (0.18%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	6 / 2805 (0.21%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve disease			
subjects affected / exposed	8 / 2805 (0.29%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	5 / 2805 (0.18%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac disorder			

subjects affected / exposed	5 / 2805 (0.18%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 4	0 / 1	
Mitral valve incompetence			
subjects affected / exposed	1 / 2805 (0.04%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease mixed			
subjects affected / exposed	0 / 2805 (0.00%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	4 / 2805 (0.14%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block left			
subjects affected / exposed	3 / 2805 (0.11%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sick sinus syndrome			
subjects affected / exposed	2 / 2805 (0.07%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trifascicular block			
subjects affected / exposed	3 / 2805 (0.11%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	2 / 2805 (0.07%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			



subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	4 / 2805 (0.14%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 8	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	1 / 2805 (0.04%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Aortic valve incompetence			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			
subjects affected / exposed	0 / 2805 (0.00%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Arteriosclerosis coronary artery			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiogenic shock			

subjects affected / exposed	3 / 2805 (0.11%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
Cardiomegaly			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Mitral valve prolapse			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Bifascicular block			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure chronic			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiomyopathy			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conduction disorder			

subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracardiac thrombus			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular hypertrophy			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus bradycardia			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia paroxysmal			

subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute cardiac event			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arteriospasm coronary			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block right			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac amyloidosis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac aneurysm			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiomyopathy alcoholic			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiorenal syndrome			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive cardiomyopathy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cor pulmonale acute			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery thrombosis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diastolic dysfunction			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (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			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypertrophic cardiomyopathy			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic cardiomyopathy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (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			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve disease			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve stenosis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial fibrosis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial rupture			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulseless electrical activity			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular dysfunction			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	47 / 2805 (1.68%)	38 / 2868 (1.32%)	
occurrences causally related to treatment / all	0 / 52	0 / 43	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	37 / 2805 (1.32%)	39 / 2868 (1.36%)	
occurrences causally related to treatment / all	0 / 39	0 / 41	
deaths causally related to treatment / all	0 / 2	0 / 2	
Cerebral infarction			
subjects affected / exposed	27 / 2805 (0.96%)	22 / 2868 (0.77%)	
occurrences causally related to treatment / all	0 / 30	0 / 24	
deaths causally related to treatment / all	0 / 1	0 / 1	
Carpal tunnel syndrome			
subjects affected / exposed	16 / 2805 (0.57%)	27 / 2868 (0.94%)	
occurrences causally related to treatment / all	0 / 20	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	14 / 2805 (0.50%)	29 / 2868 (1.01%)	
occurrences causally related to treatment / all	0 / 14	0 / 29	
deaths causally related to treatment / all	0 / 1	0 / 2	
Parkinson's disease			
subjects affected / exposed	14 / 2805 (0.50%)	16 / 2868 (0.56%)	
occurrences causally related to treatment / all	0 / 17	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dementia Alzheimer's type			
subjects affected / exposed	15 / 2805 (0.53%)	14 / 2868 (0.49%)	
occurrences causally related to treatment / all	0 / 15	0 / 14	
deaths causally related to treatment / all	0 / 1	0 / 1	
Dizziness			

subjects affected / exposed	17 / 2805 (0.61%)	11 / 2868 (0.38%)	
occurrences causally related to treatment / all	0 / 18	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	12 / 2805 (0.43%)	16 / 2868 (0.56%)	
occurrences causally related to treatment / all	0 / 12	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radiculopathy			
subjects affected / exposed	11 / 2805 (0.39%)	16 / 2868 (0.56%)	
occurrences causally related to treatment / all	0 / 17	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	8 / 2805 (0.29%)	17 / 2868 (0.59%)	
occurrences causally related to treatment / all	0 / 10	0 / 18	
deaths causally related to treatment / all	0 / 1	0 / 0	
Headache			
subjects affected / exposed	8 / 2805 (0.29%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	1 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	7 / 2805 (0.25%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cerebral haemorrhage			
subjects affected / exposed	10 / 2805 (0.36%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 12	0 / 2	
deaths causally related to treatment / all	0 / 6	0 / 1	
Lacunar infarction			
subjects affected / exposed	7 / 2805 (0.25%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			



subjects affected / exposed	5 / 2805 (0.18%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	7 / 2805 (0.25%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 3	0 / 0	
Migraine			
subjects affected / exposed	5 / 2805 (0.18%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral nerve lesion			
subjects affected / exposed	5 / 2805 (0.18%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	4 / 2805 (0.14%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
subjects affected / exposed	1 / 2805 (0.04%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	4 / 2805 (0.14%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	3 / 2805 (0.11%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mixed dementia			

subjects affected / exposed	5 / 2805 (0.18%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurological symptom			
subjects affected / exposed	2 / 2805 (0.07%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	2 / 2805 (0.07%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sciatica			
subjects affected / exposed	3 / 2805 (0.11%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 2	
Loss of consciousness			
subjects affected / exposed	1 / 2805 (0.04%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	1 / 2805 (0.04%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar infarction			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia of the Alzheimer's type, with delirium			

subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hemiparesis			
subjects affected / exposed	4 / 2805 (0.14%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myelopathy			
subjects affected / exposed	0 / 2805 (0.00%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyneuropathy			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular disorder			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Embolic cerebral infarction			
subjects affected / exposed	3 / 2805 (0.11%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nerve root compression			

subjects affected / exposed	3 / 2805 (0.11%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tension headache			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal ganglia infarction			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cauda equina syndrome			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical myelopathy			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia with Lewy bodies			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathy			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyskinesia			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Grand mal convulsion			

subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
IIIrd nerve paralysis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
IVth nerve paralysis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Motor neurone disease			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Partial seizures			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic cerebral infarction			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amnesia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arachnoid cyst			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autonomic neuropathy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem haemorrhage			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Brain stem infarction			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Carotid artery disease			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar haemorrhage			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar stroke			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar syndrome			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral amyloid angiopathy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery occlusion			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cerebral disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral small vessel ischaemic disease			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coma			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complex partial seizures			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Frontotemporal dementia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemianopia homonymous			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxic-ischaemic encephalopathy			



subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Idiopathic generalised epilepsy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial aneurysm			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar stroke			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine with aura			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mononeuropathy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Motor dysfunction			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myasthenia gravis			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurodegenerative disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post herpetic neuralgia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Quadriplegia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radial nerve palsy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Simple partial seizures			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Slow response to stimuli			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal claudication			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord ischaemia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitic myelopathy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stupor			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporal lobe epilepsy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thalamus haemorrhage			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tremor			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigeminal neuralgia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Unresponsive to stimuli			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIIth nerve paralysis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIth nerve paralysis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery thrombosis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo CNS origin			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	43 / 2805 (1.53%)	43 / 2868 (1.50%)	
occurrences causally related to treatment / all	0 / 53	0 / 50	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			

subjects affected / exposed	49 / 2805 (1.75%)	36 / 2868 (1.26%)	
occurrences causally related to treatment / all	0 / 58	0 / 41	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	4 / 2805 (0.14%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agranulocytosis			
subjects affected / exposed	3 / 2805 (0.11%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia folate deficiency			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune haemolytic anaemia			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypergammaglobulinaemia			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic thrombocytopenic purpura			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic anaemia			

subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia haemolytic autoimmune			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia of malignant disease			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone marrow disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone marrow oedema syndrome			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic anaemia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypereosinophilic syndrome			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paratracheal lymphadenopathy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pernicious anaemia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Purpura non-thrombocytopenic			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenomegaly			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
White blood cell disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo positional			

subjects affected / exposed	7 / 2805 (0.25%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 9	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	2 / 2805 (0.07%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniere's disease			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inner ear disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanic membrane perforation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanosclerosis			



subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	301 / 2805 (10.73%)	301 / 2868 (10.50%)	
occurrences causally related to treatment / all	1 / 451	0 / 437	
deaths causally related to treatment / all	0 / 0	0 / 0	
Posterior capsule opacification			
subjects affected / exposed	16 / 2805 (0.57%)	15 / 2868 (0.52%)	
occurrences causally related to treatment / all	0 / 18	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular degeneration			
subjects affected / exposed	12 / 2805 (0.43%)	12 / 2868 (0.42%)	
occurrences causally related to treatment / all	0 / 19	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	9 / 2805 (0.32%)	12 / 2868 (0.42%)	
occurrences causally related to treatment / all	0 / 10	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ectropion			
subjects affected / exposed	5 / 2805 (0.18%)	9 / 2868 (0.31%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open angle glaucoma			
subjects affected / exposed	5 / 2805 (0.18%)	9 / 2868 (0.31%)	
occurrences causally related to treatment / all	0 / 5	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Entropion			
subjects affected / exposed	4 / 2805 (0.14%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			

subjects affected / exposed	5 / 2805 (0.18%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid disorder			
subjects affected / exposed	3 / 2805 (0.11%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacrimation increased			
subjects affected / exposed	2 / 2805 (0.07%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	5 / 2805 (0.18%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eyelid ptosis			
subjects affected / exposed	1 / 2805 (0.04%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diplopia			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal disorder			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	4 / 2805 (0.14%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amaurosis fugax			

subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	1 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryostenosis acquired			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorder			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal degeneration			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic eye disease			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation of lacrimal passage			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein occlusion			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous disorder			

subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blepharospasm			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chalazion			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal disorder			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ocular myasthenia			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parophthalmia			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal haemorrhage			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal tear			

subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Serous retinal detachment			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tractional retinal detachment			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual acuity reduced			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphakia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Binocular eye movement disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract diabetic			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract nuclear			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctival deposit			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal decompensation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal oedema			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iridocyclitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keratitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lens dislocation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lens disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neovascular age-related macular degeneration			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery embolism			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vascular disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diverticulum			
subjects affected / exposed	70 / 2805 (2.50%)	83 / 2868 (2.89%)	
occurrences causally related to treatment / all	0 / 74	0 / 92	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	50 / 2805 (1.78%)	57 / 2868 (1.99%)	
occurrences causally related to treatment / all	0 / 53	0 / 61	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroesophageal reflux disease			
subjects affected / exposed	49 / 2805 (1.75%)	44 / 2868 (1.53%)	
occurrences causally related to treatment / all	1 / 52	0 / 48	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	43 / 2805 (1.53%)	43 / 2868 (1.50%)	
occurrences causally related to treatment / all	0 / 51	0 / 51	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	28 / 2805 (1.00%)	39 / 2868 (1.36%)	
occurrences causally related to treatment / all	0 / 28	0 / 41	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			

subjects affected / exposed	20 / 2805 (0.71%)	40 / 2868 (1.39%)	
occurrences causally related to treatment / all	0 / 21	0 / 41	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	28 / 2805 (1.00%)	29 / 2868 (1.01%)	
occurrences causally related to treatment / all	0 / 31	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 1	
Abdominal pain			
subjects affected / exposed	23 / 2805 (0.82%)	29 / 2868 (1.01%)	
occurrences causally related to treatment / all	2 / 26	0 / 30	
deaths causally related to treatment / all	0 / 0	0 / 0	
Barrett's oesophagus			
subjects affected / exposed	30 / 2805 (1.07%)	21 / 2868 (0.73%)	
occurrences causally related to treatment / all	0 / 43	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	25 / 2805 (0.89%)	20 / 2868 (0.70%)	
occurrences causally related to treatment / all	0 / 27	0 / 20	
deaths causally related to treatment / all	0 / 1	0 / 0	
Constipation			
subjects affected / exposed	18 / 2805 (0.64%)	20 / 2868 (0.70%)	
occurrences causally related to treatment / all	0 / 19	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Change of bowel habit			
subjects affected / exposed	11 / 2805 (0.39%)	25 / 2868 (0.87%)	
occurrences causally related to treatment / all	0 / 11	0 / 25	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragmatic hernia			
subjects affected / exposed	16 / 2805 (0.57%)	18 / 2868 (0.63%)	
occurrences causally related to treatment / all	0 / 18	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			



subjects affected / exposed	16 / 2805 (0.57%)	15 / 2868 (0.52%)	
occurrences causally related to treatment / all	0 / 19	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal polyp			
subjects affected / exposed	12 / 2805 (0.43%)	14 / 2868 (0.49%)	
occurrences causally related to treatment / all	0 / 14	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	12 / 2805 (0.43%)	14 / 2868 (0.49%)	
occurrences causally related to treatment / all	0 / 15	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
Colonic polyp			
subjects affected / exposed	9 / 2805 (0.32%)	16 / 2868 (0.56%)	
occurrences causally related to treatment / all	0 / 9	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal inflammation			
subjects affected / exposed	12 / 2805 (0.43%)	13 / 2868 (0.45%)	
occurrences causally related to treatment / all	0 / 13	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	13 / 2805 (0.46%)	12 / 2868 (0.42%)	
occurrences causally related to treatment / all	0 / 13	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	12 / 2805 (0.43%)	12 / 2868 (0.42%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorder			
subjects affected / exposed	12 / 2805 (0.43%)	11 / 2868 (0.38%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			

subjects affected / exposed	8 / 2805 (0.29%)	11 / 2868 (0.38%)	
occurrences causally related to treatment / all	0 / 9	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	9 / 2805 (0.32%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	5 / 2805 (0.18%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 5	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	4 / 2805 (0.14%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 4	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	9 / 2805 (0.32%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	5 / 2805 (0.18%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 5	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	9 / 2805 (0.32%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	5 / 2805 (0.18%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			

subjects affected / exposed	8 / 2805 (0.29%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	5 / 2805 (0.18%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 6	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyskinesia oesophageal			
subjects affected / exposed	6 / 2805 (0.21%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	6 / 2805 (0.21%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 11	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	5 / 2805 (0.18%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal obstruction			
subjects affected / exposed	4 / 2805 (0.14%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	4 / 2805 (0.14%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth disorder			
subjects affected / exposed	6 / 2805 (0.21%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal toxicity			

subjects affected / exposed	3 / 2805 (0.11%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	4 / 2805 (0.14%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	5 / 2805 (0.18%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	3 / 2805 (0.11%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abnormal faeces			
subjects affected / exposed	2 / 2805 (0.07%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	3 / 2805 (0.11%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 1	
Dental caries			
subjects affected / exposed	4 / 2805 (0.14%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia, Obstructive			
subjects affected / exposed	2 / 2805 (0.07%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ischaemia			

subjects affected / exposed	1 / 2805 (0.04%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 5	
Oral disorder			
subjects affected / exposed	3 / 2805 (0.11%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	3 / 2805 (0.11%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal incontinence			
subjects affected / exposed	4 / 2805 (0.14%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	3 / 2805 (0.11%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis microscopic			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			

subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal prolapse			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	3 / 2805 (0.11%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric vascular insufficiency			

subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic cyst			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salivary gland disorder			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue disorder			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	3 / 2805 (0.11%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia obstructive			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic pancreatitis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anorectal disorder			

subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coeliac disease			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diverticular perforation			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral hernia			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis atrophic			



subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gingival disorder			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal ulcer			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Irritable bowel syndrome			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			

subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal disorder			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic disorder			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctitis ulcerative			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudopolyposis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth development disorder			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal adhesions			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal mass			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal strangulated hernia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal polyp			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coeliac artery stenosis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic fistula			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea haemorrhagic			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum gastric			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal obstruction			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Enteritis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovesical fistula			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Functional gastrointestinal disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallstone ileus			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis alcoholic			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroduodenitis			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glossitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoperitoneum			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Intestinal fistula			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal polyp			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal haemorrhage			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukoplakia oral			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malabsorption			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal achalasia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal dilatation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal spasm			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic calcification			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic failure			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis necrotising			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Peptic ulcer haemorrhage			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer perforation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Peritoneal adhesions			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctitis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radicular cyst			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal ulcer			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Salivary gland mucocoele			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth socket haemorrhage			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia, Obstructive airways disorder			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Skin disorder			
subjects affected / exposed	8 / 2805 (0.29%)	15 / 2868 (0.52%)	
occurrences causally related to treatment / all	0 / 8	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Actinic keratosis			
subjects affected / exposed	4 / 2805 (0.14%)	12 / 2868 (0.42%)	
occurrences causally related to treatment / all	0 / 4	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal cyst			
subjects affected / exposed	5 / 2805 (0.18%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	4 / 2805 (0.14%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	3 / 2805 (0.11%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scar			



subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	3 / 2805 (0.11%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rosacea			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lichen planus			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pemphigoid			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cold sweat			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ulcer			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry gangrene			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ecchymosis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Idiopathic angioedema			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Keloid scar			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lichen sclerosis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurodermatitis			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Precancerous skin lesion			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash generalised			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin hyperpigmentation			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin hypertrophy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	38 / 2805 (1.35%)	32 / 2868 (1.12%)	
occurrences causally related to treatment / all	0 / 45	0 / 39	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	24 / 2805 (0.86%)	41 / 2868 (1.43%)	
occurrences causally related to treatment / all	0 / 27	0 / 48	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			
subjects affected / exposed	16 / 2805 (0.57%)	28 / 2868 (0.98%)	
occurrences causally related to treatment / all	0 / 17	0 / 35	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nephrolithiasis			

subjects affected / exposed	17 / 2805 (0.61%)	16 / 2868 (0.56%)	
occurrences causally related to treatment / all	0 / 24	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder disorder			
subjects affected / exposed	10 / 2805 (0.36%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 11	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	10 / 2805 (0.36%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 12	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	10 / 2805 (0.36%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 11	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure acute			
subjects affected / exposed	7 / 2805 (0.25%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	5 / 2805 (0.18%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus ureteric			
subjects affected / exposed	7 / 2805 (0.25%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract disorder			
subjects affected / exposed	3 / 2805 (0.11%)	9 / 2868 (0.31%)	
occurrences causally related to treatment / all	0 / 3	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck obstruction			

subjects affected / exposed	2 / 2805 (0.07%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	6 / 2805 (0.21%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure chronic			
subjects affected / exposed	1 / 2805 (0.04%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Calculus bladder			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Renal impairment			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Calculus urinary			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis interstitial			

subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysuria			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder dysfunction			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower urinary tract symptoms			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrotic syndrome			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyuria			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal disorder			

subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anuria			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder diverticulum			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic nephropathy			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Focal segmental glomerulosclerosis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerulonephritis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydroureter			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvi-ureteric obstruction			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal atrophy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal mass			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteral spasm			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric stenosis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Goitre			



subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acromegaly			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Addison's disease			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenocortical insufficiency acute			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes insipidus			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperparathyroidism primary			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypopituitarism			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothalamo-pituitary disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	103 / 2805 (3.67%)	122 / 2868 (4.25%)	
occurrences causally related to treatment / all	0 / 125	0 / 146	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	19 / 2805 (0.68%)	31 / 2868 (1.08%)	
occurrences causally related to treatment / all	0 / 24	0 / 44	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	24 / 2805 (0.86%)	24 / 2868 (0.84%)	
occurrences causally related to treatment / all	1 / 28	0 / 27	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			
subjects affected / exposed	20 / 2805 (0.71%)	17 / 2868 (0.59%)	
occurrences causally related to treatment / all	0 / 21	0 / 24	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	15 / 2805 (0.53%)	20 / 2868 (0.70%)	
occurrences causally related to treatment / all	0 / 17	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue disorder			

subjects affected / exposed	15 / 2805 (0.53%)	19 / 2868 (0.66%)	
occurrences causally related to treatment / all	0 / 17	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	10 / 2805 (0.36%)	17 / 2868 (0.59%)	
occurrences causally related to treatment / all	0 / 10	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dupuytren's contracture			
subjects affected / exposed	11 / 2805 (0.39%)	13 / 2868 (0.45%)	
occurrences causally related to treatment / all	0 / 11	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	10 / 2805 (0.36%)	13 / 2868 (0.45%)	
occurrences causally related to treatment / all	0 / 10	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	8 / 2805 (0.29%)	13 / 2868 (0.45%)	
occurrences causally related to treatment / all	0 / 9	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	14 / 2805 (0.50%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 17	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyarthritis			
subjects affected / exposed	8 / 2805 (0.29%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 8	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	14 / 2805 (0.50%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 14	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			

subjects affected / exposed	10 / 2805 (0.36%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 12	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid arthritis			
subjects affected / exposed	7 / 2805 (0.25%)	10 / 2868 (0.35%)	
occurrences causally related to treatment / all	0 / 7	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	6 / 2805 (0.21%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporotic fracture			
subjects affected / exposed	5 / 2805 (0.18%)	9 / 2868 (0.31%)	
occurrences causally related to treatment / all	0 / 7	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigger finger			
subjects affected / exposed	5 / 2805 (0.18%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	2 / 2805 (0.07%)	9 / 2868 (0.31%)	
occurrences causally related to treatment / all	0 / 2	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	8 / 2805 (0.29%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 9	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	8 / 2805 (0.29%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 8	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint effusion			

subjects affected / exposed	3 / 2805 (0.11%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	6 / 2805 (0.21%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	1 / 2805 (0.04%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovial cyst			
subjects affected / exposed	4 / 2805 (0.14%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Costochondritis			
subjects affected / exposed	1 / 2805 (0.04%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibromyalgia			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc displacement			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mobility decreased			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle disorder			

subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone disorder			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periarthritis			
subjects affected / exposed	3 / 2805 (0.11%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondyloarthropathy			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			

subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin pain			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw disorder			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint stiffness			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint swelling			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monarthrititis			

subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudarthrosis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriatic arthropathy			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rheumatoid nodule			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scoliosis			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis			



subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone cyst			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursa disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CREST syndrome			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture nonunion			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty tophus			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb deformity			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loose body in joint			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle haemorrhage			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathic arthropathy			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nodal osteoarthritis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteolysis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteopenia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plantar fascial fibromatosis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plantar fasciitis			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyositis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Spinal pain			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic sclerosis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporomandibular joint syndrome			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral wedging			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	106 / 2805 (3.78%)	111 / 2868 (3.87%)	
occurrences causally related to treatment / all	0 / 124	0 / 133	
deaths causally related to treatment / all	0 / 23	0 / 21	
Urinary tract infection			

subjects affected / exposed	66 / 2805 (2.35%)	73 / 2868 (2.55%)	
occurrences causally related to treatment / all	0 / 76	0 / 88	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lower respiratory tract infection			
subjects affected / exposed	51 / 2805 (1.82%)	81 / 2868 (2.82%)	
occurrences causally related to treatment / all	0 / 58	0 / 93	
deaths causally related to treatment / all	0 / 3	0 / 3	
Sepsis			
subjects affected / exposed	44 / 2805 (1.57%)	51 / 2868 (1.78%)	
occurrences causally related to treatment / all	0 / 45	0 / 54	
deaths causally related to treatment / all	0 / 9	0 / 5	
Cellulitis			
subjects affected / exposed	29 / 2805 (1.03%)	36 / 2868 (1.26%)	
occurrences causally related to treatment / all	0 / 31	0 / 41	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	30 / 2805 (1.07%)	31 / 2868 (1.08%)	
occurrences causally related to treatment / all	0 / 30	0 / 34	
deaths causally related to treatment / all	0 / 10	0 / 10	
Gastroenteritis			
subjects affected / exposed	22 / 2805 (0.78%)	39 / 2868 (1.36%)	
occurrences causally related to treatment / all	0 / 22	0 / 43	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	18 / 2805 (0.64%)	23 / 2868 (0.80%)	
occurrences causally related to treatment / all	0 / 20	0 / 26	
deaths causally related to treatment / all	0 / 1	0 / 3	
Lobar pneumonia			
subjects affected / exposed	15 / 2805 (0.53%)	17 / 2868 (0.59%)	
occurrences causally related to treatment / all	0 / 15	0 / 17	
deaths causally related to treatment / all	0 / 2	0 / 1	
Urosepsis			

subjects affected / exposed	12 / 2805 (0.43%)	13 / 2868 (0.45%)	
occurrences causally related to treatment / all	0 / 12	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 3	
Device related infection			
subjects affected / exposed	9 / 2805 (0.32%)	13 / 2868 (0.45%)	
occurrences causally related to treatment / all	0 / 11	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	9 / 2805 (0.32%)	12 / 2868 (0.42%)	
occurrences causally related to treatment / all	0 / 9	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	5 / 2805 (0.18%)	13 / 2868 (0.45%)	
occurrences causally related to treatment / all	0 / 5	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	9 / 2805 (0.32%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 9	0 / 8	
deaths causally related to treatment / all	0 / 7	0 / 7	
Cystitis			
subjects affected / exposed	9 / 2805 (0.32%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	5 / 2805 (0.18%)	9 / 2868 (0.31%)	
occurrences causally related to treatment / all	0 / 5	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carbuncle			
subjects affected / exposed	7 / 2805 (0.25%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			

subjects affected / exposed	8 / 2805 (0.29%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Labyrinthitis			
subjects affected / exposed	3 / 2805 (0.11%)	8 / 2868 (0.28%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	3 / 2805 (0.11%)	7 / 2868 (0.24%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 1	0 / 0	
Influenza			
subjects affected / exposed	4 / 2805 (0.14%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Enterocolitis infectious			
subjects affected / exposed	4 / 2805 (0.14%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal viral infection			
subjects affected / exposed	4 / 2805 (0.14%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumonia			
subjects affected / exposed	5 / 2805 (0.18%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 3	0 / 2	
Campylobacter gastroenteritis			
subjects affected / exposed	2 / 2805 (0.07%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			

subjects affected / exposed	1 / 2805 (0.04%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			
subjects affected / exposed	4 / 2805 (0.14%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	3 / 2805 (0.11%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	1 / 2805 (0.04%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 1	
Osteomyelitis			
subjects affected / exposed	1 / 2805 (0.04%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontitis			
subjects affected / exposed	4 / 2805 (0.14%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Bacterial infection			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary sepsis			

subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	1 / 2805 (0.04%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	4 / 2805 (0.14%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral discitis			
subjects affected / exposed	3 / 2805 (0.11%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			



subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	3 / 2805 (0.11%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pilonidal cyst			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural sepsis			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	0 / 2805 (0.00%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sialoadenitis			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			

subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal sepsis			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Appendicitis perforated			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candida infection			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis infective			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			

subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis bacterial			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal bacterial infection			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma infection			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis viral			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lyme disease			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycobacterial infection			

subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis externa			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perichondritis			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial viral			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyonephrosis			
subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Streptococcal infection			

subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Acute endocarditis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Candidiasis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis infective			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridial infection			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Creutzfeldt-Jakob disease			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Device related sepsis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated tuberculosis			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Empyema			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis viral			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endophthalmitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiglottitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia infection			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
External ear cellulitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis viral			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophilus infection			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis E			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes simplex encephalitis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes virus infection			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster infection neurological			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hordeolum			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella infection			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			



subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection pseudomonal			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (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 infection			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (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			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis streptococcal			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metapneumovirus infection			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngitis fungal			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media chronic			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotitis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic abscess			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal abscess			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perinephric abscess			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital infection			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural infection			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal sepsis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia bacterial			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia escherichia			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia klebsiella			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia necrotising			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia parainfluenzae viral			

subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Prostatic abscess			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomembranous colitis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonas infection			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal abscess			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (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 bronchiolitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suspected COVID-19			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tuberculosis			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular neuronitis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			

subjects affected / exposed	58 / 2805 (2.07%)	56 / 2868 (1.95%)	
occurrences causally related to treatment / all	0 / 58	0 / 59	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	8 / 2805 (0.29%)	12 / 2868 (0.42%)	
occurrences causally related to treatment / all	0 / 8	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gout			
subjects affected / exposed	4 / 2805 (0.14%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	5 / 2805 (0.18%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 1	
Hypoglycaemia			
subjects affected / exposed	4 / 2805 (0.14%)	4 / 2868 (0.14%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	2 / 2805 (0.07%)	6 / 2868 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Magnesium metabolism disorder			
subjects affected / exposed	2 / 2805 (0.07%)	5 / 2868 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abnormal loss of weight			
subjects affected / exposed	3 / 2805 (0.11%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			

subjects affected / exposed	2 / 2805 (0.07%)	3 / 2868 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid overload			
subjects affected / exposed	4 / 2805 (0.14%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron metabolism disorder			
subjects affected / exposed	4 / 2805 (0.14%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	2 / 2805 (0.07%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemochromatosis			
subjects affected / exposed	1 / 2805 (0.04%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency			
subjects affected / exposed	2 / 2805 (0.07%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			

subjects affected / exposed	2 / 2805 (0.07%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 2805 (0.00%)	2 / 2868 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	1 / 2805 (0.04%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calcium metabolism disorder			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Folate deficiency			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperlipidaemia			



subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hyperosmolar state			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudohyperkalaemia			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Starvation			
subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 2805 (0.00%)	1 / 2868 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitamin B complex deficiency			

subjects affected / exposed	1 / 2805 (0.04%)	0 / 2868 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

<b>Non-serious adverse events</b>	Safety analysis set - allopurinol arm	Safety analysis set - usual care arm	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	210 / 2805 (7.49%)	0 / 2868 (0.00%)	
Skin and subcutaneous tissue disorders			
Rash	Additional description: Only potentially treatment-related non-serious adverse events were reported in this trial. Therefore, non-serious adverse events were only reported in the allopurinol group (not the usual care group).		
subjects affected / exposed	210 / 2805 (7.49%)	0 / 2868 (0.00%)	
occurrences (all)	216	0	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

n/a
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Notes:

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/36216006>